Legal protection for consumers of Pharmaceutical products

Thesis submitted

by

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CERTIFICATE OF THE SUPERVISING TEACHER

Certified that to the best of my knowledge the thesis, "Legal Protection for Consumer of Pharmaceutical Products" is the record of bonafide research work carried out by Mr. S.V. Pulla Reddy in the School of Legal Studies, Cochin University of Science and Technology, Kochi from 3-8-1989 under my supervision.

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DECLARATION

I hereby declare that the thesis, "Legal protection for consumers of pharmaceutical products", is the record of original research work carried out by me and it has not previously formed the basis for the award of any degree, diploma, associateship, fellowship or other title or recognition.

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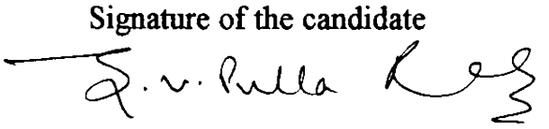

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PREFACE

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 out set, 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 has 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 any 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 is 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.

The guidance rendered by my supervising teacher Dr. A.M. Varkey has been of great help to me. I have been benefited by discussions with him. I record my indebtedness towards him for the pain he has taken to read and correct the draft of my thesis and for the valuable suggestion made by him for improving the thesis. I express my sincere gratitude towards him for his guidance and encouragement. Dr. K. Chandra Sekharan Pillai, professor, School of Legal Studies, Cochin University

of Science and Technology has been keenly interested in the progress of my research work. I express my sincere gratitude towards him for his constant encouragement.

I missed the pleasure of company of my wife Smt. Usha Rani and my children Spurthy and Sadhana for long duration when I had to be away from them at various stages of my research work. This would not have been completed without causing them that displeasure and inconvenience in my absence.

I thank Miss Mythily, research scholar in the Department of law, CUSAT and Dr.N.S.Soman, my friend and lecturer in law Mahatma Gandhi University, Kottayam who helped me in preparing the list of cases and bibliography. I also thank all other persons who have extended their helping hands in the course of my research programme especially the library staff. My thanks are also due to Miss Reeba Varghese of the A.D. 2000 Computer Centre, Kalamassery who devoted herself to type my thesis in the computer from the manuscript and giving a good finish with full care and interest.

CONTENTS

LIST OF CASES

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 news paper 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.

[2] See generally W.H.O., *Essential Drugs Monitor*, January, 1988.

[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 addictive value and usually ponder to the consumer's notion that a 'strong' drug is the most effective one. See *Indian Express*, (Bombay) Oct 23, 1989.)

[4] A progress report by Director General of WHO to the World Health Assembly in May 1992 on world drug situation, quoted by K Balasubramaniam, "A Healthy Drug Policy for the Third World", *Multinational Monitor*, Dec 1992, p 25 at 26.

most reputed medical institutes in the Capital city of India[5]. 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[6]. 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...".[7]

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 frame work that is available for this purpose and the functioning of regulating mechanism that is envisaged under it. The

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[5] See *Indian Express*, Oct.18, 1989. P ( )

[6] Charles Medawar, *Insult or Injury*, Social Audit Ltd., London (1981) at pp. 112-113..

[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 shop-keeper, 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 philosophy[9]. 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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[8] Adam Smith, *The Wealth of Nations*, Modern Library, New York (1937).

[9] See generally, Khan-Freund, "A note on Status and Contract in British Labour Law", 30 Mod. L.Rev. 635 (1967). See also Gorden Borrie and Anbrey L. Dimond, *Consumer, Society and The Law*, Penguin Books, London,(1973) pp.17 - 19 and 36 - 63

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 competetion 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 competetion, 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 above analysis is subject to strong qualifications[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[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 have to have regard to the economic environment in which the

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[10] John Kenneth Galbraith. *The New Industrial State*, Hamish Hamilton, London(1967) p. 212 .

[11] *Ibid.*

protection operates. It is a fact that many economists in the 19 th century itself recognised oligopoly as a prevalent form of market organisation[12].

(a) Consumer soverignity : 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[13].

(b) Market imperfection:

Another assumption of the free market is that competetion 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 competetive 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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[12] See generally P.S. Atiyah, *The Rise and Fall of Freedom of Contract*, (Clarendon Press, Oxford, (1979), pp.717-779

[13] See D.N. Sharaf, *Law of Consumer Protection*, N.M. Tripathi Pvt.Ltd., (1995), pp.1 - 3 .

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[14]. 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

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[14] Brian W. Harvey, *The Law of Consumer Protection and Fair Trading*, Butterworths, London, (1978)pp. 6 -11. See also Brian W. Harvey, *Consumer Protection Laws and the Perfect Market*, The Institute of Trading Standards Administration, England, (1979) pp.1-10

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 employee have been regulated by statutes[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 legislations 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 Pharmacuetical 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 *in toto* or go without. Since it is not feasible to

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[15] See Industial Disputes Act, 1947. Factories Act, 1948, Payment of Wages Act, 1936, Minimum Wages Act, 1948. Essential Commodities Act, 1955, Rent Control legislations. Monopolies 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 wass 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.

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[16] It may be notd 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 imptus to the freedom of contract theory.

[17] A.I.R. 1959 S.C 627.

Again in *Shree Meenakshi Mills v. Union of India*,[18] 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*,[19] 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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[18] A.I.R. 1974 S.C 366.

[19] A.I.R. 1986 S.C.1571 See also *Sethani v. Bhana* , A.I.R. 1993 S.C. 956 in which the Court came to the rescue of an illiterate Tribal woman.

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 stand* 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 occassions. 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.

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[20] *Id.*, p. 1615.

[21] See *Vincent v. Union of India*, A.I.R. 1987 S.C. 990.; *Common Cause v. Drug Controller of India*, (1991) 2 C.P.J. 698 and *Common Cause v. Union of India*, A.I.R. 1996 S.C. 929.

[22] See Dr. A.M. Varkey, "Judicial Activism to promote Consumer Protection", (1997) C.U.L.R. 423.

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. Povery 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 takes 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 out look 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 developoing 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 1947~~[23]. 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[24]. 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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[23] Report from the Select Committee [on] Examination of Drugs to Prevent Adulteration (1747) Journal [H.C.], Vol.25,p.592 quoted by Ross Cranston, *Consumers and the Law*, Weiden field and Nicolson, London, (1978)pp 387-395

[24] *Ibid.*

constituted an adulterant and what was an acceptable ingredient[25]. In 1874 a Select Committee was established to examine the Act in detail and to make suggestions for change. The outcome of the Select Committtee report was a new Act called Sale of Food and Drugs Act 1875. This Act was generally recognised to be the first substantial legislation. This law provided for criminal function 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[26]. 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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[25] See Stephen J Fallows, *Food Legislative System of UK*, Butterworths, (1988)pp 32-34,

[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 genereal prohibited except under licence. The fourth category included radioactive substances regulated under 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 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[27]

These Acts provide a frame work 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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[27] See 30 *Halsbury's Laws of England*, (4th Edition Re-issue, 1992), paras 851-853,

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[28].

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 madicines 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[29], in which over a hundred people died as a result of

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[28] See 25 Am Jur,(2nd) 284.

[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[30]. It also punishes the sale as well as distribution of adulterated drug from any dispensary for medicinal purpose[31]. 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[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[33] that there can be no test and untill 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[34].

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[32] See *id.*, S. 276.

[33] Hari Singh Gour, *The Penal Law of India*, Vol.2 Law Publishers, Allahabad, (1972) Para 1937,

[34] Constitution of India, , List III, Entry 19.

Consequently under the Constitution it is the Central Law which prevail[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 through out 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 Amentment 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 madicines prepared in accordance with the Ayurvedic or Unani system of medicine[36], to prevent adulteration of drugs and production of injurious and substandard drugs by imposing stringent penalties[37]. Consumer organisations have also been empowered by a recent amendment to initiate action in CourtS against the wrongdoer under the Act[38]. To enable consumers to buy medicines at a fair price, use is being made of the Essential Commodities Act by framing Drugs Price (Cntrol) Orders under it. To prevent the misleading and exaggerated calims in advertisements of pharmaceutical products Drugs and Magic Remedies (Objectionable Advertisements) Act[39] has been enacted. The rules framed under the Drugs

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[35] *Id.* at Article 254.

[36] Act 13 of 1964.

[37] Act 68 of 1982.

[38] Drugs and Cosmetics (Amendment) Act, 1986.

[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[40].

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[41]. 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 availablity of essential drugs in rural areas and to examine suggestions and complaints from the public.

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[40] Drugs and Cosmetics Act, 1940. Section5 provided for the establlishment 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.

[41] See brochure published by Directorate of Drugs Control Administration, Government of A.P. dt.1-11-1987.

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[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

[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 competetive 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[43].

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[44]:

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.

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[43] Drugs Cosmetics (Amendment) Act, 1986.

[44] Consumer Protection Act 1986. Section 2(1)9d) 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 remediers 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 medicnal 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 foreseability 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. Shantha*[45], 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[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[47]. To circumvent the argument that government hospitals cannot be equated with the commercial institutions the Court said,

> " 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"[48].

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'.

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[46] *Id.* at 676, *per* S.C.Agrawal, J.

[47] *Ibid.*

[48] *Ibid.*

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*[49]. 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 re-imbursement 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[50]."

In this context the Supreme Court referred to its own decision in *Kathri II 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

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[49] (1996) 4 S.C.C. 37.

[50] *Id*, at p. 48.

[51] (1981) 1 S.C.C. 627.

on account of financial constraints. It held that these findings would apply with equal, if not greater, force in the matter of discharge of constituional 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.[52]"

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[53] as any chemical agent that affects living protoplasm. The term drug is usually used in its narrower sense to refer to a chemcial whose specific purpose is the treatment of a disease.

Meaning of drug under English Law

Medicines Act 1968[54] (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'[55]. (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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[53] 9 *Encyclopedia Americana*404.

[54] Section 130(1)

[55] Such a purpose being for the treatment or prevention of desease or providing information as to a physiological condition, contraception, inducing anaesthesia, or anyhow preventing or interferring 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[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[57].

Drug under the U.S. law

The Federal Food, Drug, and Cosmetic Act[58] of the United States provides that the term "drug" means (1) articles recognised in the official

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[56] 30 *Halsbury's Law of England*, (fourth edition, Reissue) (1992)at paras 859 and 860.

[57] *Ibid.*

[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 diagonis, 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 accessaries 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

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[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[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 syranges can also be included in the definition of drug[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 themeaning 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

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[61] *Ibid.*

[62] See *Indian Express* January, 1998.

such devices and things used in the treatment such as gauze, absorbent cotton wool, and roller bandages . In *Chimanlal Jagjivandas v. State of Maharastra*[63], it was held that the definitiondoes 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 inorder that it might serve its purpose. Otherwise the fluid which oozes is left to accumulate at the site of the wound or sore[64].

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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[63] A.I.R. 1963 S.C. 665.

[64] *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[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 Culcutta High Court held that Boroline contain certain medicine. It was, therfore, as a drug[66].

The products like dust powder was considered to constitute a drug. The products that claim to cure baldness or a skin disease and harmone creams and antibiotic deodorants are in fact drugs because their ingredients affect the function of the human body. The term 'drugs' embraces patent or proprietory remedies that possess or are reputed to posses 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 circimstances 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.

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[65] *Ramachandra Sundarka v. State of West Bengal,* 1971 Cr.L.J. 1369 (Cal.).

[66] *Abdul Moid v. State,* [1977] Cr.L.J. 1325 at pp. 1326& 1327.

For the purpose of regulating its collection, storage and supply, "blood" is treated as a 'drug' under the Act[67]. Already claims have been made in respect of 'contaminated blood' and blood products supplied by blood banks[68]. Claims were also been made in respect of defective heart-valves, infra-uterine devices and breast implants[69]. It would be difficult to think of other products which could provoke litigation[70]. It is not clear whether donated human organs, contaminated or deffective 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[71]. 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[72]. 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

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[67] See Drugs and Cosmetics Rules, 1945. Rules 122 F to 122 P

[68] *Re HIV Haemophiliac Liligation*, (1990) 140 New L.J. 1349.

[69] *Hollis v. Dow Corning Corp.* (1993) 103 D.L.R. (4th) 520 quoted by Michael A. Jones, *Medical Negligence*, Swect & Maxwell, Tort Law Library, London, at para. 8.001, (1996)

[70] For exampl heart pacemakers, limb joints, tampous, which can cause toxic shock syndrome

[71] See Transplantation of Human Organs Act 1994 (42 of 1994) of India and National Organs Transplant Act of 1984 U.S.

[72] Notes, "Developments in Medical Technology and the Law", (1990) 103 H.L.R. 1519.

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.

CHAPTER II

CONTROLS ON PRODUCTION AND CONSUMPTION OF DRUGS

Mandate in the Directive principles of Indian Constitution[1] has laid stress on the improvement of public health and prohibition of drugs injurious to health as one of the primary duties of the State. Taking thread from these constituional provisions, the Supreme Court in *Vincent v. Union of India*[2], explained the scope of this primary duty of the State. It pointed out ;

> "Maintainance and improvement of public health have to rank high as these are indispensable to the very physical existance of the community and on the betterment of these depends the building of the society of the constitution makers envisaged. Attending public health, in our opinion, therefore, is of high priority - perhaps the one at the top."[3]

The Supreme Court of India expressed the view[4] that such drugs which are found necessary should be manufactured in abundance and

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

[2] A.I.R. 1987 S.C. 990.

[3] *Id.* at p. 995.

[4] *Id.* at p. 996

availability to satisfy every demand should be ensured. According to the Court undue competetion in the matter of production of drugs by allowing too many substitutes should be reduced as it introduces unhealthy practice and ultimately tends to affect quality. The State's obligation to enforce production of qualitative drugs and elimination of the injurious ones from the market must take within its sweep an obligation to make useful drugs available at reasonable price so as to be within the common man's reach[5]. Court also held the view that for every illness which can be cured by treatment, the patient must be in a position to get medicine.

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

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[5] *Ibid.*

essential to the large sections of the society is underlined in this part of the study.

A profile of drug industry and production

The drugs and pharmaceutical industry in India is one of the most important sectors of the Indian economy. It is of crucial significance to the public health of the nation. Since independence, the industry has expanded considerably and India today has wide-ranging capability in production of basic drugs and formulations. There are about 8000 pharmaceutical companies in India. They include some of the well known multi-national giants. They produce approximately 70,000 drug formulations. The production pattern of the industry in general indicate that pharmaceutical industry produces much more formulations than bulk drugs[6]. The break up of production of bulk drugs and formulations by various sectors of the industry clearly shows that only public sector undertakings are using their capabilities to produce bulk drugs and formulations on equal proportion.

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

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

Annual report of the Department of Chemical and Petrochemicals for 1992 - 93, published by Hindu Research Bureau, *The Hindu*, May 24, 1993. (Business, Monday monotor)

The foreign drug manufacturing firms and Indian owned private sector are concentrating mainly on formulations[7].

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

The Indian Government's enquiry[9] into the drug and pharmaceutical industry concluded that the transnational drug companies are interested in carryingout research only on products which will have a global demand

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[7] (Rs. In Crores)

	Bulk	Formulation
(I) Public Sector	48	47
(ii) Forcign Sector	63	293
(iii)Indian Private Sector including small scale sector	39	361
Total	150	700

See "Statement of Drug Policy 1978" published in Mazhar Hussain's, *Law Relating to Drugs and Cosmetics*, Eastern Book Company, Lucknow, (1990) pp. 673-695.

[8] **Percentage share of different groups of drugs in the market during 1985.**

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

Quoted in Editor, *A decade after Hathi Committee Report*. Kerala Sasthra Sahitya Parishad, Trivandrum (1988) p.24.

[9] Report of the Committee on Drugs and Pharmaceutical Industry (1975) herin after referred to as Hathi Committee Report (1975).

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

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[10] *Indian Express*, October 24, 1990.

[11] Arun Bal, "Distortions in Drug Policy : Who is to be blamed?" *Economic and PoliticalWweekly*, June 7, 1986 .p.1029.

[12] TABLE 1

DISTORTED PRODUCTION PATTERN OF ANTI-T.B. DRUGS

Drug	Amount	1980-81		1981-82		1982-83	
		Target	Production	Target	Production	Target	Production
SJM	Tons	302.0	227.3	320	225.4	320	266.0
INH	Tons	154	129.2	140	110.4	158	-128.0
Thiacetazone	Tons	20.0	8.4	16.4	14.4	21	-25.0
Ehambutol	Tons	33.0	24.9	32.0	66.9	54	-85.0

TABLE 2

PRODUCTION OF VITAMIN - A

Unit	1980-81		1981-82		1982083		1983-84		1984-85	
	Target	production	Target	Production	Target	Production	Target	Production	Target	Production
Vitamin	66.0	59.8	66.6	52.6	77.0	52.0	90.0	60.23	105.0	41.92

Source : Government of India, "Indian Pharmaceutical Industry : Problems and Perspectives", contained in Department of Chemical and fertilisers, performance Budget, 1982-83, pp. 250-253.

This shortfall in the production cannot be attributed to limited production capacities. The installed capacities are under utilised for obvious reasons. Thus artificial demand has been created by the pharmaceutical industry. The real reasons are evident from the fact that certain essential generic drugs are not available where as their formulations and combinations are made available. For example, streptomycin is not available but it is possible to get injections of streptomycin in combination with penicillin. The fact is that these combination are more expensive though more profitable for the manufacturer.

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

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

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[13] See for details Report of Hathi Committee (1975), para 12.55.

[14] *Ibid.*

It is interesting to note that Indian owned small scale sector is producing more share of the total bulk drugs when compared to the foreign and foreign majority units owned by the multinationals. The total production of bulk drugs by small scale units was estimated[15] to be at about 500 tonnes including synthetic bulk drugs. Out of this only about 3 percent was produced by the small scale units of foreign and foreign majority units and about 97 percent by the Indian units. At the same time these multinational have concentrated their effort in the production of formulations. They accounted for over 24 percent of the total tounover in formulation.[16]

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

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

Norms imposed upon production of drugs under 1978 Drug Policy

Different norms were imposed on public sector, Indian private sector and foreign sector for production of drugs. Public sector was given untill recently the leading role to manufacture certain drugs exclusively to enable it to meet substantial healthcare needs of the Country[17]. Approved production policy for Indian manufactures of drugs in private sector was that they were

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

[16] *Ibid.*

[17] The Statement of Drug Policy 1978, para.10, see *supra.* n.7. It may be noted that these guidelines have been substantially altered by the new drug policy 1994. See *infra* text carrying footnote 63 for details.

allowed for formulation licence upto ten times of the value of their bulk drug production[18]. But out of the total bulk drugs used by such firms for manufacture of formulation, fifty percent must be consumed from the indigenously produced bulk drugs. This condition was imposed to encourage the consumption of indigeously produced bulk drugs. There was power to review whether Indian companies should be allowed to expand formulation capacity freely if it is based on consumption of indigenous bulk drugs and whether the restriction on expansion of formulation capacity should be imposed when the Indian companies are seeking imported bulk drugs[19]. Hence the policy appeared to be that Indian companies should be encouraged even in the formulation activity provided they use substantially the indigenously produced bulk drugs. The policy was to discourage the production of formulations based on imported bulk drugs.

Norms for foreign companies

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

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[18] *Id.* at para 12 (xi).

[19] *Id.* at para 12 (xiii)

[20] *Id.* at para 14 (b).

[21] *Id.* at para 15.

[22] *Id.* at para 20.

bulk drugs from basic stage[23]. Extention of formulation licence to the existing foreign companies was linked with the production of high technology bulk drugs from the basic stage[24]. Foreign companies were prohibited from entering into the area of small scale sector and no foreign company was to be given loan licence[25] for operating in drugs field[26].

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

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

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

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[23] *Id.* at para 21.

[24] *Id.* at para 22.

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

[26] Supra n.17 at paras 23 & 24.

[27] Report of Hathi Committe (1975), para 8.55.

[28] See Andrew J. Rebello, "Drugs Policy needs to be changed", The Hindu, Oct. 25, 1989.

quantities. The most essential drugs are those intended to fight infection, parasitic respiratory diseases such as T.B., malaria, dysentery, diarrhoea, cholera etc. Even drugs which are available, such as streptomycin which is basic drug to cure T.B. is made use of and manufactured in wasteful combinations and sold under brand names such as Chlorostrep, Enterostrep, Intestrep thus reducing its use for T.B.[29]

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

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[29] Ibid.

[30] For example, Novalgin (Manufactured by Hoechst) an over the counter (OTC) drug which needs no prescriptions from a doctor in India, has recorded a 94 per cent increse in sales in India. It, however, has been banned in 15 countries as being hazardous and resulting in a fatal disease if taken often. For details see Avewrthanur, "National drug policy: Basic Desiderata" *Mainstream*, January 17, 1987, pp.23-25. Also see N.Battacharya, "Distorted Drug Policy 1986" *Mainstream*, January 17, 1987, p.27.

evident not merely from this admission by the Drug Controller, but from the various reports that come up so often.[31]

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

Meaning of essential drugs

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

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[31] "Adulterated anaesthesia claims lives at AIIMS" - read one news report; "Over 50 kids paralysed after inoculation" - read another; "ESIS faces shortage of essential drugs" - says a third; "Banned drugs still freely available" - said yet another. Quoted in *supra* n.28.

[32] See C.M.Francis, Essential Drugs : "The Why and the How?" 5 *Health Action*, No.12, December 1992, at p.5.

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

Need for preparation of essential drugs list

The list should be meant to include only those drugs which our country considered necessary to treat the diseases which are afflicting our people. The quantum of essential drugs may vary from country to country depending upon the health conditions prevailing in that country[33]. At present, if we compare with what we consider as needed with those what was actually circulated in the country there is a vast discrepancy. About 70000 varieties of drugs were being sold[34] Whereas all that we needed were approximately 200. Hathi Committee had drawn up its list of 116 drugs for

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

[34] Staff Reporter of *The Hindu* quoting speakers of a National Seminar Organised by (VHAI) Voluntary Health Association of India, Rajasthan Chapter, reported in *The Hindu*, January 22, 1991.

the purpose[35], while the World Health Organisation (WHO) maintained in 1985 that 250 drug combinations are sufficient to cover all ailments.. In the absence of such a list there would be no way to ensure the production, distribution or availability of the needed drugs can be ensured. If much care is not taken in preparing the essential drugs list, it might do the just reverse of its objectives.[36]

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

Rational consumption of drugs

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

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[35] Hathi Committee Report, (1975)

[36] Indian Express, Oct. 30, 1991.

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

Need to regulate prescribing habits of the doctors

Two thirds of all visits to the doctor end up in the writing of a prescription. Often these prescriptions are justified on medical and phychological grrounds. But it is also true that the doctors while prescribing are under intense sales promotional pressures of drug manufacturing companies. There is definite possibility that in good number of instances where drugs are prescribed and purchased not based on the need but in response to such promotional pressures. Association of British Pharmaceutical Industry long before estimated approximaterly £4800 as the cost of promotion for every doctor in Britain[37]. Some studies have suggested that doctor's prescribing habits can be strongly influenced by sales representatives who constitute their primary source of information[38]. Even though the free hospitality, gifts and samples are usually of trivial financial

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[37] *The Times*, February 22, 1983.

[38] Medical Sociology Research Centre, University College of Swansea, "Prescribing in general Practice" (1976) 26 J. Roy Coll. Gen.practit. (Suppl.1) 69-76. See also "Doctors to Blame for Poor Standard of Industry Advertising" (1982) *Pharmaceutical Journal* 517 and J.Avon, M. Chen and R, Hartley, "Scientific versus commercial sources of influence on the prescribing behaviour of physicians" (1982) 73 Am.J. Med. 4-8 quoted in Havey Teff, "Regulation under the Medicines Act 1968 : A continuing prescription for health", 47 Mod.L.Rev.303 (1984).

value, they help to create a relationship that is not necessarily conducive to the best interest of patients.

Objections in regulating prescription habits

Attempts to regulate the prescribing habits of the doctors may have to meet stiff resistance on the ground that it would constitute undue interference with the clinical freedom of the doctors. Doctors may argue that the concepts such as 'safety' and 'efficacy' are openended and the quantum of drug to be prescribed to a patient has to be calculated in the light of such considerations as the seriousness of the illness, the condition of the patient and the proposed length of treatment. According to them, the issue of what constitutes 'efficacy' for the drug can't be satisfactorily determined[39]. Similarly they contend that it is artificial to assess the drug's 'efficacy' without considering the relative effectiveness of the various determinants of a 'healthy life'. And these yardstics, according to them, vary in each individual patient's case[40]. They argue that it is sufficient to have strong pre-market controls on drugs and the society can afford to keep faith on the doctors prescribing habits[41].

Need to regulate

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

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[39] *Id.* at p.314

[40] *Id.* at pp.308-309.

[41] *Ibid.*

both manufacturers and importers seems necessary for obvious reasons[42]. Competition among various manufacturers of the same drug persuades doctors or in the case of house hold remedies persuade the consumers to patronize a particular brand of drug. The use of brand names as opposed to generic names enables the drug industry to sell essentially similar drug formulations at widely varying prices. Quite often it is difficult for the doctor and almost impossible for the patient to have at their disposal information which would enable them to compare prices of drugs which are virtually identical.

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

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[42] See A.K.M.N.Anwar, "Towards Rational Drug Prescribing " (mimeo) presented in the seminar on *'Role of Mass Media in Rational Prescription of Drugs'* held in Dhaka, November 2-3, quoted in S.Srinivasan, "Signing about the dark times : Bangladesh Drug Policy " *Economic and Political Weekly*, May 25, 1996, p.1252. See also Zafrulla Chowdhury, *The Politics of Essential Drugs - The Makings of a Successful Health Strategy : Lesson from Bangladesh*, Vistar publications, New Delhi, (1995) p.128.

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

Need to substitute generic drugs

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

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

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

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[43] Hathi Committee report (1975), para 10-253.

substantial misbranded and spurious products reported by various drugs control organisations and drug testing laboratories of Government of India revealed that there are more instances of branded products being misbranded or spurious[44]. There has been no instance where a product marketed under generic name has ever been reported to be spurious. Thus, branding of products promotes a tendency to prepare misbranded or spurious products.

The changeover from brand name to generic be brought about in phased manner. A beginning was already made with few drugs identified and kept in a separate Schedule[45]. But it provides for only five names of the drugs which are considered inadequate. There is need to expand the list provided under the Schedule. Non-proprietory names as recommended by WHO from time to time should be adopted. In order to keep the medical profession, particularly the general practitioners, well informed about new drugs and also to popularise the generic names it is essential to take the following steps immediately as recommended by the Hathi Committee:

(1) To revise the Indian Formulary and make it upto-date.

(2) To publish journals on the lines of Prescriber's Journals, U.K., Medical Letter, USA, or Formulary Notes of Sri Lanka. Such publications will have to be under the control of an editorial board comprising of the leaders of medical profession in the country. From the legal point of view, there

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[44] *Id.* at para.18-254.

[45] See Drugs and Cosmetics Rules 1945, Schedule 'W'. This includes 5 drugs namely Analgin, Aspirin and its salts, Chloropromazine and its salts, Ferrus Sulphate and Piperazine and its salts which should be marketed only under generic names.

should be no difficulty in abolishing the brand names. Abolishing of brand names will entail first the amendment of the Trade and Merchandise Marks Act 1958 and subsequently the Drugs and Cosmetics Rules. An undertaking from all the members of Indian Medical Association must be obtained to the effect that they would not prescribe any drug out side such list.

Government need to regulate very stringently the import, manufacture, sale or distribution of any drug outside the essential drugs list. In the meanwhile, drugs have to be advertised and sold under generic names so that when the pharmacists labels their drugs, the generic name must appear very boldly under the brand name. It should be at least three quarters of the size of the brand name.[46] There should be an independent department with all the financial support to monitor every aspect of this policy.

Considerations of a drug policy :

Need for production oriented to the poor

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

[46] For example, the advertisement for "Panadol" must immediately mention 'Paracetamol' under it. After the brand name is given it has to be followed by the words "brand of' followed by the generic name.

population live in rural areas. Their needs for drugs are no less pressing than those of urban dwellers. But because of logistical and other problems, it is relatively easy to underserve the rural communities while the urban ones are overserved.

In a more general manner, the problem of product appropriateness is of special relevance in developing countries when a consumption pattern, originating in the developed countries is forced on consumer in developing countries by means of extensive sales promotions, without due regard to the real needs of these consumers. Products originally developed with regard to standards of living, climatic and racial needs in developed countries may have characteristics that do not fit into the consumption patterns and needs of the developing countries.[47] There is also a possibility that firms from developing countries will choose to direct their attention to the market segments in a developing country where the demands are similar to those in the developed countries while the vast majority of the consumers - poor and inarticulate as they are remain unsupplied.[48]

Legal support to producers and distributors of generic drugs

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

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[47] See International Organisation of Consumer Union, *Law and the Consumer*, (1980), p. 9.

[48] *Ibid.*

that at least there are pharmaceutical companies and chemist's shops, though very few, set up solely to produce and sell generic drugs.[49] That the prices are cheap can be seen from a comparison of some of the more common and often used medications.[50] How these forms can sell these drugs at rates much below than what the rest of the drug manufacturers?. Would their quality be bad or substandard ? Clearly, it is not so because all these drugs are doubly tested for quality in reputed laboratories and proved that their quality control is 100 per cent[51]. This experiment proves that it is possible to ensure high quality drugs at low cost. So consumercan see that low cost can also be best and not what most advertisers propagate that cheap necessarily means poor or substandard. Therefore, what is required is the socio-legal effort to encourage such firms and popularise the generic drugs. In order to reduce the cost of advertisement for such firms, voluntary consumer organisations must canvass for these firms. State should

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

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

[51] *Ibid.*

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

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

Need to reconcile the interests of industry and consumers

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

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[52] *The Hindu*, Feb. 1, 1991.

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

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

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[53] Editorial, *Financial Express*, Feb.1, 1990.

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

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[54] *Ibid.*

[55] *Ibid.*

[56] See the discussion by Assocham at the workshop on "Drugs and pharmaceuticals : Protection of consumer interest" organised by it in association with the Council of Fair Business Practices in Bombay during September, 1989 quoted in Editorial, *Finance Express* Sept.9, 1989..

[57] SeeKalpana Sharma, "Health care and Government funding", *The Hindu* July 27 1993 quoting World Bank official on 1993 World Development Report of World Bank.

Mudaliar Committee had recommended more than two decades ago that at least a tenth of the plan outlay should be earmarked for health.[58] Unfortunately, even now the allocation for the health sector is less than two per cent of the total out lay.[59] No less disconcerting is the fact that Union and state governments treat medicines as a source of revenue. It is bad enough that the government is tardy in lowering the incidence of taxes on medicines. What is worse is that, the state governments are still to aim for uniformity in the rates of sales tax and octroi. As the maximum retail price is fixed under the drugs price control orders which is exclusive of local taxes, retailers get an opportunity to defraud consumer by inflating local taxes. Therefore, there is a need to levy local taxes at uniform rates throughout the country for protecting consumers. The Union Government has been advising the state governments to exempt drugs from the turnover tax and other local taxes since drugs are controlled. Unfortunately, the advise fell on deaf ears.[60] Like the state governments, Union Government too is reluctant to sacrifise revenue yielded by imposts on this industry.[61] This will lead to unhealthy consequences like shortage of essential drugs. Because of the price regulation industry is not permitted to sell drugs beyond

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[58] See Editorial, *Financial Express*, September 9, 1989.

[59] *Ibid.*

[60] State of Andhra Pradesh reimposed turnover tax on all goods including medicines on the ground that other States are collecting. See *Enadu*, June 25, 1996 and also see *Enadu*, Nov.9, 1993, p.6.

[61] See the 1996 Central Budget Reports.

a particular price and the producers are unlikely to intensify their efforts to raise production of those drugs whose prices are not remunerative. The prices can only be controlled without affecting supply of drugs if production costs are contained and there is free play of the forces of demand and supply.

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

Need for proper co-ordination

The policy statement should also ensure that negotiations would be under taken with the departments of customs and excise to ensure that duties and levies on raw materials and excipients for manufacture of essential drugs are minimised or removed and substantial duties be levied on imported finished products which are also manufactured locally.[62]

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[62] See C.J.. Porshaw, P.J. Graft, P.R. Khonje and P.S.P. Tembo, "Malawi; New Drug Legislation and National Drug Policy Introduced." 12 *Essential Drugs Monitor*, 7 (1991).

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

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

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

health related goals include improving prescribing and dispensing practice and promoting the correct use of medicines by the public.

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

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

policy provides a unique opportunity to evaluate the present, identify problems and plan for the future.

New drug policy of 1994 : A critique

In the light of what has been said about factors to be considered for a ratrional drug policy, one should analyse the provisions of the modified drug[63] policy. It may lead us to the conclusion that the present policy guidelines have negated the objectives of the 1986 policy and are also against to the spirit of the Hathi Committee recommendations. In effect it would go against the directives of the Constitution.

The main objective of the drug policy 1986 was "ensuring abundant availability, at reasonable prices of essential and life saving and prophylactie medicines of good quality"[64]. Because of the production pattern of the pharmaceutical industry and their record in producing only profit spinning formulations and their disinclination to concentrate on bulk drugs and essential drugs and the consequent inadequancy of bulk drugs, Hathi Committe was of the opinion that " a large number of bulk drugs are still required to be imported to meet the present demands"[65]. According to it, progress attained so far is not commensurate, with the increasing needs of

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[63] Government of India, " Modification in Drug Policy, 1986" issued by the Department of chemicals and petrochemicals of the Ministry of Chemicals and Fertilisers. Sept.1994, herein after referred to as Drug Policy, 1994 . See for the text of the policy (1994) 4 Comp. L.J. (Statutes) 49.

[64] *Ibid.*

[65] Hathi committee (1975) Part II para 19.20.

the country particularly in respect of bulk drugs[66]. Committee held the view that the response of the multinationals for the persuasive efforts of the Government of India to produce bulk drugs has been "negative or poor"[67].

As against this background and without taking cognizance of these facts into account the new policy document says[68] that the "conditions stipulating mandatory supply of percentage of bulk drug production will be abolished". This will lead to large scale import of bulk drugs while the pharmaceutical industry in India will decide to concentrate only on formulations. The policy also states that the "ratio parameters linking bulk drugs and formulation production and limiting the use of imported bulk drugs will stand abolished"[69].

Hathi Committee was of the opinion that in the case of licensing for the manufacture of new drugs developed abroad, the main consideration should be that the proposed new drug must have distinct advantages over the existing range of drugs[70]. The Committee further recommended that the therapeutic character of such new drugs should be scrutinised by a Committe of experts[71]. Whereas the revised policy[72] seeks to abolish all licensing for formulations except in cases of specific cell or tissue targetted formulations"

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[66] *Id.* at para 17-20.

[67] *Id.* at Part III, para 60.60.

[68] See *supra* n.63 at para. 22.1.2.

[69] *Id.*, at paras 22-1-4

[70] See report of the Hathi Committee (1975), para 59.60.

[71] *Ibid.*

[72] *Supra.*, n. 63 para 22.1.3.

and thereby the government denied itself the opportunity to scrutinise the application for licence to a new formulations and screen out if they are found to be irrational. It is clearly against the reasoned recommendations of the Hathi Committee. This is considered to be unwarranted in the light of the fact that multinationals have a tendency to introduce newer products of similar activities with marginal differences. Since such products are patented, they are usually priced high.

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

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

CHAPTER III

APPROVAL PROCESS FOR NEW DRUGS AND RIGHTS OF THE CLINICAL TRIAL SUBJECTS

There appears to be a constant competition between nature which can be said to be responsible for new ailments on one side and human ingenuity engaged in research to find out new curative process. What is considered to be a best medicine today for treatment of a particular disease becomes out of date and soon go out of the market with the discovery of new drugs. Again what is considered to be incurable at any given point of time becomes subjected to treatment and cure with new medicines. With the onward march of science and complexities of living process hitherto unknown diseases are noticed. AIDS and Cancer still pose great challenge to the researchers in medicine. Major breakthroughs are yet to be made to effectively combat these and other new diseases.

To meet these new challenges, new drugs have to be identified. There is every need to accelerate research and development in the field of medicine and bio-technology. Therefore, the change appears to be the rule in this field. Legal provisions should help the growth of knowledge intended to minimise the human misery caused due to diseases. At the same time, the need to respect the human being as a member of the human species is to be recognised. It is necessary to recognise the importance of the dignity of the human being. We

must be conscious of the probable misuse of biology and medicine and endangering human dignity.

In the process of medical research, human beings should not be used as subject for experimentation without due safe guards. Trading in human tissue is also prevalent, in different parts of the world. There is commercial activity going on in human blood, foetus, organs, embryos, eggs and wombs. The development in medicine has thus made many things today which were impossible previously. Trading, in human tissues is perceived as lucrative business. It also means good money for those who are willing to sell their body in parts one by one for the purpose of transplantation to others who need and can afford to purchase. Thus, the advances in biotechnology has made the body a valuable propery. The consequences of such kind were not contemplated before. therefore, the need for concern for human rights in this area.

It is true that humanity, both present and future generation must be allowed to enjoy the benefits of development in biology and medicine and at the same time it must be resolved to take all such measures as are necessary to safeguard human dignity and fundamental freedom of the individual in the application of biology and medicine.

The Supreme Court, by reading Article 21 with Articles 39 and 47 ruled that the right to life would cover amenities ensuring good living which include medical attention, life free from diseases and longivity upto normal

expectations. In *Bandhua Mukti Morcha v. Union of India*[1] , the Court aptly observed that it is the fundamental right of everyone in this country, assured under the interpretation given to Article 21 to live with human dignity, free from exploitation.

Several global conventions[2] were adopted to protect the dignity and identity of all human beings and guarantee every one, without discrimination, respect for their integrity and fundamental freedom with regard to the application of biology and medicine.

The guidelines of the World Health Organisation (herein after referred to as WHO) insists on the protection of the rights and safety of the subjects including patients in the process of investigations directed to the advancement of public health objectives[3]. The declaration of World Medical Association at Geneva held the view that in research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject and the mission of the physician should always be the health of his patient[4].

In the backgroud of these guidelines and objectives, it is intended to examine the clinical trial procedures envisaged for the approval of new drug to be marketed in India either by manufacturing in India or by importing into

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[1] A.I.R. 1984 S.C. 802. Also see *Francis Coralie Mullin v.Union Territory of Delhi*, A.I.R. 1981 S.C. 746 and *Vincent v. Union of india* AIR 1987 S.C. 990.

[2] See European Convention on Human Rights and Bio medicine" (1997).

[3] WHO, "Consultative Document", *WHO Drug information*, Vol. 6 No. 4, 1992 at p. 170.

[4] World medical Association, "Declaration of Helsinki Recommendations guiding Physicians in Biomedical Research involving Human Subjects ", *Id at. p.186.*

India. Identically, the provisions for clinical trial procedure to approval new drugs in the U.S. are also discussed. It is also proposed to study the provisions for protection of the subjects of bio-medical research in the light of the guidliness issued by the Supreme Court of India and international agencies like World Health Organisation. The European Convention on Human Rights and Declaration of Helsinki on duties of physicians are also examined..

Approval process for new drug:- The new drugs are very complex and their discovery and development require costly technology. The regulatory control has also become very strict. The drug has to pass through more stringent safety and other tests. Therefore, the introduction of new drugs has been on the decline. In India number of new drugs declined from 564 in 1953 to 166 in 1962[5]. The number of drus introduced in the U.S. market declined from early average of 100 in 1960 to less than 40 in 1980s. Though the discovery rate has increased due to explosive growth of biomedical knowledge, the number of new drugs has continued to decline in the 90s because of the strict regulatory requirements. Only 28 new drugs were approved in the U.S. in 1995 and only 40 new drugs were introduced Worldwide during the same year[6]. The pharmaceutical industry in India and elsewhere expressed the view that controls on new drugs are stringent and costly [7]. The procedures stand in the

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[5] See Keayla, " TRIPS agreement on patent laws : Impact on pharmaceuticals and health for all" a paper presented at International Conference as Global Health Law organised by the Indian Law Institute in collaboration with World Health Organisation during December 5-7, 1997 at p.12.

[6] *Id.* at p.13.

[7] F. Steward & G. Wibberly, "Drug innovation - what is slowing it down?" (1980) 284 *Nature* 118 at p.120; Also see K. Hartley and Maynard, *"The cost and benefits of regulating new product development in the U.K. Pharmaceutical Industry"*, (1982), a study produced for the Pharmaceutical

way of innovations and prevent the availability of new therapies quickly. It is necessary to reconcile the conflicting interests of the pharmaceutical industry and the requirements of the needy patients in the process of approval of new drugs. The role of the authorities in this context is not only to ensure that innovative drugs are marketed at the earliest but also to protect the public from unsafe drugs.

Definition of new drug

A new drug according to the provisions of the Act[8] is a drug, the composition of which is such that the drug is not generally recognised among experts as safe for use. It includes a drug which may have been found safe for use under investigational conditions but which has not been used for any appreciable length of time under the said conditions[9]. Thus a new drug would cover drugs under the following categories.

Industry's Office of Health Economics. The authors findings were based on postal questionnaire sent to 25 major U.K and foreign owned firms. The same consisted of firms selected by the British Pharmaceutical Industry together with a set of firms chosen by the authors on a random sample basis.

[8] Drugs and Cosmetics Rules 1945, Explanation to Rule 30A. These rules were framed in exercise of the powers conferred by Sections 6(2), 12, and 33 of the Drugs and Cosmetics Act 1940.

It reads : " 30-A. Explanation :- For the purpose of this rule, "new drug" means a drug the composition of which is such that the drug is not generally recognised among experts as safe for use under the conditions recommended or suggested in the label thereof and includes any drug the composition of which is such that the drug as a result of investigations for determining its safety for use under such conditions, is so recognised, but which has not otherwise than during the course of such investigations, been used to any large extent or for any appreciable length of time under the said conditions".

[9] *Ibid.*

(i) a new therapeutic discovery,

(ii) a new therapeutic use for an established drug for another disease,

(iii) a drug recommended for administration by a new route,

(iv) combination of established drugs for new indications or when claims are made that the combination contribute an improvement in therapy as compared to the individual components when used separately.

With a view to ensure uniform yardstick in clearance of new drugs, authority to clear new drugs has been vested with Drugs Controller of India.[10] No new drug can be manufactured or imported into the country without his approval. Procedure for importing of new drugs are also prescribed[11]. For clearance of import or manufacture of a new drug, a person is required to produce before the Drugs Controller of India detailed particulars regarding

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[10] *Id.*, Rule 21(b) and 22 read:

"21. licensing authority" means the authority appointed by the Central Government to perform the duties of the licensing authority under these Rules and includes any person to whom the powers of a licensing authority may be delegated under Rule 22";

"22The licensing authority may with the approval of the Central Government by an order in writing delegate the power to sign licences and such other powers as may be specified in the order to any other person under his control".

[11] *Id.*, Rule 30 (A) reads :

"30-A (1) No new drug shall be imported except under and in accordance with the permission in writing of the licensing authority.

(2) The importer of a new drug when applying for permission shall provide before the licensing authority all documentary and other evidence, relating to its standards of quality, purity and strength and such other information as may be required by the licensing authority including the results of therapeutic trials carried out with it"

toxicological, pharmacological, bio-chemical and terrato genic studies carried out with drug and clinical trial reports.[12] the manufacturer or importer has to produce before the licensing authority all the documentary and other evidence relating to the standards of quality, purity and strength and any other information required by the licensing authority. This information may include therapeutic trials carried out with such drugs. For obtaining licence to manufacture new drug, the manufactures has to produce evidence that the drug for the manufacture of which application is made has already been approved. The clinical data furnished by the applicant would be screened by experts. Some drugs may be new to India but they may have history of use and clinical test in other countries. The reports of clinical tests made in other countries must be submitted with the application. In practice, this foreign test data, if extensive and accepted in many countries, may be sufficient to support approval of the drug in India. There appears to be similarities in the approach of new drug regulation in most part of the world.

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[12] *Id.*, Rule 69-B. The Rule reads, " Applications to manufacture 'new drugs' other than the drugs classifiable under schedules C and C(1) products ;- Subject to other provisions of these Rules:-

(i) no 'new drug' shall be manufactured unless it is previously approved by the licensing authority mentioned in Rule 21;

(ii) the manufacturer of a 'new drug' when applying for approval to the licensing authority in sub-rule (I) shall produce all documentary and other evidence relating to its standards of quality, purity and strength and such other information as may be required including the results of therapeutic trials carried out with it;

(iii) while applying for a licence to manufacture a 'new drug' or its preparation an applicant shall produce along with his application evidence that the drug for the manufacture of which application is made has already been approved". See also Rule 75(B), which reads :

"75-B Applications to manufacture 'new drugs' classifiable under Shedules C and C(1) ...

In European countries, authorisation for putting a new product on the market are granted by national authorities.[13] The U.S. law requires pre-market approval of all new drugs.[14] Approval is based on controlled clinical tests showing safety and efficacy of the drug. The FDA also accepts foreign data and clinical studies in support of a new drug approval when satisfied about relevance of the testing to the U.S. population.[15]

In China the law establishes a pre-market licensing system for new drugs not previously sold in that country.[16] Controlled clinical tests are also required for certain categories of drugs. In China, as in the U.S., full clinical tests are not necessarily required for "generic" drugs that are identical to or similar to an approved pioneer drug. Bio-availability test can be sufficient as the basis of approval for a generic drug when the authority is satisfied about similarity and bio-availability of the drug.[17]

When the conditions for authorisation of new medicinal products are identical, when the same tests are carried out, the same test animals are used and the same documents are forwarded to the authorities, it appears, the only decision left to the individual countries is the evaluation of the documents

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(Please note that the rest of this rule reads same as 69-B (i) (ii) (iii))

[13] See Alberto Grignolo, "How Drug Companies are preparing for 1992", 44 *Food Drug Cosmetic Law Journal* 557, (1989).

[14] See 22 C.F.R. 314 - 104; 314, 105, See also L. Kranes, *EEC Consumer Law*, Droit Ed. Consummation (1986), at pp. 206-213.

[15] 21 C.F.R. 114.106.

[16] Margaret Gilhooley, "Pharmaceutical Drug Regulation in China," 44 *Food Drug Cosmetic Law Journal* 21 (1989)

[17] Id. at p. 24. See also 21 U.S.C. 1§§355 J (Supp. III 1985) and 21 C.F.R. 314-55, 314-56.

received. When all national decisions regarding the authorisation of pharmaceutical production are based on the same factual considerations which are harmonised, it is difficult to conceive that a product which is considered safe and has consequently been granted approval in one country, could be considered unsafe in other countries. The legal principle underlying this idea is that a product deemed reasonable in a given country should be reasonable in all the countries.

But due to some peculiar conditions prevailing in India, every new drug is required to undergo clinical trial before they are permitted to be marketed.[18] The physiological norms like height and weight of people in this country differ from those in developed countries from where new drug normally emanates. The nutritional status of people of India is low when compared to that of the developed countries with the result that dosage patterns which are considered safe enough in developed countries may not be applicable in India. A substanital portion of the population suffers from chronic diseases such as amoebic infection or malaria and this could affect the function of the liver and spleen. Since most drugs are metabolised through liver, there is a possibility that efficacy, including side effects of these drugs in the Indian population may be different. Genetic or racial factors may also affect response to a drug. While primary considerations for granting permission for a new drug is safety and efficacy, clinical superiority over existing drugs is to be taken into

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[18] See V.C. Sane, "Drug Control: India", *World Congress on Law and Medicine*, New Delhi, Feb 23, 1985 at p. 3.

consideration while clearing new drug application, as India cannot afford the luxury of permitting introduction of a new drug, which does not show any clinical superiority over an existing drug[19].

The analysis of the above provisions reveal that the legal provisions to monitor the procedure followed during the clinical trials when the drug was experimented on animals and human beings before an application for approval to manufacture is completely absent and hence there is no means to protect the rights of persons who are called trial subjects during the trial of the drug since these clinical trials are not controlled. The procedure envisaged under law only intends to verify the documents relating to test carried out in clinical trials. In addition to this the demands of some new diseases like AIDS have refocussed the whole issue about development process of new drugs in the world. Because of this reason, the authorities appeared to have shown considerable urgency to allow the drug to be marketed than it was in the past.[20]

Clinical trial procedures of the U.S.A.

It is not out of context here to analyse briefly the procedure followed in clinical trials in the U.S. since it is considered as the standard procedure accepted by most of the countries.[21] This procedure must not only serve the interest of those who are actively involved in the research process but also

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[19] *Ibid.*

[20] See Jonathan S. Khan, Esq. and David T. Read, Esq., "Expedited availability of New Drugs," 45 *Food Drugs Cosmetic Law Journal* 81 (1990).

[21] See also WHO, "Consultative Documents", *WHO Drug Information*, Vol. 6, No.4, 1992, at p. 170.

protect the rights and safety of the subjects apart from advancing public health objectives.

The analysis of the clinical trial procedure of the U.S. is also important in the light of the fact that there are no strict rules available in India to monitor the ongoing clinical trails where drugs are put to test on human beings. The procedure existing in India under the rules only intends to verify whether the new drug is effective and qualitative as per the standards prescribed before it is marketed.[22] A study of the procedure for approval of new drug application in the U.S. will disclose the need for the similar or improved provisions in India to monitor the ongoing clinical trials. To expedite the procedure for approval of new drug, there appears to be an immense pressure on the authorities in the U.S. to slacken its stringent attitude. This may lead to violation of some safety standards. Analysis would bring to light certain issues regarding rights of the subject involved in these trials and correlative obligation of sponsors and investigators.

First, the drug must be tested for safety in animals before clinical trials[23] in human beings may begin. The clinical testing is performed under an investigational new drug[24] application which must be reviewed by the

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[22] See *Supra* nn. 8-12.

[23] Clinical Trial means any systematic study on pharmaceutical products in human subjects whether in patients or non-patient volunteers in order to ascertain their efficacy and safety. It is not possible to draw distinct lines between the various phases of these trials. There are also divergent opinions about details and methodology adopted in each of these phases.

[24] Investigational product means any pharmaceutical product or placebo being tested or used as a reference in a clinical trial. See Jonathan S. Khan, Esq. And David T. Read, esq., "Expedited

regulating authority. Clinical trials may continue for 2 to 10 years before new drugs application (NDA) may be submitted for marketing approval.

The lengthy clinical testing period is divided into three phases. Phase I is designed to determine the metabolism and pharmacological action of the drug in human beings, the side effects associated with increasing doses and to gain, if possible, easily evidence of effectiveness. Phase 2 involves limited controlled studies in which safety and effectiveness for particular indications are studied; Phase 3 consists of expanded controlled and uncontrolled trials in which the effects of the drug on large population are observed and dosages are adjusted.

Procedure for 'Treatment use' of Investigational New Drug (IND)

Ordinarily, a new drug is not available to patients other than those enrolled in clinical studies until phase 3 is completed and an NDA is approved. However, new rules are framed for "treatment use" of investigational new drugs (IND). These regulations allow patients to use an experimental drug if the drug is being studied for use against a serious or life threatening disease. This treatment use will be granted if certain conditions are met. For instance where (1) there is no satisfactory alternative drug or other therapy available to treat the same stage of the particular disease in the intended patient population (2) controlled clinical trials under an approved IND are underway or have been

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availability of New Drugs," 45 (1990) 81, *Food Drug Cosmetic Law Journal*. Also see WHO, "Consultative and Document," *WHO Drug information*, vol. 6. No. 4, 1992, at p. 170.

completed, and (3) the sponsor is pursuing ultimate market approval actively and with due diligence, the treatment use can be granted.

'Treatment use' may be requested either by the sponsor or by the physician treating the patient. A drug sponsor[25] may submit a treatment protocol[26]. It contains, among other things, (1) a description of the intended use of the drug, (2) an explanation of the rationale for use of the drug, (3) a description of the criteria for patient selection, (4) an informational brochure to be supplied to each treating physician and (5) a commitment that all participating investigators will comply with informed consent[27] requirements. Alternatively an individual physician may submit a request for treatment through IND if the sponsor agrees to provide him with the experimental drug. The request for treatment through IND must contain information similar to that in the treatment protocol.

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[25] Sponsor is an individual, a company or a research organisation which takes responsibility for the initiation, management and financing of a clinical trial. When an investigator independently initiates and takes full responsibility for a trial, then the investigator also assumes the role of the sponsor.

[26] Protocol means a document which states the background, rationale and objectives of the trial. It describes the design and methodology to be adopted in the trial. It also includes statistical considerations and conditions under which the clinical trial is to be conducted. It can also function as a contract between the sponsor and investigator.

[27] Informed consent is a subject's voluntary confirmation of willingness to participate in a particular trial. This consent should only be sought after all appropriate information has been given about the trial including an explanation of its status as research, its objectives, potential benefits, risks and inconvenience, alternative treatment that may be available and the subjects rights and responsibilities. *Ibid.*

The regulating authority will review a treatment protocol for a drug indicated for a serious disease either during phase 3 investigations or after all clinical trials have been completed. They may deny the request if there is insufficient evidence of safety and effectiveness to support treatment use. A drug indicated for an "immediately life threatening" disease on the other hand may be made available for treatment use during phase 2. The regulating authority may deny the latter request if the available scientific evidence, taken as a whole, fails to provide a reasonable basis for concluding that the (1) drug is either effective for the intended use of the intended patient population or (2) could not expose the patients to an unreasonable and significant additional risk of illness or injury. Thus the standard of review for treatment use for an "immediately life-threatening disease" is significantly lower than that for a serious disease. This is considered to be reasonable policy distinction in as much as that risk/benefit analysis in life-threatening situation is skewed so heavily in favour of use of any therapy which can be of some benefit.

An "immediately life-threatening disease" is defined as one in which there is reasonable likelihood that death will occur within a matter of months or in which pre-mature death is likely without early treatment[28]. The term "serious disease" is not defined. However, "advanced cases of AIDS" and "most advanced metastatic refractory cancers" can be included as immediately life-threatening cases - and "Alzheimer's disease" and certain forms of epilepsy can be included as serious diseases.

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[28] 21 C.F.R 312. 34 (b) (3) (ii).

Treating physicians are considered to be investigators and patients are

considered to be investigational subjects[29]. Rules of Treatment use of an investigational drug requires informed consent from the subject or from his lawful guardian. It also requires supervision of the treatment by an institutional review board and collection of certain information by the sponsor and submission of reports to the regulatory authority.

A sponsor may charge for a 'drug under treatment use', but the charges cannot be more than what is necessary to meet the costs of manufacture, research, development and handling of investigational drug. To ensure that treatment use does not overshadow concurrent controlled investigations, no charge will be allowed unless there is adequate enrolment in an ongoing clinical investigation in pursuit of marketing. Promotion of the drug and other indices of commercialisation are prohibited. However the regulatory authority publishes announcements of treatment use approvals in medical journals to allow interested physicians to enroll. Many companies may feel that the good publicity gained by making the drug freely available outweighs the amount to be gained by charging and avoids unsavoury task of justifying the amount being charged and the negative publicity resulting from charging.

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[29] Trial subject: The trial subject may be (a) a healthy person volunteering in a trial, (b) a person with a condition unrelated to the use of investigational product, or (c) a person (usually a patient) whose condition is relevant to the use of the investigational product and who participates in a clinical trial, as a recipient of the pharmaceutical product under investigation.

Procedure for implementation of "Parallel track' proposal

Another proposal by name "Parallel track" proposal is devised by some research groups[30] to expand access to promising new drugs that have adequate safety data demonstrated in Phase I studies itself. It has potentiality to make qualified investigational drugs available even earlier than might be possible under treatment IND. The major aspects of the programme are that certain drugs, with priority being granted to those showing encouraging signs of efficacy, are to be made available at the time they are entering efficacy trials, if adequate safety is demonstrated in Phase I studies. The intent of the programme is to provide research data, although safety data, probably in the form of adverse drug reaction reports as required for investigational drug, is expected. The programme is primarily targeted towards patients who cannot or will not participate in a clinical trial. It further appears that the programme may be limited to people with a condition for which there is no standard therapy and people who live far from or are too sick to participate in appropriate controlled trials.

This proposal, appears to be mainly, intended to allow the drug to be made available to AIDS patients whose disease has substantially progressed despite Zidomidine (AZT) therapy and who have no other treatment options. It is considered to be an interim measure to make a promising investigational

[30] *Supra* n. 20 at p. 85. See also *New York Times*, June 26, 1989, at p. A.1.

therapy available for people with AIDS who do not have satisfactory treatment options[31].

Despite the initial use of the "Parallel track" concept, the overall reactions to the concept of expanded access to investigational drugs after only phase I data seems somewhat cautious. Many AIDS activists may applaud the proposal[32], but there are others who raise significant questions regarding procedures to identify eligibility criteria, informed consent and liability issues[33]. The source of this concern may stem from the apprehension that it may cripple the clinical trial system because many patients may not be willing to participate in clinical trials because of the wide availability of experimental treatments. Drug manufacturing associations are also concerned about the potential product liability issues relating to adverse events and decrease in the regulatory authorities motivation to expedite the approval if the drug is already widely available and also the possibility of black market copies of drugs in the parallel track system[34]. Others question is whether the safety can be determined on the basis of phase I studies. Phase I studies typically involve so few patients, some times from twenty to eighty, that it is difficult to draw conclusions from the data[35].

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[31] *The Washington Post*, Sept. 29, 1989 at p.A1; FDA Press release 2 (C Sept.28, 1989) quoted in *id.* at p. 87.

[32] *New York Times*, June 26, 1989 at p.A1 quoted in *ibid.*.

[33] *F.D.C.Reports* ("The Pink Sheet"), July 24, 1989, at p. 18 quoted in *ibid.*

[34] *Ibid.*

[35] *Ibid.*

"Sub part E" procedure[36]

To reduce regulatory burdens, the FDA announced its new 'sub part E' procedures for therapies intended to treat "life threatening" and "seriously debilitating" illness. The procedures are in the form of amendments to the IND regulation. They apply to new drugs, antibiotics and biological products, and are of potential importance to many new products under development. The new "subpart E" of IND regulations signals the FDA's willingness to approve, not just make available, products for marketing after phase 2 clinical trails instead of the traditional phase 3. These regulations do not represent a change in the procedures as such but only formalize the set of procedures already permitted under existing laws on therapies for life threatening and severely debilitating diseases.

Nevertheless, while 'sub part E' is neither procedurally nor conceptually new, it does constitute formal recognition by the agency of something previously done on an *ad hoc* basis and significantly, it demonstrates further willingness on the part of the FDA to adjust the approval process to expedite the marketing of important new drug.

'Sub part E' defines[37], "Life-threatening diseases or conditions" as those "where the likelihood of death is high unless the course of the disease is interrupted" or those "with potentially fatal outcomes," Examples of life-threatening diseases include progression from asymptomatic to symptomatic

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[36] *Id.* at pp. 89-91.

[37] *Ibid.*

HIV infection or further progression to a later stage of AIDS, matastatic senses, or amyotrophic lateral sclerosis. Also included are conditions in which treatment may have a beneficial effect of survival, such as after a stroke of heart attack.

Sub part E defines[38] "severely debilitating" diseases or conditions as those "that cause major irreversible morbidity." Examples of severe debilitating diseases include severe functional deficits* in multiple sclerosis, Alzheimer's disease or progressive ankylosing spondylitis, and the prevention of blindness due to cytomegalovirus infection in AIDS patients.

Under traditional IND procedures, especially in the cases of new molecular entities or major new uses of marketed drugs, the FDA encourages the sponsor to request an end-of-phase 2 meeting. The purpose of such meeting is to establish agreements between FDA and the sponsor on the overall plan for phase 3, and objectives and designs of particular studies. Phase 3 studies are usually large. These are clinical efficacy trials which are the central piece in the sponsor's marketing application. The new 'sub part E' offers the opportunity to have such meeting at the end of phase I, rather than waiting until the end of phase 2 to enable them to use the drug for treatment for life threatening and severely debilitating illnesses.

It appears from this that 'subpart E' is truly eliminating phase 3 testing. From the point of view of the sponsors who desire to market the drug at the earliest it appears as though it is only a means of merging phase 3 in phase 2

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[38] *Ibid.*

so that there is a net saving of time and resources. But it would severely compromise the quality of data submitted to the agency for review in marketing application. 'Sub-part E' proposal contains the use of phase 4 (post marketing) studies[39]. Although these are a requirement of approval under this system, it is expected that, to the extent this system is used to conduct post marketing studies will be a routine element of approval because of agreement with the sponsor.

It is clear that the agency, FDA, is under political pressure in AIDS related diseases to be receptive to an end-of-phase I meeting[40]. How far the agency will be pushed to use these procedures for diseases that do not come so clearly under the definitions of "life threatening" or "severely debilitating"?. Already comments were submitted to the agency that these procedures should be available to all treatments[41]. In such context, it may be difficult for the agency to justify a restrictive use of this procedure.

It is likely that the following three criteria will be employed on a sliding scale in determining whether the phase 2 approval mechanism is appropriate[42].

(1) Qualaity of Phase I data and the prospects for Phase 2 studies producing data adequate for approval

This will probably be the single most important factor in determining whether the FDA will agree to pursue a 'sub part E' IND with the sponsor.

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[39] *Id.* at p. 90.

[40] See *New York Times*, June 27, 1989, at p. A1.

[41] *F.D.C.Reports* ("Thc Pink Sheets"), Jan. 2, 1989 at p. T & G 4-5. Quoted in *id.* at p.91.

[42] 21 C.F.R.§ 312. 82.

There is nothing mandatory about sub part E. The entire process is dependent on agreement between FDA and the sponsor of a new drug. The FDA must be persuaded that this is an appropriate development strategy and FDA is best persuaded by good data.

(2) Availability of alaterative treatment :

Probably more significant than argument over "life threatening" or "severely debilitating," the agency could be strongly influenced in its decision in 'sub part E' if no suitable alternative treatment exists.

(3) Seriousness of the Disease

If the FDA is presented with strong phase I data with a sound plan for phase 2 that should produce adequate data for an NDA, and it is widely accepted that no suitable alternative treatment for the disease exists, the FDA will carefully consider the ramifications of refusing to use 'sub part E' procedures merely because the disease is not sufficiently "life threatening" or "severely debilitating." It is unlikely that the FDA will risk the potential political fallout of refusing to use 'sub part E' procedures over issues as sensitive as definition of "severely debilitating." Conversely, where there is no question that the disease in question is "life threatening" or "severely debilitating,' but the phase 1 data are not especially impressive and/ or there exists alternative therapy, the FDA probably will be reluctant to proceed under 'sub part E'.

Therefore, while much attention has been focused on the definition of 'life threatening' and 'severely debilitating,' in fact these terms may become

sufficiently broad as not to present serious hurdle for the FDA to widen the concept of 'subpart E.'

Regulating authorities have no doubt been traditionally loathe to approve any drug without detailed evidence of safety and efficacy. But in the cases of AIDS where patient, will certainly die without some drug therapy, the authorities may be willing to be more lenient both with respect to treatment use of unapproved drugs and relax approval standards. In sum, the era of expedited drug approvals has not fully arrived except for AIDS drugs where the risk/benefit ratio of drug approval coupled with strong voiced activists politically have demanded action. The future of these expediated procedures for approvals is unclear partially due to concern raised by scientists about safety, the sanctity of the clinical trial, and traditional intransigence of the regulatory authorities to new ideas concerning drug approvals.

Need to control clinical trial procedure in India

There is urgent need for such legal controls in India for undertaking clinical trials. The aim of such legal controls should be protect the safety and rights of the subjects participating in the trials. It should allow only trials which may lead to conclusive data. The system must allow for on-site inspection of the quality of the data obtained. The drug regulatory authority should ensure that protocols of clinical trials be submitted in advance for its review. It may propose revisions or request additional data on a clinical trial or may direct termination of a trial. It should also be possible for the authorities to check the reliability and quality of the reported results.

may direct termination of a trial. It should also be possible for the authorities to check the reliability and quality of the reported results.

Duties of the physicians in bio-medical research involving human subjects

It is the mission of the physician to safeguard the health of the people. His or her knowledge should be dedicated to the fulfilment of this mission. The Helsinki Declaration,[43] binds the physician with the words: "The health of my patient will be my first considerations". The International Code of Medical Ethics declares that "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."[44]

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World medical Association has prepared the guidelines to be followed by every physician in bio-medical research involving human beings. European Council has also adopted similar resolution for the protection of human rights and dignity of the human being with regard to the application of biology and medicine[45]. These are only a guide to physicians all over the world. It must be stressed that they are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

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[43] See *supra* n.4.

[44] *Ibid.*

[45] See *supra* n.2.

(1) Basic principles

Bio-medical research involving human subject must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.[46] The design and performance of each experimental procedure should be clearly formulated in the protocol which should be transmitted for consideration to a committee independent of the investigator and sponsor.[47] This research should be conducted only by qualified persons under the supervision of a clinically competent medical person.[48] The responsibility for human subject must always rest with a medically qualified person even through the subject has given his or her consent.

The research cannot legitimately be carried out unless the importance of the objectives is in proportion to the inherent risk or benefit to the subject. It should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subjects or to others[49]. Concern for the interests of the subject must always prevail over the interests of science and society.[50] The right of the subject to safeguard his or his integrity must always be respected. Every precaution should be taken to respect the privacy of the subject[51] The physicians must abstain from engaging in research projects

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[46] *Ibid.*

[47] *Id.*, Article 4.

[48] *Ibid.*

[49] *Id.*, Article 16 (ii).

[50] *Supra* n.4 at p. 187.

[51] *Supra* n.2 Article 10.

involving human subjects unless they are satisfied that hazards involved are believed to be predictable. They should cease any investigation if the hazards are fund to outweigh the potential benefits.[52]

Rights of the subject

In any research on human beings, each potential subject must be adequately informed about the anticipated benefits and potential hazards of the clinical study and the discomfort it may entail.[53] He should be informed that he is at liberty to obstain from participation in the study and that he is free to withdraw his consent to participation at any time. The physician should then obtain the subjects freely - given informed consent preferably in writing.[54]

While obtaining the consent, the physician should be cautions if the subject is in a dependent relation to him. In such conditions, the consent, if obtained, would be deemed to be under undue influence. In such situation consent should be obtained by another physician who is completely independent of this relationship. In case of legal incompetence of the subject to give consent, it must be obtained from the legal guardian[55]. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative should be obtained.

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[52] *Ibid.*

[53] *Ibid.*

[54] *Id.*, Article 5.

[55] *Id.*, Article 6.

Whenever the minor child is in fact able to give a consent, the minor's consent must be obtained in addition to the consent of the minor's legal guardian[56].

In the treatment of the sick person, the physician must be free to use a new diagnostic and therapeutic measure, if in his or her judgement it offers hope of saving life, re-establishing health or alleviating suffering.[57] The investigator or his team should discontinue the research if in his or their judgement it may if continued, be harmful to the individual.

The tests which are predictive of genetic deseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptability to a disease may be performed only for health purposes or for scientific research linked to health purposes and subject to appropriate genetic counselling[58]. An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendents[59]. The use of techniques of medically assisted procreation should not be allowed for the purpose of choosing a furture child's sex, except where hereditory sex-related disease is to be avoided[60].

Removal of organs or tissue from a living person for transplantation purposes may be carried out solely for the therapeutic benefit of the recipient

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[56] *Id.*, Article 7.

[57] *Id.*, Article 8.

[58] *Id.*, Article 12.

[59] *Id.*, Article 13.

[60] *Id.*, Article 14.

and where there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness is available[61]. The necessary consent for such removal must be given in written form before an official body[62]. No organ or tissue removal may be carried out on a person who does not have the capacity to consent. But it may be authorised when there is no compatible donor available who has the capacity to consent and the recipient is a brother or sister of the donor and donation has the potential to be life saving to the recipient and potential donor concerned does not object[63]. No financial gain should be allowed to be made out of any human body or its parts. When in the course of intervention any part of the human body is removed, it may be stored and used for a purpose other than that of which it was removed, only if this is done in confirmity with appropriate information and consent procedures[64].

Where the law allows research on embryos in vitro, it must ensure adequate protection of the embryo. The creation of human embryos for research purposes is prohibited[65]

The idea behind all these guidelines appear to be that in research on man, the interest of science and society should never take precedence over considerations related to the well being of the subject[66]. All these guidelines

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[61] *Id.*, Article 19(1).

[62] *Id.*, Article 19(2).

[63] *Id.*, Article 20.

[64] *Id.*, Article 21 & 22..

[65] *Id.*, Article 18.

[66] *Id.*, Article 2.

should as far as possible be incorporated in the new drug regulation system so as to have a binding effect on all concerned in this research.

CHAPTER IV

IMPACT OF PATENT LAW ON CONSUMERS OF PHARMACEUTICAL PRODUCTS

Patent is a monopoly for commercial exploitation of an invention. It means an exclusive right to make use, exercise or sell an invention granted to a person for a limited period in consideration of the disclosure of the invention[1]. The idea in conferring such exclusive right is that it stimulates technological progress by inducing the inventor to disclose his discoveries instead of keeping them as trade secrets. By rewarding the inventor, it encourages research. It also provides an inducement to invest capital in new lines of production which might not appear profitable if many competing producers embarked on them simultaneously[2]. But at the same time it must be remembered that every monopoly is liable to be abused and patent monopoly is no exception. Therefore sufficient safeguards in law are required to ensure that patent inventions are properly worked in the country to protect the public interest. In case of patents on drugs and medicines which are essential to the life and health of the community, there is every need to prevent such abuse of monopoly rights. The law has to reconcile the conflicting interests of the holder of the patent and the interest of the public.

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[1] Patents Act 1970, S.48.

[2] *Report on the Revision of the Patents Law* (1959) para 17. See also Narayanan, *Patent Law*, (1975), Eastern Law House, Calcutta, at p.2.

In this context the study on the impact of the patent law on consumers of pharmaceutical products become relevant. For this purpose, a brief survey of the provision of the Patents and Designs Act 1911 and the Patents Act 1970 dealing with pharmaceuticals is made. Analysis of these provisions would reveal the extent of protecting consumer interest in pharmaceutical products. Impact of the TRIPs incorporated in the Final Act of World Trades Organisation dealing with pharmaceuticals is also studied.

Patent system in India

The patent system in India is currently regulated by the Patent Act 1970. It replaced the Patents and Designs Act 1911. A study of some of the relevent provisions of the Act of 1911 bring out ambiguities and deficiencies in that Act which were fully exploited by the foreign owned pharmaceutical companies called Trans National Corporations (herein after referred to as TNCs) to the detriment of Indian interests. This analysis also helps to see how the Patent Act 1970 tried to rectify these lapses to protect the pharmaceutical consumers of India.

Provisions of the Patents and Designs Act 1911

Under this Act, the life of the patent was for 16 years. The Act says

> " The term limited in every patent for the duration thereof shall, save as otherwise expressly provided by this Act, be sixteen years from its date"[3].

This term could be extended to a maximum of another ten years. The patentee may present a petetion to the Central Government praying for futher

[3] Patents and Designs Act 1911. Section 14(1).

extention of term. The Central Government or the High Court when the petition is referred to it may extend the term of the patent for a further period not exceeding ten years if it appears to it that the patent has not been sufficiently remunerative[4]. Thus, a patentee on an invention relating to a drug could enjoy exclusive monopoly rights of producing, selling and distributing for a period of 25 years on the whole.

In addition to this the Patents and Designs Act 1911 did not categorically state what was patentable[5]. The interpretation followed by the Patent office was that any new process for manufacturing a drug, whether old or new, was patentable. A new drug was also patentable provided the process of manufacture was described in the patent. The process, however, in such a case was not required to be new[6]. This was possible because the patentee, while patenting a new drug could describe all the known and possible processes. Hence the product patent for drugs was implicitly recognised under the Act. In practice the patent holders, most of them being transnational corporations, made maximum use of this lacuna in the Act to prevent the indigenous firms from developing a new process to manufacture an existing product. Even an old process, so specified by the patentees,

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[4] *Id.*, "Section15(1) and 15(6) which reads : (1)The patentee may present a petition to the Central Government praying that his patent may be extended for a further term,

(6)If it appears to the Central Government or to the High Court when the petition is referred to it, that the patent has not been sufficiently remunerative, the Central government or High Court as the case may be, may by order extend the term of the patent for a further term not exceeding five or in exceptional cases ten years....."

[5] For the comments on this Act, see *Report of the Patents Enquiry Committee* (1948-50) p.64 quoted in Sudip Choudhuri, "Dunkel Draft on Drug patents : Background Implications ", *Economics and Political Weekly*, September 4,1993 at p. 1861 at 1862.

[6] *Supra.* n.2 paras 20,34 and 36.

could not be used by the indigenous firms for atleast 16 years. Indian firms were also forbidden from processing a potential drug into formulations or importing it[7].

Thus the TNCs holding the patents enjoyed a monopoly status for at least 16 years. Ofcourse, the law permitted indigenous firms to manufacture a new drug if it could develop or use a process not mentioned in the patent. But there is ample evidence to show that these patentees could prevent or delay the use of these new processes developed through indigenous efforts even when these were not specifically covered in the patents of the patent holders.

The facts of two cases decided by Bombay and Culcutta High Courts would disclose the coercive tactics adopted by the transnational pharmaceutical corporations to prevent the local industries from making use of the indegenously developed new process in the field of manufacturing drugs. In *F.H.&B Corporation v. Unichem Laboratories* [8], Haffkin Institute, a public sector firm, worked out a process for manufacturing 'tolbutamide' from locally available raw materials. A patent was also obtained. Unichem Laboratories, an indigenous firm obtained a licence from it and started manufacturing the drug from 1961. Hoechst, a TNC filed a suit claiming

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[7] Joint Committee on Patents Bill, *Evidence*, 1965, Vol.1.pp 149-150. For example, a TNC was importing a drug at Rs. 8 per 20 tablets. It sued an indigenous firm, CIPLA, when the latter started importing it at Rs. 2 per 40 tablets. Chloramphenicol and metronidazole are among the other drugs for which the TNCs took legal action to prevent the indigenous firms from formulating quoted by *ibid*. Also see *Hathi Committee Report* (1975), p. 92.

[8] A.I.R. 1969 Bom. 255.

that 'tolbutamide' had been manufactured by Unichem on the basis of one of the formulaes as mentioned in the Hoechst patent granted in 1956. The judgement of the Bombay High Court went in favour of Hoechst. What is important here is that Hoechst won the case despite the fact that its patent did not specifically mention Haffkine's process. What clinched the issue was that Hoechst's description was open-ended. One of the claims of the Hoechst was, in the opinion of Justice Vimadlal,

> "Wide enough to cover all methods of eliminating sulphur from thioureas whether desulphurisation is effected, by means of hydrogen peroxide or by the use of any other substance[9].

It may appear to be strange but such widely worded claims were permitted under the Act of 1911.

The same patent was also sought to be used for preventing Bengal Chemicals and Pharmaceutical Works (BCPW), an indigenous firm, manufacturing another drug, chlorpropamide[10]. BCPW developed a new process for manufacturing it and obtained a patent in 1956. But in 1961, BCPW received a letter from Hoechst, alleging that BCPW had infringed upon the letters patent under which pfizer had been given a licence to produce it. BCPW sought legal action when it continued to receive such threats. Hoechst and pfizer on their part, filed a suit in the Calcutta High Court against BCPW. This time the judgement went in favour of the

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[9] *Id*. at p.264

[10] In an unreported case of Calcutta High Court in Suit No.1124 of 1962. Quoted in *supra* n.5

indigenous firm. The judge concluded that BCPW's patent was an independent one and it was not in any way influenced by Hoechst's patent which in fact, did not relate to the manufacture of chlorpropamide at all.

These cases are quite revealing so far as the issues relating to development of indigenous technology and role of patent legislation are concerned. Hoechst's patent did not refer to any specific drug. It was for the broad group of sulphonyl ureas. Nearly forty examples were given, but it was claimed that other compounds could be obtained easily from the general formula and chlorpropamide was one of them. Hoechst, however, failed to establish in the court that chlorpropamide could be or had been produced on the basis of the process described in their patent.

Even an expert witness appearing for Hoechst admitted[11] that the information disclosed in the patent was not enough to carryout the experiment. Thus TNCs could enjoy product patent though such patenting was not explicitly provided under Act of 1911.

As has already been pointed out, one of the objectives behind the patent laws is to induce the inventors to disclose the inventions in return for the exclusive right of using the invention for a specified period so that knowledge may be diffused to facilitate further technological progress. The above mentioned cases illustrates how the TNCs used the then existing Indian patent law to suppress indigenous growth. Hoechst's patent contained inadequate and misleading information which prevented and distorted the

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[11] *Ibid.*

diffusion of knowledge. The patent was a general type, intended to cover a large and unspecified number of products and processes[12]. Thus, other firms could be threatened with legal consequences even when their product was not at all connected with the patent. All the patent disputes are not fought out in a court of law. A mere threat may be enough deterrent in many cases[13].

A patentee may grant a licence voluntarily to any one on mutually acceptable terms. Compulsory licence is a licence granted by the Controller of Patents or by the Patentee as directed by the Controller to a non-patentee to use a patent on payment of royalties to the patentee. The Act of 1911 provided for the grant of compulsory licence in the case of misuse or abuse of patent rights[14]. Under Section 22, a compulsory licence could be claimed if "the demand for a patented article in India is not being met to an adequate extent and on reasonable terms[15].

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[12] Significantly enough, in this case, before the hearing started, Hoechst approached BCPW in 1968 to settle the dispute outside the court which however BCPW refused.

[13] For example Hindustan Antibiotic Ltd (HAL) a public sector firm, claimed that it had developed an indigenous process for manufacturing oxytetracycline (Hcl). A plant was set up and production began in 1961 without any external technical help. In the same year a TNC viz. Pfizer too started manufacturing the same drug HAL, however, unlike BCPW decided to suspend production rather than to contest Pfizer, which claimed infringement of their patent rights. See HAL, Annual Report, 1961 quoted in *supra* n. 5 at 1862.

[14] Patents and Designs Act 1911, Section 22.

[15] *Id.*, Section 22 (2) (b).

It was pointed out[16] that the foreign patentees did misuse or abuse their rights by importing the patented products rather than manufacturing it here in India and by fixing the prices at high levels, not allowing others to manufacture the product even when it was not itself engaged in the manufacture. It was also observed that the provisions regarding compulsory licences were "wholly inadequate to prevent misuse or abuse of patent rights, particularly by foreigners[17]" It may be noted that not a single compulsory licence could be obtained because of the wording of the relevant provisions. The section unnecessarily demanded that it had to be proved that as a result of the misuse or abuse any trade or industry had been unfairly prejudiced. Obviously, it appeared very difficult to establish such a link[18]. Though these provisions were amended in 1950 and 1952 by adding Section 23 CC to deal specially with drugs, it appeared that the foreign patentees were still in a position to effectively prevent or delay the use of compulsory licence[19].

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[16] Report of the Patents Enquiry Committee (1948-50), p.162. See *supra* n.5.

[17] *Id.* at p. 172.

[18] *Id.* at p. 168.

[19] Evidence of C.V. *Deliwaler* of the Haffkine Institute given to Joint Committee on Patent Bill 1967: *Evidence* Vol. 1.pp. 437-452.

Thus the need to change the patent law was felt immediately after independence. But it was not before the enactment of the Patents Act 1970 that the patent system could be changed[20].

Provisions of the Patents Act of 1970

Keeping these loopholes in mind Ayyangar Committee and other committees appointed by the Government recommended for substantial changes to the 1911 Act. After overcoming tremendous resistance India enacted the Patents Act 1970. The Patents Act 1970 introduced revolutionary changes in the Indian patent system and more particularly in the area of patents for inventions relating to drugs and medicines. It provided a stimulus to the indigenous pharmaceutical industry. A major departure was made from the patent systems of Great Britian, the U.S.A. and other Countries in certain crucial areas.

An important feature of the Act of 1970 is the special provisions regarding drugs and few other products. The life of the drug patents has been reduced from 16 years in the previous Act to a maximum period of seven years[21]. A patent is sealed after it is granted.

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[20] Several Official Committees for example Patent Enquiry Committee (1948-50) and Committee on the Revision of Patent Law (1959) examined the patent system and suggested revisions. The Parliament too debated a number of Patent Bills in 1950, 1953, 1965 and 1967.

[21] Patents Act 1970, Section 53 states : "Term of Patent: (1) Subject to the provisions of this Act, the term of every patent granted under this Act shall -

(a) in respect of an invention claiming the method or process of manufacture or a substance, where the substance is intended for use or is capable of being used, as food or as a medicine or drug, be five years from the date of sealing of the patent or seven years from the date of the patent which ever is shorter..."

The Act categorically states that drugs and those manufactured by chemical processes can be patented only for a new method or process of manufacture and not for products as such[22]. Thus, any firm whether foreign or indigenous inventing a new drug could at best patent the process of manufacturing it, provided it is new. Unlike in the previous patent regime[23], it cannot patent all the processes known to it even if these are new for a particular drug. Only one method or process the best known to the applicant can be patented[24].

The Act practically eliminated the monopoly status enjoyed by the patentees till then. The indigenous firms could immediately manufacture the new drugs if it could use an old process or develop a new one not mentioned in the patent. Even when they can't, the period of monopoly of the patentee would be significantly shorter. Under the provisions of compulsory licensing[25], manufacturing by non patentees can begin even earlier.

Every patent relating to processes for manufacturing drugs has to be endorsed with the words 'licences of right' after three years of the date

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[22] Section 5 reads : "S.5 Inventions where only methods or processes of manufacture patentable - In the case of invention -

(a) claiming substances intended for use or capable of being used as food or as medicine or drug.

(b).....no patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable."

[23] *Supra* n.10.

[24] Patents Act 1970, Section 10 (5).

[25] *Id.*, Sections 84 & 85.

of sealing[26]. This implied that anyone is automatically entitled to a licence from the patentee for using the patent on payment of royalties, the maximum rate being fixed at four per cent of the ex-factory sales[27]. Even before expiry of three years from the date of sealing, the controller is empowered to grant a compulsory licence and fix the rates of royalties if "it is necessary or expedient in the public interest[28]." There is also a special provision[29] in the Act regarding the use of patents by the Government. Anytime, a patent may be used for official purposes, including those of public undertakings. The maximum royalty payable for such a use in case of drugs has been fixed at four per cent of the ex-factory sales.

Impact of the Act on the pharmaceuticals

The indigenous firms were quick to respond to the favourable provisions in the Act of 1970. The complete elimination of product patent brought about significant changes in the pharmaceutical industry in India. The result is summed up in the words of I.A. Modi, Managing director of Cadila Laboratories :

> "The real turn for us and for the Indian drug industry came in 1970 when the Indian Patent Act was implemented. Until then we were prevented by the old

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[26] *Id.*, Section 87.
[27] See *id.*, Section 88.
[28] *Id.*, Section 97 (1).
[29] See *id.*, Sections 99 and 100.

British Act from manufacturing a patented product. The Government introduced a process patent instead: the industry was allowed to market products with a different process.

"With our new-found freedom, Cadila eveloped its own processes for any product introduced in the world market....."[30]

Thus new drugs began to be manufactured in India much earlier compared to the previous regime[31]. Moreover, the competition that followed among the foreign multinational companies and the indigenous firms reduced drug prices in India below the international levels[32].

Impact of the Patent Act 1970 on Prices

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[30] I.A. Modi, Managing Director of Cadila Laboratories, Minutes of the Director's Meet (1993) quoted in *supra* n.5

[31] Glaxo, TNC introduced abroad an anti-ulcer drug, ranitidine (Glaxo brand, Zantac) in 1981. By 1985 an Indian Company Ranboxy put the drug in the Indian Market followed by many other Indian firms - Dr. Reddy's Laboratories, Lyka, Albert David etc. Other examples of drugs which were introduced by Indian Companies in India within 4 years are Sulbutamol (anti-asthinatic) mebendazole (anti-helmenthic), naproxen (anti-rheumatic), Captopril (anti-hypertensive) norfloxacin (anti-bacterial). See Tables in Annexure I.

[32] See Tables in Annexure II. This is revealed in a comparison of the prices of a sample of drug products in India with those countries, where per-capita income and wage costs are similar to India's. Prices were lower in India for drugs considered in the annexure. See also Prasad & Bhut, "Strengthening India's Patent systems: Implications for pharmaceutical sector", *Economic and Political Weekly*, May 22, 1993.p.1037.

In the prices of drugs and pharmaceuticals there had been substantial reduction after the enactment of 1970. A committee of the US Senate had commented in 1959 that prices of certain drugs and antibiotics in India were amongst the highest in the world[33]. This was before the enactment of the Patent Act 1970. It is noteworthy that prices of drugs in India are now amongst the lowest in the world. In most countries which followed product patents, the prices are high.

The tables[34] in Annexure show that the prices of important drugs in India have risen in 1992 compared to 1986 though marginally in many cases. If we compare the prices of some drugs in India and other countries, we can notice that drug prices are comparatively lower in India. Among the Asian countries Indonesia and Srilanka joined Paris Convention in 1950 and 1952 respectively.[35] Indonesia, under its liberalised policy has accepted product patents in pharmaceuticals. Interestingly the prices of important drugs in that country, are very much higher compared to prices in India. It may be due to product patents introduced in that country[36].

Impact on Exports

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[33] Quoted by B.K. Keayala, "Chemical-based Industries - Drugs and pharmaceuticals and pesticides - foreign pressure for changing the Indian Patents Act, 1970" a paper presented in National working group on Patent laws, *Proceedings of National Conference on Scientists and Science, Technology and patents*, Dec. 4, 1989.

[34] *Supra* n.31.

[35] *Ibid.*

[36] *Ibid.*

The dynamism witnessed among the indigenous firms following the introduction of the Patent Act 1970 is also indicated in the sharp rise in the exports of drugs and pharmaceuticals in 1970's and 1980's. In fact India is now a net exporter of drugs and pharmaceuticals[37]. But for the Patent Law of countries like U.S., and Germany, which recognise product patents, India's exports would have been even higher. These countries do not allow imports of patented drugs from India. India exports drugs to these countries after the expiry of the patents[38].

Pressure brought on India to change the patent laws

In the 1980s the developed countries started taking concrete steps to force India to modify its patent laws. India as a member of General Agreement on Tariffs and Trade (here in after referred to as GATT) was bound by its principles and rules. The role of GATT was traditionally restricted to international trade in goods. It did not extend to intellectual property like patents, copy rights and trade marks, or services[39]. Hence the Patents Act, 1970 in no way violated the GATT principles. In 1986, a new round of trade talks started at Punta del Este in Uruguay.

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[37] India exports a large number of bulk drugs - ampicillin, chlorpropamide, pyrazinamide, trimethoprim, diazepam, ethambutol, nifedipine etc. See Annual report of IDMA 1992. (IDMA stands for Indian Drugs Manufactures Association)

[38] For example exports of Ibuprofen started in a big way after the patent expired in the U.S. in 1985. Similarly exports of ampicillin and amoxillin trihidrate stepped up following expiry of patents in 1987 and 1986 respectively. See for details *Report of Export Import Bank of India* (1991).

[39] IIPO,36 *Economic Report* (1993), at p. 25. (IIPO stands for Indian Institute of Public Opinion).

The developed countries proposed and succeeded in including Trade Related Aspects of Intellectual Property Rights (here in after referred to as TRIPS) as part of the Uruguay Round of Multilateral Trade Negotiations.

It was alleged that the provisions on TRIPS closely resemble the submissions made by the American, Japanese and European business communities to the negotiating committee[40]. The developed countries were fighting among themselves on some issues like farm subsidies. But they unanimously supported TRIPS. These countries attached tremendous importance to TRIPS in the Urugnay Round of talks[41].

The Uruguay trade talks were over in December, 1993. Countries like India who initially opposed TRIPS have been subjected to different kinds of pressures. The U.S. in particular had threatened India with retaliatory action unless India revises her patent laws[42]. Under the Special 301 intellectual property provisions of the Omnibus Trade and Competitiveness Act of 1988, the U.S. Government is empowered to take retaliatory action against any country which deny adequate and effective intellectual property protection. The US National

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[40] *Id.*, at pp. 28-29.

[41] Indian Institution of Public Opinion, *Economic Report*, Quarterly (1993) Jan - March, p.3.

[42] In April 1992, the U.S. President suspended the duty free benefits under Generalised System of Preferences (GSP) to imports of pharmaceutical and chemical products from India on the ground that India has failed to provide effective protection to American Intellectual Property. Quoted from Sudhip Chowdhuri. "Dunkel Draft on Drug Patents", *Economic and Political weekly*, September 4, 1993, p.1861.

Trade Estimates Report of Foreign Trade Barries 1991 states that India's patent protection is weak and has especially adverse effect on US pharmaceutical and chemical firms[43]. According to its report many US invented drugs are widely reproduced since patent protection is not available. The United States Trade Representative too alleged that "as a result of total lack of protection for certain classes of investigations, particularly pharmaceuticals, many US patented products are widely pirated[44]."

The pressures exerted by U.S. ultimately might have worked. India accepted the TRIPS, though there is strong and articulate popular opinion in the country against the terms set by the developed countries through TRIPS[45].

Provisions of the TRIPS Agreement

The aim of this agreement is to enforce globally tough standards in respect of several forms of intellectual property including patents. Out of all the provisions of the Final Act , the agreement on TRIPS is considered to be the most contentious part. A critical study of these provisions would reveal that health related needs of the developing countries were totally ignored in formulating these provisions.

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[43] Report quoted in *The Economic Times*, (Calcutta), May 5, 1991.

[44] *Ibid.*

[45] *Supra* n. 39 at pp. 24 & 25.

There was also strong demand that the GATT issues be examined by a Joint Parliamentary Committee before the Government takes a stand on them. See also Ammu Balachandran, "Patenting a product" , *The Hindu*, July 4, 1993 at Sunday Magazine..

The preamble of the TRIPS Agreement "recognises the need for multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods"[46]. The preamble also explicitly "recognises the underlying public policy objectives of national system for the protection of intellectual property including developmental and technological objectives"[47]. Article 7 of the TRIPS agreement provides that the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and transfer and dissemination of technology, to the mutual advantage of the producers and users of technological knowledge in a manner conducive to social and economic welfare and to *balance of rights and obligations"*[48]. Similarly, the Agreement also provides that "Member may, in formulating or amending their laws and regulations adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development provided that such measures are consistant with the provisions of TRIPS agreement"[49].

These are laudable objectives and principles. In spite of these provisions, substantive provisions in the Agreement do not provide for any obligations on the patent holder to be able to safeguard these national

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[46] TRIPS, Preamble. TRIPS stands for Trade Related aspects of Intellectual Property Rights, herein after referred to as TRIPS.

[47] *Ibid.*

[48] *Id.*, Article 7, (Emphasis is added).

[49] *Id.*, Article 8.

interests mentioned in the preamble and Articles 7 and 8. According to Article 27, "the patents shall be available for any invention *whether products or processes* in all fields of technologies provided that they are new, involve an inventive step and are capable of industrial application[50].

TRIPS agreement has totally changed the aspect of 'working of the patent'. 'Imports' are generally not regarded as 'working of the patent' in the Indian patent law. The patent holder had an obligation to work the patent in the country which grants the patent. It was considered as an important element of the patent system. The TRIPS Agreement however, provided that "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and *whether products are imported or locally produced*"[51]. The implication of this is that patent holders will have no obligation towards the country conferring the patent rights under the new system to produce the patented product in that country. There will thus be free flow of imports of patented products.

Ofcourse, the TRIPS provides for authorisation for uses of patented product by the country granting patent. Article 31 of TRIPS deals with other use without authorisation of the right holder[52]. It could be extended to measures necessary to protect health and nutrition and to promote the public

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[50] *Id.*, Article 27 (1), (Emphasis added).

[51] *Ibid.* (Emphasis is added).

[52] *Id.*, Article 31.

interest in sectors of vital importance to their socio economic and technological development, provided that such measures are consistant with provisions of TRIPS Agreement[53]. These provisions are considered to be in no way comparable to the usual provisions of 'compulsory licensing' or 'licence of right' provided under Indian patent laws for nonworking of the patent.

Under the TRIPS agreement period of protection, "shall not end before the expiration of a period of twenty years counted from the date of filing"[54]. Since the patentability extends to products and processes, it may be pointed out that the term would be applied for twenty years for product patent in the chemical field, including drugs and pharmaceuticals.

The agreement also provides for reversal of burden of proof during process patent regime for civil proceedings in respect of infringement of the rights of the patent owner. The onus of proving that the process used by enterprise is totally different from the patented process would lie with the defendent and he will have to prove that he is not guilty of infringement[55].

A general grace period of one year from the beginning of 1995 to all countries for applying the provisions of TRIPS Agreement is recognised[56]. The developing countries have been allowed further four years to implement

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[53] *Ibid.*

[54] *Id.*, Article 33.

[55] *Id.*, Article 34(1).

[56] *Id.*, Article 65(1).

the Agreement[57]. However, the developing countries who do not extend product patent protection will have further period of five years to recognise product patent in their national laws[58]. Thus countries like India will have a period of ten years to apply product patent for chemical based products including pharmaceuticals.

However, there is an obligation under TRIPS to receive applications immediately from 1995 for product patents for pharmaceuticals and agro-chemicals if product patent is not available in the domestic laws of a country[59]. It also provides for another obligation for grant of exclusive marketting rights to the applicants of product patents for pharmaceuticals and agrochemicals[60].

It provides that the new World Trade Organisation (WTO) dispute settlement procedures will apply to the TRIPS Agreement. However, during the first five years commencing from 1995 the Council for TRIPS will examine scope and modalities for complaints[61].

Critique of TRIPS Agreement

TRIPs when implemented will bring about drastic changes, among others, in

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[57] *Id.*, Article 65 (2).

[58] *Id.*, Article 65 (3).

[59] *Id.*, Article 70 (8).

[60] *Id.*, Article 70 (9).

[61] *Id.*, Article 64 (3).

the pharmaceutical industry in India. The gains from the Patents Act 1970 will be negated. The situation in fact will be worse than that under 1911 Act. TRIPS takes away the sovereign right of the countries to enact laws to suit the needs of its people. It categorically states that they will have to implement the provisions of the agreement in their own legal system and practice[62]. It will force India to change its Patent Act 1970 beyond recognition. Already many studies indicated[63] that the different aspects of TRIPS will adversely affect the interest of the developing countries.

Longivity of patent rights

India will now have to recognise and grant product patents. The patent holder will have not only the sole right to produce but also to import. Thus when a foreign firm introduces a new drug abroad and gets a patent for it, indigenous firms will be prevented from manufacturing for domestic market or for exports or importing it. This prohibition lasts for 20 years i.e. during the life of the patents as agreed in TRIPS even if they can develop their own processes of manufacturing it. This is in sharp contrast to the present situation. As pointed out earlier, the non-

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[62] *Id.*, Article 1 (1).

[63] B.K. Keayla, " TRIPs Agreement on Patent Laws; Impact on Pharmaceuticals and Health for All", A paper presented in an International Conference on *Global Health Law* organised by Indian Law Institute in collaboration with the World Health Organisation, New Delhi December 5-7, 1997. And Dhar & Rao, " Patent System Pharmaceutical Sector", *Economical and Political Weekly,* October 2, 1993, p.1861. S. Srinivas, " Signing about Dark Times", *Economic and Political Weekly,* May 25, 1996, p.1252.

patentees at least had the right to manufacture a new drug under the provisions of 1911 Act, provided it could use or develop a process not mentioned in the patent.

In the case of medicines it seems patents are available in USA for usage form, dosage form and combinations and the same would be extended to other countries on implementation of TRIPS provisions[64]. The table[65] gives an idea of new combinations for which patents have been taken in USA even when the product patent on the basic drug expired long back.

Procedural implications

The provisions dealing with burden of proof in the TRIPS would also be vulnerable for misuse by powerful foreign pharmaceutical industries to curb competition from others particularly the small companies, even when their process may be different.

Adverse impact on prices

With no one to compete against them, the TNCs can afford to charge higher prices. Official price control measures are unlikely to be effective. The TNC's may not be interested in manufacturing the drugs in India but try to import to India. They may also refuse to import to India unless their terms including exemption from price controls are met. Such threats will in all likelihood force the Government to yield to any price particularly if drugs are of life saving nature. Under the 1970 Act, a

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[64] *Ibid.*

[65] see the table in the Annuxure III.

patent can be revoked if "the demand for the patented article is not being met to an adequate extent or on reasonable terms from manufacture in India."[66] No such safeguards have been provided in the TRIPS. In TRIPS, failure to provide the product on reasonable terms is not cited as a justification for punitive action.

The decision of the patentees about the extent of manufacturing, imports and exports from a particular country, especially when a patentee is a TNC, depends on their global strategy of operations. It will not depend on the needs of the country granting patent rights

Transitional Concession : An Empty Shell

The Agreement provides for transitional period of 5 to 10 years for developing countries for implementing the TRIPS agreement[67]. This provision for transitional period has been virtually invalidated by the provisions in Article 70.8 of the TRIPS agreement which insists member countries to provide for means for acceptance of product patent applications with immediate effect. According to Article 33, the term of the protection, ie. the patent rights, are available to the holder from the date of filing of the patent application[68]. The composite interpretation of these Articles would virtually exclude domestic enterprises from developing process technologies

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[66] Patents Act 1970, section 90 (a) (ii).

[67] See *Supra* n. 55 to 57.

[68] See *supra* n. 54

for any new product from the date of the agreement. Thus, there is a clear distortion in providing for transitional period until the establishment of product patent regime

Working of patent : a non-issue

It may be stated that this agreement is a "Charter of Rights" for the patent holders and there are no specific obligations towards the country conferring patent rights. The element of 'public interest' is totally absent in the Agreement. The interest of the consumer which is the primary obligation of the patent system has been ignored. There is provision for allowing the patent rights without discriminating 'imports' against domestic production[69]. This is completely contrary to the provisions of the present patent law which states that patents "are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article."[70] Apart from this there is no provision for 'compulsory licensing' for'commercial purposes'. Unless there is such provision, public interest would not be served at all and there would be no way to ensure easy availablity of the patented product through commercial channels.

The member countries have to fulfill the obligations immediately from the date of entry of WTO. India became a member of WTO on 1st January 1995. To satisfy the requirements, the Government immediately introduced the Patents (Amendment) Bill, 1995 which was

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[69] See *supra* n. 50.

[70] Patent Act 1970, section 83 (b).

passed by the Lok Sabha . It lapsed in the Rajya Sabha due to the dissolution of 11th Lok Sabha. However, a study of the provisions of the Bill is relevant to enable one to forecast the prospective legislation that may come into existance at any time.

Salient features of the Patent (Amendment) Bill 1995

From the Preamble of the Bill it is clear that the Bill sought to achieve three objectives.

(a) to make the Patent Act 1970 to be in confirmity with obligations under the TRIPS agreement,

(b) to adopt measures consistent with the TRIPs Agreement, and

(c) to take steps to protect public health and nutrition and to promote public interest in sectors of vital importance to the socio-economic and technological development.

A provision was made in the form of amendment to section 5 of the Act of 1970 to incorporate patent rights for pharmaceutical products. It provided -

> " a claim for patent of an invention for a substance itself intended for use, or capable of being used, as medicine or drug"[71].

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[71] The whole Section 5 of the 1970 Act was re-numbered as subsection (1) of section 5 and the amended provisions are re-named as sub-section 2 of section 5. S. 5 (2) reads;
"Notwithstanding anything contained in sub-section (1), a claim for patent of an invention for a substance itself intended for use or capable of being used, as medicine or drug may be made and shall be dealt without prejudice to the other provisions of this Act, in the manner provided in chapter IV A." For the text of the Bill, see (1995) 2 Comp. L.J. 33 (Statutes)

The controller of the patents is empowered " to grant exclusive right to sell or distribute the article or substance"[72] after being satisfied that the applicant complied with the patentability requirements of the Act.

The exclusive right of the applicant or his agents or licensees to sell or distribute any such article or substance used as drug, whether the invention has been made in India or outside is recognised. But to claim such exclusive marketing rights in India, the right of patent must have been approved by such other countries where an application has been made claiming for such rights[73]. Implication of this provision is that if in any other country in which such claim has been made and rejected for identical article or substance, he cannot claim such exclusive rights in India.

Compulsory licences, can be given only when the patented drug is not available either by indigenous production or by importing. The provisions of the Bill says, "working of the invention shall be deemed to be selling or distributing of the article or substance"[74]. 'Patented article' means an article for which exclusive right to sell or distribute has been granted. By implication, it means working of the invention need not be by way of manufacturing in India.

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[72] *Id.*, section 24 A (3).

[73] See *id.*, section 24 B.

[74] See *id.*, section 24 C.

The Central Government can authorise persons other than the person to whom exclusive marketing rights have been granted to sell the same article or substance if it is satisfied and thought it expedient in public interest. The Bill also enables the Central government to direct that such substance or article for sale and distribution of which rights have been granted "be sold at a price determined" by the authority specified by it[75].

Patent Bill 1995 : A critique

The foregoing discussion reveals that the Bill was one of the most ill drafted legislations. The whole objective provided in the preamble of the legislation appears to be not to satisfy the requirements of the people of this vast country but to suit demands of international big brothers who coerced India to sign TRIPs.

A critical analysis of some of the provisions of the Bill reveals that it will not be able to protect the interests of the large number of consumers of pharmaceutical products. These provisions have been incorporated obviously in pursuance of Article 70.8 of the TRIPS agreement . Section 24 C in the Bill would negate the spirit of Section 90 of 1970 Act dealing with compulsory licensing. With this new section, the only ground on which a compulsory licence can be granted is non availablility of products at reasonable price. This will be beneficial only if the products are manufactured in India. If the products are

[75] See *Id.*, section 24 D.

made available by way of import, such licence will be of no use and naturally any one would hesitate to apply for compulsory licence[76].

The price control mechanism contemplated in Section 24-D (2) of the Bill also appears to have the same fate[77]. If the product is not manufactured in India, the imposition of price control may cause its withdrawal from the market since the Government has no control on the manufacture. Since the working of the invention is not mandatory the possiblity of technology development which is the enshrined objective of TRIPS in pursuance of which this Bill had been introduced, will also become difficult. Only by the licensing process our industry can develop the product. In that case industry has to pay high royalty for such products and it will be difficult for them to make the drug available at reasonable price. The net result is that domestic industry will face major setback and the consumer will have to pay increased prices for drugs.

The provisions of the Bill and new the Drugs Policy clearly indicate the limitations of the country to legislate for the nation according to the needs of its people.

It appears that all these developments are part of the globalisation process. This globalisation intends to allow the big business gaints like TNCS to have unrestricted business operations in the developing countries. General Agreement on Tariff and Trade (GATT) and the WTO are the

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[76] See N.S. Gopalakrishnan, "Patents Amendment Bill, 1995 - A Critique" (1996) 3 S.C.C. (Journal)1.

[77] *Id.* at. p.7.

platforms used by them through which they have been attempting to impose the terms of globalisation. Few big business interests with collaborative arrangements with foreign corporate gaints may favour these provisions, but informed popular opinion in the country is against to the terms imposed by the developed countries through TRIPS[78]. These provisions come into conflict with not only the existing laws including those dealing with protection to the consumers of pharmaceutical products but also with India's fundamental law, the Constitution itself.

India's dependence on other countries for technology is shown[79] as one of the main reason which has put pressure on India to such changes in our patent laws. This dependence was considered to have far reaching implications in today's unipolar world[80]. Apart from the dependence on foreign technology the political and economic weaknesses in India have made her vulnerable for such pressures to change patent regime

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[78] Ammu Balachandran, 'Patenting a Product', *The Hindu*, July 4, 1993 (Sunday magazine).

[79] Ashok Chandra Prasad and Shripad Bhat, "Strengthening India's Patent System, Implications for pharmaceutical sector", *Economic and Political Weekly*, May 22, 1993, p.1037.

[80] *Ibid.* The fall of Soviet Union has made the world a unipolar world with the U.S. as the only superpower.

CHAPTER V

QUALITY CONTROL MEASURES IN THE MANUFACTURE OF DRUGS

INTRODUCTION

The issue of drug safety and quality was pitchforked into the lime light in 1961 after the "Thalidomide disaster", when thalidomide was prescribed as a sedative to be used widely by pregnant women to offset morning sickness. What followed was a disaster. Babies born to these women had 'seal limbs'. It was a kind of congenital deformity .Babies are born with defective or rudimentary hands and feet. Nearly half a century has passed since the first thalidomide children were born. In the wake of that disaster stricter controls were imposed on the manufacture and sale of medicines throught Europe. In England such regulations are now governed by the Medicine Act 1968.

In early 1937 the United States enacted the first comprehensive drug regulatory law[1] after the death of 107 people due to the consumption of a drug used in treating common infection. However, this concept of safety and quality of drug still remains utopian in several developing countries including India. Justice Lentin Commission which looked into the JJ Hospital glycerol tragedy in Mumbai,

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[1] Food, Drug & Cosmetic Act 1938 which was codified in 21 USC §301-392 (1976) as amended from time to time.

in which 14 people died after glycerin was intravenously administered to patients, found that the glycerin was adulterated with diethylene glycol - a toxic chemical which converted the drug into industrial grade glycerin[2].

Several such instances exposed the loopholes in the system of regulating drug manufacture and enforcing safety standards. Only a few spectacular instances of wrong medication and defective medicine find their way into the media[3] There may be scores that go undetected, especially in small towns and rural areas.

The problem both in terms of quality and quantity is enormously complex and has several dimensions. Therefore, one cannot resort to generalisations or over simplified solutions. The concept of drug safety and quality assumes importance in the light of large-scale illiteracy and ignorance of the people.

Pharmaceutical products involve complex mixtures of ingredients. Manufacture of these products require application of secret scientific findings. It is very difficult for a consumer to judge its quality when these are manufactured on a massive scale. The complexity of the product and frequent changes in the formulations and in designs of the product makes it difficult for enforcement agencies to regulate its quality. May be because of this reason , there is little case

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[2] See generally, Report of commission of inquiry (1988). It was appointed by the Government of Maharastra was headed by Justice Lentin of Bombay High Court. It submitted its report in March 1988.

[3] See *TheHindu*, July 28, 1991 for details of other incidents that took place in India. Also see *Indian Express*, May 26, 1998 at p. 12.

law in India on the subject. These changes also make the product susceptible to incorrect use and misuse.

It is proposed to discuss various provisions of the Drugs and Cosmetics Act 1940 dealing with standards of drugs, good manufacturing practices, provisions dealing with prohibition of manufacture and importation of misbranded, adulterated and spurious drugs, powers and responsibilities of the inspectors and provisions dealing with penalties. It is also intended here to deal with other civil remidies that would be available to the drug injured claimants in the light of the special plans devised in the developed countries to overcome the difficulties posed by the tort law solutions.

Indian Constitution included improvement of public health as one of the primary duties of the State.[4] Basing on this provision Supreme Court has carved out the State's obligations to enforce production of qualitative drugs and elimination of injurious ones from the market.[5] When Constitution of India came into force, regulation and control of manufacture, sale and distribution was

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[4] Constitution of India, Article 47 reads :

"Duty of the State to raise the level of nutrition and standard of living and to improve public health. The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as its primary duties and ...."

[5] *Vincent v. Union of India*, A.I.R. 1987, S.C. 990.

included in the Concurrent List. Consequently the central law still continues to govern the subject..

Quality control over drugs is made under the provisions of Drugs & Cosmetics Act 1940 and the Drugs & Cosmetics Rules 1945. 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. These amendments 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. India has a federal structure of government and therefore, the responsibility for enforcing the regulating provisions are divided between central and state governments. The state governments are responsible for exercising control over drugs manufactured, sold and distributed in their respective states.

Scheme of the Drugs and Cosmetics Act

The basic legislation enforced by the Drug control department is the Drugs and Cosmetics Act 1940. This statute gives the drug control agencies in the country the general regulatory authority over drugs and cosmetics. The agencies have very wide powers with respect to drugs. The import, manufacture and sale of adulterated and misbrand drugs are prohibited[6]. Standards relating to content and process of manufacture are set and label and warning requirements are imposed.

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[6] See Drugs and Cosmetics Act, 1940, sections 9, 9.A, 9.B, 17, 17.A, 17.B and 17.C.

In this area, the regulatory agencies have extnesive powers of licencing and inspection. All new drugs must be supported by extensive laboratory research and testing and by reports indicating efficacy and safety. After approval, the regulating agency may revoke its acceptance of a new drug if further information leads to the conclusion that the drug is unsafe or ineffective. If the original application contained an untrue statement of material fact again the licence can be revoked.

In addition to the ordinary inspections of manufacturing process, the administration is also empowered to maintain strict controls over special drugs like antibiotic drugs[7]. Each batch of such drugs produced must be inspected and certified by the agency. No such drugs may be sold unless the batch in which it was produced has met requirements with respect to identity, purity and strength.

In exercise of the powers conferred by the Act, the department of the Ministry of Health and Family Welfare of the Central Government can make rules. But 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 Board is a technical body with the Director General of Health Services as the chairman and Drugs Controller of India as the member-secretary. The Board includes *inter alia* president of Medical Council of India, president of

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[7] See Drugs and Cosmetic Rules 1945 Rule 78 and 78 A, from 28 and 28.A in Schedule.A and also see Schedule F and F(1).

Pharmacy Council of India, representatives of the Indian Medical Association, Indian Pharmaceutical Association, pharmaceutical industry, as well as state drug controllers and government analysts.

Drugs standards

Under the Act, Indian Pharmacopoeia is the sole book of standards for drugs manufactured in India.[8] However, for drugs for which no standards have been provided in Indian Pharmacopoeia, standards laid down in other pharmacopoeias are applicable[9] .For compiling and revising standards in Indian pharmacopoeia, a permanent Indian Pharmacopoeia Committee is constituted. Similar standards are made applicable to drugs imported into India.

Similarly for drugs intended for veterinary use, the standards should be those given in the latest edition of the British Veterinary Codex[10]. The standards for patent and proprietary medicines should be those laid down in Schedule V and such medicines should also comply with the standards laid down in the Second Schedule to the Act[11]. For instance, the test for disintegration to be complied with by the manufacturer of patent or proprietary medicines in the form of tablets intended to be swallowed is that it should disintegrate in not more than thirty

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[8] See *supra* n.6, section 16 and Second Schedule.

[9] Authorised pharmacopoeia for the purposes of the Act are the Indian Pharmacopoeia, the Pharmacopoeia of U.S, National Formulary of the U.S., International Pharmacopoeia and the Pharmacopoeia of Russia. *Id.* Section 3(h).

[10] *Supra* n.7, Rule 124 - A

[11] *Id.*, Rule 124 - B

minutes if it is not coated and in not more than sixty minutes if it is sugar coated or film coated. The standards for patent or proprietary medicines containing vitamines for prophlactic, therapeutic or pediatric use should contain the vitamines in quantities not less than and not more than those specified in the table annexed to the Schedule[12]. Schedule R provides for the standards for medicinal contraceptives. The standards which other contraceptive will have to comply with should be in confirmity with the formulae approved as safe and efficacious by the Central Government. Such formulae should be displayed on the label of every container of such contraceptive[13]. Standards for substances intended to be used for the destruction of the vermin or insects which cause disease in human beings and animals should be such as are laid down in Schedule O[14]. Schedule FF lays down the standards for opthalmic preparations and such preparations should also comply with the standards set out in the Second Schedule of the Act[15]. The Rules also provide for the permitted colours that a drug should contain[16].

Requirement of Premises, Plant and Equipment

The factory buildings for manufacture of drugs should take such measures as to avoid contamination from open sewage, drain, public lavatory or any factory

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[12] *Id.*, Schedule V.

[13] *Id.*, Rule 125.

[14] *Id.*, Rule 126.

[15] *Id.*, Rule 126-A.

[16] *Id.*, Rule 127.

which provides disagreeable fumes, dust or smoke[17]. The buildings used for the factory should be constructed in such a way to permit production of drugs under hygienic conditions. They should also conform to the conditions laid down in the Factories Act, 1948.

The premises used for manufacturing, processing, packaging, labelling and testing purposes should be compatible with other manufacturing operations that may be carried out in the same or adjacent premises. It should be adequately provided with the working space to allow orderly and logical placement of equipment and materials so as to avoid the risk of mix up between different drugs. It should also control the possibility of cross contamination by other drugs or substances and to avoid the risk of omission of any manufacturing or control step. The buildings must be designed to prevent entry of insects and rodents. Interior surface should be smooth and free from cracks and permit easy cleaning and disinfection. It must be provided with adequate lighting and ventilation and if necessary air conditioning to maintain a satisfactory temparature and relative humidity that will not adversely affect the drug during manufacture and storage or the accuracy of the functioning of the laboratory instruments. Buildings should also be provided with underground drainage system in the processing area. The sanitory fittings and electrical fixtures in the manufacturing area should be

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[17] See *id.*, Schedule M inserted by Drugs and Cosmetics (Sixth Amendment) Rules 1988 which came into force from 24th June, 1988 by Vide G.S.R. 735 (E), dated 24th June 1988.

concealed and ventilation and air inlet points should be even with the surface of the wall as far as possible[18].

Water used in the manufacture should be pure and of drinkable quality, free from pathogenic micro-organisms. Waste water and other residues from the laboratory which might be prejudicial to the workers or to public health should be disposed of after suitable treatment as per the prevailing requirements of water pollution control to render them harmless[19].

Requirements for manufacturing of sterile products

For the manufacture of sterile drugs, separate enclosed areas specifically designed for the purpose should provided. These areas should be provided with air locks for entry and should be essentially dust free and ventilated with an air supply. For all areas where aseptic manufacture has to be carried out, air supply should be filtered through bacteria retaining filters and should be at a pressure higher than that in the adjecent areas. The filters should be checked for performance on installation and periodically thereafter and records of such checks should be maintained[20]. All surfaces in manufacturing areas should be designed to facilitate clearing and disinfection. Routine microbial counts of all sterile areas should be carried out during manufacturing operations. The results of such counts should be checked against established house standards. Access to the

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[18] *Id.* Schedule M at para. 1.1.2.

[19] *Id.* at para. 1.1.4.

[20] *Id.* at para. 1.2.1.

manufacturing areas should be restricted to minimum number of authorised personnel. Special procedures to be followed for entering and leaving the manufacturing area should exhibited. The design of the areas should preclude the possibility of products intended for sterilisation from from being mixed with or taken to be products already sterilised. In case of terminally sterilised products the design of the area should preclude the possibility of mix up between nonsterile and sterile products[21].

The manufacturer should provide adequate working space and adequate room for the orderly placement of equipments and materials used in any of the operation for which it is employed so as to minimise or eliminate any risk of mix up between different drugs, raw materials and to control the possibilities of cross contamination of one drug by another drug that is manufactured, stored or handled in the same premises. There should be adequate space in storage areas for materials 'under test'. Arrangements are to be made to allow the equipment to dry, a clean and for to orderly placement of stored materials and products wherever necessary under controlled temparature and humidity[22].

All the personnel including the temporary staff who come into direct contact with the product or raw materials should undergo periodic health check up. They should be free form contageous or obnoxious diseases. Their clothing

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[21] *Ibid.*

[22] *Id.* at para. 1.2.2.

should consist of white or coloured material made up of cotton or synthetic fabric suitable to the nature of work and climate and should be clean[23]. Just before entry to the manufacturing area, there should be change room with adequate facility for personal cleanliness, such as clean towels and hand dryers, soap, disinfectant and hand scrubbing brushes so that all personnel change their street clothes and wash and wear clean factory uniform, head gear and footwear before entering the manufacturing area and analytical laboratory. For all workers engaged in filling and sealing of containers of sterile preparations suitable sterile gowns, headgears, footwears and marks made of synthetic fabric should be provided to cover the nostrils and mouth during work[24].

The manufacturer should also provide adequate facilities for first aid. There should be provision for medical examination of workers at the time of employment and periodical check up once in a year, with particular attention being devoted to freedom from infectious conditions. There should also be a facility for vaccination or other exigencies. The licesee should provide the services of a qualified physician for assessing the health status of personnel involved in the manufacturing and quality control of drugs[25].

The manufacturing area should not be utilised for any other purpose. It should be maintained clean and in an orderly manner free from accumulated

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[23] *Id.* at para. 1.2.3.
[24] *Ibid.*
[25] *Id.* at para. 1.2.4.

waste, dust or debris etc. Eating, chewing, smoking or any unhygienic practices should not be permitted in the manufacturing area. A routine sanitation programme should be drawn up and observed which should be properly recorded and should indicate specific areas to be cleaned. Cleaning intervals cleaning procedures including equipment and materials to be used for cleaningis to be indicated. The personnel who are to and responsible for cleaning operations is to be specified. Records of compliance in respect of sanitation should be maintained for inspection[26].

Equipment used for manufacture of drugs should constructed, designed, installed and maintained to achieve operational efficiency to attain the desired quality and to prevent physical, chemical and physiochemical changes through surface contact. Facilities for thorough cleaning whenever necesary to minimise any contamination of drugs and their containers during manufacture should also be provided[27].

Specific written cleaning instructions for all equipment and utensils should be readily available and the operators are required to be familiar with them. Manufacturing equipment and utensils should be thoroughly cleaned and if necessary sterilised in accordance with the written and specific instructions. When indicated all equipment should be disassembled and thoroughly cleaned to

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[26] *Id.* at para. 1.2.5.

[27] *Id.* at para. 1.2.6.

preclude the carry over of drug residues from previous operations or batches[28]. The accuracy and precision of the equipment used for specific filling should be checked and confirmed at regular intervals and records of such checks should be maintained. The accuracy of premise filling should be checked, confirmed and caliberated at regular intervals and records of such checks should be maintained. Equipment used for sterilisation of drugs should be filled with recording devices so as to monitor and evaluate the performance of the equipment and should be caliberated and checked at regular intervals. Equipments used for critical steps in processing should be monitored by devices capable of recording the permanent parameters or with alarm system to indicate malfunctions. These devices should also be caliberated and tested and records be maintained[29].

The licensee should keep an inventory of all raw materials to be used at any stage of manufacture of drugs and maintain records as per law[30]. All such materials should be identified and their containers examined for damage and assigned control numbers. They should be stored at optimum temperatures and relative humidity. They should be conspicuously labelled indicating the name of the materials, control numbers, name of the manufacturer and be specially labelled 'under test' or 'approved' or 'rejected'. They should be systematically sampled by quality control personnel and be tested for compliance with required standards of

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[28] *Ibid.*

[29] *Ibid.*

[30] See *id.*, Schedule 'U'.

quality and released by quality control personnel through written instructions. These should be so organised that stock rotation is on the basis of the first inand first out principle in storage areas. They should be arranged in such a way that all rejected materials are conspicuously identified and are destroyed or returned to the suppliers as soon as possible and records of it should be maintained[31].

Master formula records

The licensee should maintain master formula records relating to all manufacturing procedures for each product which should be prepared and endorsed by the competent technical staff that is the head of production and quality control. The master formula records should give the patent or proprietory name of the product along with the generic name if any, strength and dosage form. It has to give a description or identification of the final containers, packing materials, labels and closures to be used. Record must show the identity, quantity and quality of such raw mateial to be used irrespective of whether or not it appears in the finished product. The permissible average that may be included in a formulated batch should be indicated. The formula should also give a description of all vessels and equipment and sizes used in the process and manufacturing and control instructions along with parameters for critical steps, such as mixing, drying blendings and sterilising the products. The particulars of the formula should show the theoretical yield to be expected from the formulation at different stages of

[31] *Supra.* n.17 at para. 1.2.7.

manufacture and permissible yield limits[32]. The detailed instructions and precautions to be taken in manufcture and storage of drugs and of semi-finished products should be given in the formula. It should also specify the requirements of in process quality control tests and analysis to be carried out during each stage of manufacture including the designation of persons or departments responsible for the execution of such tests and analysis[33].

The licensee should also maintain batch manufacturing record as per law for each batch of the drug produced[34]. Manufacturing records are required to provide a complete account of the manufacturing history of each batch of a drug showing that it has been manufactured, tested and analysed in accordance with the manufacturing procedures and written instructions as per the master formula[35].

Manufacturing operations and control

All manufacturing operations and controls are to be carried out under the supervision of competent technical staff approved by the Licensing Authority. Each critical step in the process relating to the selection, weighing and measuring of raw materials, addition during the process and weighing and measuring during the various stages are to be performed under the direct personal supervision of a competent technical staff. Products not prepared under aseptic conditions are

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[32] *Id.*, para.1.2.8.

[33] *Ibid.*

[34] See Schedule U.

[35] *Supra.* n.17 at para. 1.2.9.

required to be free from pathogens. The contents of all vessels and containers used in manufacture and storage during various manufacturing stages shall be conspicuously labelled with the names of the product, batch number, batch size and stage of manufacture. Labels are to be attached to all mechanical manufacturing equipment during their operation with conspicuous labels bearing the name of the product and batch number[36].

The licensee should prevent cross contamination of drugs with sex hormones and B.Lactum antibiotics by appropriate methods. These methods may include carrying and manufacturing operations in separate building or adequately isolating the operation by total enclosure within the building and using appropriate pressure differential in the process and providing a suitable exhaust system and designing laminar flow sterils air system for sterils products[37].

The germicidal efficiency of UV lamps should be checked and recorded indicating the burning hours or checked by using intensity meter. The water for injection shall be used either immediately or stored to prevent microbial growth at a specified temparature in a jacketted stainless steel storage tank. Individual containers of liquid orals, parenterals and opthalmic solutions should be examined against black or white background fitted with diffused light after filling to ensure freedom from contamination wtih foreign suspended matters. Finished tables

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[36] *Id.* at para. 1.2.10.

[37] *Ibid.*

should be inspected for presence of foreign matters besides any other defects. Expert technical staff approved by the Licensing Authority should check and compare actual yield against theoretical yield before final distribution of the batch. All process controls as required under master formula including room temperature, relative humidity, weight variation disintegration time and mixing time, homogenicity of suspension, volume filled, leakage and clarity should be checked and recorded[38].

If a product batch has to be reprocessed, reprocessing procedure should be authorised and recorded. An investigation should be carried out into the causes necessitating reprocessing and appropriate corrective measures should be taken for prevention of recurrence. Recovery of product residue may be carried out by incorporating in subsequent batches of the product, if permitted in the master formula.

All containers and closures should comply with the pharmacopoeal requirements. Suitable specifications, testmethods, cleaning procedure and sterilisation procedure, when indicated should be used. It should be assured that containers, closures and other component parts of drug packages are suitable and they are not reactive, absorptive or leach to an extent that significantly affects the

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[38] *Ibid.*

quality. Written shedule of cleaning should be laid down. Cleaning should be done using deionised water or distilled water[39].

Labels and other printed materials

Printed packaging materials including leaflets should be stored, labelled and accounted in such a way to ensure that batch packaging materials and leaflets relating to different products do not become intermixed. Access to such materials should be restricted to authorised personnel only. Prior to issue, all labels for containers, cartons and boxes and all circulars, inserts and leaflets should be examined and released as satisfactory for use by the quality control personnel. To prevent packaging and labelling errors, a known number of labelling and packaging units should be issued and if required be coded. Such issues should be made against a written signed request which indicates the quantity and the types required. Before packaging and labelling of a given batch of a drug it must be ensured that the batch has been duly tested, approved and released by the quality control personnel[40]. Upon completion of the packaging and labelling operation, a comparison should be made between numbering of labelling and packaging units issued and number of units labelled and packaged. Any significant or unusual discrepancy in the numbers should be carefully investigated before releasing the

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[39] *Id.* at para. 1.2.12.

[40] *Id.* at para. 1.2.13.

final batch. Unused coded and spoiled labels and packaging materials should be destroyed[41].

Records of distribution, complaints and Adverse reactions

Records for distribution of drug should be maintained for distribution of finished batch of a drug in order to facilitate prompt and complete recall of the batch if necessary[42]. Reports of serious adverse reactions resulting from the use of the drug along with the comments should be informed to the concerned licensing authority[43].

Quality control system

Every drug manufacturing establishment should have a quality control department supervised by approved expert staff directly responsible to the mangement but independent of other departments. The quality control department should control all raw materials, monitor all in-process quality checks and control the quality and stability of finished products. The duties of this department are to prepare detailed instructions in writing for carrying out each test and analysis. It has to release or reject each batch of raw materials and release or reject semi-finished products if necessary. It has to release or reject packaging and labelling materials and the final containers in which drugs are to be packed and decide whether to release or reject each batch of finished product that is ready for

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[41] *Ibid.*

[42] *Id.*, at para. 1.2.14.

[43] *Id.* at para. 1.2.15.

distibution[44]. It has to evaluate the adequacy of the conditions under which raw materials semi-finished products and finished products are stored and the quality and stability of finished products. This department has to establish shelf life and storage requirements on the basis of stability tests related to storage conditions and when necessary revise control procedures and specifications and finally examine returned products as to whether such products should be released, reprocessed or destroyed[45].

Requirements of Plant and Equipment

The requirement of space and equipment vary according to the nature of pharmaceutical product to be manufactured at the Unit. Therefore, different equipment requirements for manufacture of various categories of drugs and preparation like ointments, lotions, creams, syrups, pills, tablets, powders, gelatin capsules, surgical dressings, eye-ointments, eye-lotions, suppositories, inhalers and parenteral preparations are prescribed[46]. It may be noted that these requirements do not include requirement of machinery, equipment and premises required for preparation of containers or closures for different categories of drugs. The licensing authority has the discretion to examine the suitability and adequacy of the machinery equipment and premises for the purpose, taking into account the requirements of the licensee. These requirements are subject to modifications at

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[44] *Id.* at para. 1.2.16.

[45] *Ibid.*

[46] See *id.*, Shedule M. Part II

the discretion of the licensing authority if he is of the opinion that having regard to the nature and extent of the manufacturing operations it is necessary to relax or alter them in the circumstances of a particular case. It may be further noted that the rules provide for the requirement of equipments and space for certain categories of drugs only. There are in addition, other categories of drugs such as basic drugs, pharmaceuticals, chemicals and aids, medicinal gases, empty gelatin capsules, mechanical contraceptives and new dosage forms which are not listed in the Shedule. The licensing authority, in respect of such drugs, has the discretion to examine the adequacy of the requirements by keeping in mind the nature and extent of the manufacturing operations involved and direct the manufacturer to carry out necessary modification in them and only after such modifications have been carried out by the manufacturer, he has to approve the manufacture of such drugs.

It is doubtful whether the drug manufacturers really adhere to these statutory regulations especially while testing for contamination and before introducing the drug into market. Testing for contamination for instance, involve two methods. The conventional chemical method tests only for expected quantity of chemical. Traces of contamination may go undetected. In the instrumentation method the composition of the drug is revealed[47]. It was noticed that most companies are reluctant to install the instrumentation method since it involves not

[47] See *id.*, Rule 76(4) and 76(4-A).

only huge investments in its installations but also requires highly paid, skilled and technically qualified man power[48].

In addition to this, many pharmaceutical companies including multinationals palm off their manufacturing to smaller establishments in a loan licensing arrangement[49]. They resort to this arrangement, enticed by the lower labour charge involved, without ensuring whether the establishment in question is geared up to meet the quality standards. It was noticed that the standard of hygeiene maintained at most small units is appalling[50]. It appeares that the licensing authorities also relaxed the requirements, as they are authorised to do so, by keeping in view the small extent of manufacturing operations involved in such units.

Although authorities claim that hygienic condition in small units or large units are always maintained satisfactorily, there had been serveral instances to prove it to be wrong. Justice Lentn Commission which looked into the JJ Hospital glycerol tragedy in Mumbai, found that the glycerin was adulterated with diethylene glycole - a toxic chemical which converted the drug into industrial grade glycerin[51].

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[48] See *Indian Express*, May 26, 1998.at p.12.

[49] A loan licence means a licence which a licensing authority may issue to an applicant who does not have his own arrangements for manufacture but who intends to avail himself of the manufacturing facilities owned by other licensee. See Drugs and Cosmetics Rules, 1945, explantion to Rule 69-A of.

[50] *Supra.* n.49.

[51] See *supra.* n.2

Apart from the manufacturing problems, there is another hidden danger namely side effects. The system of reporting adverse reactions is still in nascent stage in India. Though there is a duty on the manufacturer under the rules[52] to report any information about adverse reactions of any drug to the licensing authority, it may not be effective in the absence of a duty on the doctors to report such reactions immediately. There is an Adverse Drug Monitoring Cell under the Drug Controller General of India to record adverse effects of drugs which occur in patients. However, as of today no doctor is legally bound to report any such observations because there is no law which makes it mandatory to do so.

Misbranded, adulterated and spurious drugs

The Act intends to protect consumers from misbranded, adulterated and spurious drugs.

Misbranded drugs

A drug is deemed to be misbranded[53] in the following situations.

(a)if it is so coloured, coated, powdered or polished that damage is concealed, or it is made to appear of better or greater therapeutic value than it really is, or

(b)if it is not labelled in the prescribed manner, or

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[52] See *supra.* n.48.

[53] Drugs and Cosmetics Act 1940, section 17.

(c)if its label or container or anything accompanying the drugs bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular.

It will be observed that misbranding relates to description of goods in a manner as to falsify the true nature or quality of the drug. Requirements for labelling and packing of drugs are contained in the rules.[54] These provisions are comprehensive but some of them are inapplicable to medicines made up for ready treatment prescribed by a registered medical practitioner. However, the label must give information relating to name and address of the supplier, name of patient, quantity of medicine, serial number. of prescription register and if the medicine is for external use, the words 'for external use' to be printed on the label.[55]

If a product of one manufacturer is being described as the product of another, it amounts misbranding. The Allahabad High Court[56] was of the opinion that the label found on the ampules made it a misbranded drug within the meaning of all the sub-sections of Section 17[57]. These ampoules with the labels which were found on them purported to be the product of the New International Chemicals while actually they were manufactured by Andrew's Chemicals, Culcutta. They thus purported to be the product of a place other than the place where they were

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[54] Drugs and Cosmetics Rules 1945. See Rules 96 and 97.

[55] *Id.* at Rule 94.

[56] *Dharam Dea v. State* A.I.R. 1958 All. 865 at 872.

[57] It may be noted that a part of this section has been deleted and incorporated in Section 17 which defines spurious drug with the amendment to the Act in 1982.

really produced. The label used on the ampoules was false and misleading as regards the name of the monufacturer and it gave the name of a fictitious company as the manufacturer of ampoules. The word 'fictitious' means forged. It appears that before a person could be held responsible for selling a misbranded drug there must be a comparison between the impugned drug and genuine drug which it is alleged to have imitated and the labels upon the drug and their containers as well.[58]

Adulterated drug

A drug is deemed to be adulterated[59] in the following curcumstances :

(a) if it consists, in whole or in part of any filthy, putrid or decomposed substance;
(b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health;
(c) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;
(d) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed;
(e) if it contains any harmful or toxic substance which may render it injurious to health;

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[58] Misbranding is a common hoax and anonymous variations of a known drug are very common. It is to the advantage of the consumers if he knows the names of the drugs he wishes to purchase especially in the case of home remedies that are sold and are available without a prescription. Here are a few samples of how a consumer can be cheated by mis-spelt variations of a popular drug.

CORRECT NAME	INCORRECT NAME	CORRECT	INCORRECT (OR)
Analgin	Onalgin or Analagin	Amruthanjan	Amaranjan or Amarthanjan
Crocin	Rocin	Codopyrin	Codopeen
Anacin	Anapin	Iodese	Ioderex or Idorex or Iodin
Saridon	Sardon or Saridan	Vicks	Kwicks

[59] Drugs and Cosmetics Act 1940. Section 17-A.

(f) if any substance has been mixed therewith so as to reduce its quality or strength[60]

The essence of adulteration is mixing up of the drug with a foreign substance which renders it injurious to health or which may be a source of gain to the seller. State of mind of the person selling, or manufacturing is immaterial since liability under the Act is strict.

According to Chambers Twentieth Century Dictionary the word 'adulterate' means 'to debase, falsify by mixing with something inferior or spurious'. But, it will be appreciated that the framers of the Act could not feel contended with such definition alone because that would not serve the purpose. If the adulteration by itself was declared an offence the trade and commerce would probably come to an end for in that event products manufactured by combining various components would fall within the definition of the term adulteration. What the legislature intended to check and prevent was the adulteration of drugs which affected their purity. Accordingly, the legislature had to keep in its view different standards of purities in different varieties of drugs before attempting to define when and in what circumstances a drug shall be deemed to be adulterated. It was from this angle that a definition of the word ' adulteration' was given. But it may be noted that no general or all inclusive definition of the word adulteration could ever be put forth to achieve the desired effect except by laying down different standards of purities for different categories of drugs and by making the

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[60] *Ibid.*

departure punishable. All these possibilities have been contemplated by the legislature and the Act covers a wide range of situations under which adulteration would be deemed to have been committed.

The different clauses of the section are not mutually exclusive. They may overlap one another and a drug may be found adulterated under one or more clauses. It will be a question of fact whether the ingradient contained in the drug is injurious to health or not. In determining whether an adulterant is ' injurious to health' under clause (b) of the Section, regard must be had not only to the probable effect of that drug on the health of the consumer but also to the probable cumulative effect of drug on the health of the person consuming such drug in ordinary quantities. In the same clause the word 'contaminate' was used. According to Oxford English Dictionary, the word 'contaminate' means 'to render impure by contact or mixture to currupt, defile, pollute, infect'. Thus if a drug becomes contaminated or injurious to health on account of insanitory conditions in preparing, packing or keeping the drug it also amounts to adulteration.

Thus, a drug is deemed adulterated within the meaning of the Act if it consists of any filthy, putrid or decomposed substance or it is prepared, packed or stored under insanitory conditions thereby it may have been contaminated or renderd injurious to health. it is deemed adulterated if its content is composed of any poisonous or deteterious substance which may render the contents injurious to health. It can also be termed as adulterated if the colour additive is unsafe within

the meaning of the Act[61]. If the methods used in or the facilities or controls used for manufacture, processing, packing do not conform with good manufacturing practice to assure that the drug meets the quality and purity of characteristics which it purports to possess[62]. A drug is also deemd adulterated if it purports to be or represented as a drug the name of which is recognised in recognised pharmaceopoeia[63] and if its strength differs from or its quality or purity falls below the standards setforth in it. And if it is a drug, the name of which is not found in any of the recognised pharmacopoeia, it is deemed to be adulterated if its strength differes from or purity or quality falls below that which it represent to possess. Again, a drug is deemed adulterated within the meaning of the statute if any substance has been mixed or packed with it so as to reduce its quality or strength or if any substance has been substituted for it.

SPURIOUS DRUG

A spurious drug is conceptually different from an 'adulterated' or 'misbranded' drug. A drug would be spurious if it is manufactured under a name which belongs to another drug, or is an imitation of or resembles some other drug to an extent that a buyer would be deceived, or if the label gives the name of a

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[61] See *supra* n.16 for permitted colours for various categories of drugs.

[62] See *supra* n.17.

[63] See Drugs and Cosmetics Act 1940, Second Shedule.

manufactures which is fictitious or does not exist.[64] The essence of it is misleading the consumer into believing that a particular drug has been made or is the product of a manufacturer or a concern when in fact that is not true. Selling of spurious drugs is considered to be the most lucrative business in India due to weaken forcement of the laws. [65] In the case of life saving drugs, if they are of spurious nature, there are serious consequences.

The purpose of this provision appears to be that no person should be entitled to misrepresent his goods as the goods of another person nor can any body use such mark, sign, symbol or device which can mislead a customer to purchase it. One should not also misrepresent the goods manufactured at one place as goods manufactured at different place.

The part of of the section emphasises upon the drug itself and the other part emphasises upon the label or container. The misbranding should be such that it cannot be detected by a lay purchaser with his ordinary deligence. It must be sufficient to make lay public and unwary purchasers to suppose that they are

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[64] *Id.*, S. 17- B. reads : "for the purpose of this Chapter, a drug shall be deemed to be spurious, -

(a) if it is manufactured under a name which belongs to another drug; or

(b) if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or

(c) if the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or

(d) if it has been substituted wholly or in part by another drug or substance ; or

(e) if it purports to be the product of a manufacturer of whom it is not truely a product.."

[65] D.N. Sharaf, *Law of Consumer Protection in India*, N.M. Tripati Pvt. Ltd., 1990 at p. 188.

purchasing the thing to which the resemblence relates. The standard of comparision is not that of the experts but of the lay public or the unwary purchasers and the resemblance need not be in all strict details but it must be sufficient to make unwary purchasers suppose that they are purchasing the thing the resemblance relates. The resemblance should be close to the drug misbranded so as to answer its trade description either in contents or get-up so as to give rise to the elements of deception practiced upon an average deligent purchaser. There should be reasonable probability of deception[66].

The complainant should establish that the drug was previously published and imitation is neither new nor original. The defendent will be allowed to go behind the certificate of registration to show that the proprietor is not the proprietor of the registered formulae in question[67]. To disown imitation it may be proved that each principle or process of manufacture was previously well known to all persons engaged in the trade to which the drug relates. But what is necessary is to throw out the charge of imitation is that the mode of combining those processes was new and produce a beneficial result and that the specification claimed is not of the old process or any one of them but only the new combination. In such a case it will be established that the defendent had not derived his work

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[66] *Modi Sugar Mills Ltd. v Tata Oil Mills Company Ltd.*, A.I.R.1943 Lah 196.

[67] *Dowarka Das Dhanji Shah v. Chottu Lal Ravi Chambers & Co.*, 43 Bom.L.R. 280 quoted from Mahazar Hussain, *The Law relating to Drugs & Cosmetics* , Eastern (1990) at p.68.

from the plaintiff[68]. It is a case of imitation of a mark, trade name or get-up with which the goods of another are associated in the minds of the public or of a particular class of public. The basis of passing off being a false representation by the defendent, it must be proved in each case as a fact that, the false representation was made. There is no such thing as monopoly or property of the 'nature of patent' in its use. Any body may use any name to designate his goods subject to the condition that he must not make directly or through the medium of another person, a false representation that his goods are the goods of another person. Where a mark or symbol by user in trade has secured for goods, it is a reputation which no body is entitled to imitate.

In the case of similarity of names, business should be so marked that the public is not deceived, business of one is not diverted to the other or no confusion is caused between the transaction of two companies. There should be reasonable precaution to clearly, plainly and conspicuously mark the articles. It is the false representation, lie and deception upon the ultimate consumer that creates liability upon the defendent.

In *Dharam Deo v. State*,[69] the Allahabad High Court had decided apart from other things, the meaning of 'misbranding' of drugs. In this case the applicant, Dharam Deo Gupta was the Managing Director of a company known as

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[68] *National Electric Stores V. General Electric Ltd.*, A.I.R. 1944 Lah.386.

[69] A.I.R. 1958 All. 865.

'The New International Chemicals Ltd., which had its depots at Lucknow as well as at Barabank. This company did not manufacture any drug, but it dealt with drugs. The Government of India invited tenders for the supply of one lakh fifty thousand ampoules of 10 c.c. equa pro injections. The necessary conditions and specifications wer mentioned when these tenders were invited. One of the essential conditions was that the goods supplied should be 'own make' of the firm who submitted the tender. The applicant's firm, although it did not manufacture the required drug, submitted a tender and it was accepted by the Government.

As the applicant's firm could not manufacture this drug, they placed an order for its supply at Andrew's Chemicals (India)Ltd., Calcutta through some other firm by name Asha Medical Stores. Andrew's Chemicals (India) Ltd., supplied the ampoules to the proprietor of Ash Medical Stores. On the direction of the proprietor of Asha Medical Stores, the applicant took delivery of the ampoules and labelled them showing that the ampoules were purported to have been manufactured by New International Chemicals Ltd., Lucknow to which the applicant was managing director. The Director, Control Drugs Laboratory, Calcutta after testing the samples reported that oxidisable matter was above the British Pharmacopoeia limit and that the sample did not pass the pyrogen test and therefore, it was not of acceptable quality.

The question before the Court was among other things, whether the ampoules intended to be supplied by the applicant were misbranded or not. The court answered in the affirmative.

Another area where 'misbranding' of drugs appears to be rampant is the manufacturing and marketing of allopathic drugs in the name of herbal or ayurvedic drugs claiming that these are manufactured on the basis of ayurvedic principles or as advised in ayurvedic texts[70]. Several Indian and multinational drug manufacturers are marketting formulations containing herbal or ayurvedic drugs. A few drug companies have even made this thier exclusive business as it is easy to obtain a manufacturing licence for a drug labelled as ayurvedic or herbal[71]. There is no barrier of scientific requirement worth the name. These licences are given by authorities liberally, without any verification of the claims, composition and toxicities because the licensing authorities have no means to do so.

The situation may appear to be identical for the licensing of allopathic drugs, but there is a difference. The composition of allopathic drugs can be tested in laboratories. This is not possible with herbal or ayurvedic drugs. The licensing authorities, the doctors and the consumers have to rely solely on the botanical names of plants mentioned on the label. Any unscrupulous business man may

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[70] See Drugs and Cosmetics Act 1940, Chapter IV-A and Part XXIII of Rules framed under it for provisions relating to Ayurvedic, Sidha and Unani drugs.

[71] See *Id.*, section 33 EEB for Regulation of manufacture for sale of Ayurvedic drugs.

mention names of several ingredients but may actually use only a few of them and the consumer has no means of verifying the claim.

In order to encourage the use of herbal or ayurvedic medicines, the government has as a policy to waive taxation on these products. This in turn has helped to open the flood gates. Several Indian and multinational drug companies have entered the market in a very big way, as there is a huge profit in these drugs. The government has not imposed any price control over these drugs. Strangely, through these products are granted licence as ayurvedic drugs or herbal drugs, they are almost always propagated and promoted through the practitioners of allopathic medicine.

There appears to be an erroneous belief existing among most of the allopathic doctors and consumers that these drugs are free from toxicity and side-effects because they are produced from natural substances whatever that means[72]. The pharmaceutical companies have capitalised on these sentiments and reaped fortunes.

Since the practioners of modern medicine have hardly any knowledge about these formulation, they accept whatever is told to them by the representatives of drug companies without much questioning. Also, they hardly have any source of from which to verify the claim and so the allopathic physicians take the claims in their face value and go on prescribing the drugs. What is remarkable is that these

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[72] See K.B. Bala subrahmaniam, "Beware of the herbal drugs!" *Indian Express*, April 2, 1991 at p.10.

products are hardly ever advertised and promoted to the practioners of ayurveda and other indigenous systems, who are the persons who are knowledgable about these preparations.

It seems, most of these drugs neither contain the ingredients used in ayurvedic formulation nor are they prepared according to the codified processes and methods mentioned in ayurveda[73]. The drug manufacturers also do not bother to recommend methods of administration and diet restrictions as prescribed in ayurvedic texts. As regards the efficacy of these drugs, the manufacturers make wild claims without any scientific evidence whatsoever based on clinical trial or research.

There appears to be a painful misconception about the term 'natural' prevailing among the public and allopathic doctors. Natural means naturally occuring . When a substance is subjected to various processes, particularly chemical it can hardly remain natural thereafter. If by the term natural only the source is signified, many of the drugs of modern allopathic medicines are also natural. There are of cource a number of allopathic synthetic drugs which are not produced out of air by magic. Their ultimate source is nature. In any case, one might ask, what is so holy about natural substances? Are we supposed to take poisons or harmful bacteria in the guise of ayurvedic or herbal medicines.

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[73] *Ibid.*

Ayurvedic drugs are called ayurvedic not because they are natural but because they are manufactured and administered on the basis of ayurvedic principles or as advised in ayurvedic texts. It is therefore unscientific and unethical on the part of allopathic doctors to prescribe these drugs. This amounts to quackery. Unless one knows and believes in ayurvedic medical principles and applies their precepts in diognosis and treatment of patients, he has no medical , scientific , moral or ethical grounds to prescribe these medicines. This principle equally applies to the drug manufacturers and the government.

No one knows why the government is allowing the unscientific practice. It is the high time that the Union Health Ministry and the Drug Controller of India should think into the scandalous practice and enforce certain minimum requirements with regard to manufacture of herbal or indigenous drugs so that allopathic drugs or preparations do not pass on to the market in the name of herbal or natural drugs.

Prohibitions regarding imports, manufacture and sale

Section 10 of the Act prohibits import of any drug which is not of a standard quality, or is misbranded, adulterated or spurious or containing harmful ingredients. In addition, the Central Government has power to the prohibit by notifications any import of drugs which involve risks to human beings and animals or which do not have therapeutic value claimed for them.[74]

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[74] Druga and Cosmetics Act 1940. Section 10-A.

Under Section 18 of the Act the State Government by notification in the official gazette may prohibit the manufacture for sale, distribution or stock or selling of any drug which is not of a standard quality or is misbranded, adulterated or spurious. The prohibition also extend to selling patent or proprietary medicines, which do not contain labels giving list of active ingredients. Importing drugs in contravention of section 10 and 10A, or manufacturing in contravention of any provision of the Act and the Rules and more importantly, manufacturing for sale or for distribution is also forbidden except under or in accordance with the conditions of a licence issued for the purpose. The exceptions to the rule are, manufacturing of a drug in small quantity for tests or such drugs not being of standard quality for which permission has been granted [75]

Powers and Responsibilies of Inspectors

Under the scheme of the Act, inspector is the key person for enforcement of the provisions of the Act. The centre and state governments are empowered to appoint inspectors. The qualifications of the inspector have been prescribed under the Rules.[76] Some of the important powers of an Inspector are as follows:

(a)to inspect any premises where in any drug is manufactured, sold, stocked, exhibited or offered for sale;

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[75] *Id.*, proviso to S. 18(3).

[76] Drugs and Cosmetics Rules, 1945, Rule 49.

(b)to take samples of any drug or cosmetic, and

(c)to enter into a premise, search any person, vehicle, vessel or conveyance at all reasonable times if he has reason to believe that the provisions of the Act has been contravened.

(d)to examine any record, report or document and seize the same if he has reason to believe that it may furnish evidence of any contravention.

(e)to order in writing not to dispose of any stock for a period not exceeding 20 days or to seize the stocks of such drugs.[77]

There are certain special duties for inspectors who are specially authorised to inspect the manufacturing premises. It is the duty of such inspector to inspect not less than twice a year, all premises licensed for manufacture of drugs within the area alloted to him and to satisfy himself that the conditions of licence and provisions of the Act and rules framed under it are being observed[78]. In the case of establishments licensed to manufacture products specified in Schedule C and C (1), it is his duty to inspect the plant and the process of manufacture, the means employed for standardising and testing the drug, the methods and place of storage, the technical qualifications of the staff employed and all details of location, construction and administration of the establishments likely to affect the potency or purity of the product[79]. It is his duty to send a detailed report of the inspection

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[77] Drugs and Cosmetics Act 1940, section 22.

[78] Drugs and Cosmetics Rules, 1945, Rule 52 (1).

[79] *Id.*, Rule 52 (2).

to his superior officer immediately after the inspection indicating the conditions of the licence and provisions of the Act and Rules which are being observed and conditions and provisions, if any, which are not being observed. He can take samples of drugs manufactured on the premises and send them for test or analysis and institute prosecutions in respect of any breahes of the Act or Rules.

The inspectors may require any person to produce any record, register or document relating to the manufacture of any drug in respect of which he has reason to believe that there is a violation of the Act or rules. He can also exercise such other powers that may be necessary to discharge his duties effectively[80].

Compulsory inspection before licence or renewal of licence

An original licence granted for manufacture of drugs will be valid only for one year unless it is renewed. But if the application for renewal is made before its expiry, the licence would continue to be inforce untill orders are passed on the application[81]. At the time of granting licence, the licensing authority can impose conditions which the licensee has to comply with during the manufacture of drugs. These conditions are generally relating to the safety measures that the manufacturer has to undertake and the premises, equipment and qualified staff that he is required to appoint and other measures provided in Schedule M and Schedule U and other provison of the Act and Rules[82].

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[80] See Drugs and Cosmetics Act 1940, section 22 (cca) and (d).

[81] Drugs and Cosmetics Rules 1945, Rule 77.

[82] See *id.*, Rule 76, 76-A and 78.

Originally granting licence for manufacture of drugs specified in Schedule C and C(1) and X, it was made mandatory on the part of the licensing authority to inspect the establishment in which the manufacture is proposed to be conducted and examine all portions of the premises and plant and appliances, the process of manufacture intended to be employed and the means and the professional qualifications of the technical staff to be employed. With the amendment to these ruler in 1992[83], it is mandatory to inspect not only before the licence is granted but also before granting renewal of every licence. This compulsory inspection is not just confined to the licences for the manufacture of drugs specified in Schedule C and C(1) but even to the licences for other drugs also. The inspector is authorised to conduct inspection with the assistance of an expert in the field[84]. He should also examine and verify the statement made in the application in regard to their correctness and capcity with the requirements of competent technical staff manufacturing plants, testing equipments and Requirements of Good Manufacturing Practices.

The Inspector has to forward a detailed report giving his findings on each aspect of inspection along with his recommendations after completion of his inspection in accordance with the provisions of law to the licensing authority[85].

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[83] See *id.*, Rule 79 as amended in 1992 and inserted by G.S.R.No. 923(E) dt. 14-12-92. See also [1993] I C.I.S. 101 for the text of the amended rule.

[84] *Ibid.*

[85] See *id.*, Rule 80.

Thus, the duties entrusted to the inspectors are of wider range than mere inspection of retail shops. Such an inspector can search any premises including a dwelling house in order to detect any sale of drugs in contravention.[86] It may be noted that the search and seizure under the Act by a drug inspector is equivalent to the search and seizure under the authority of a warrant under Section 98 of the Criminal Procedure Code. So it is not necessary for the inspector to record reasons for the search before making it.

Procedure for taking samples

In most cases it is necessary for an inspector to take samples of the drug. It is provided that the inspector shall tender the fair price for the samples taken and inform the person from whom it has been taken the purpose in writing for taking it. It is to be divided into four parts out of which one part is returned to the person from whom it is taken. Another part is sent to government analyst, third is to be produced before the court and fourth is to be supplied to the person from whom it had been acquired.[87] Where the sample is taken from the manufacturing premises, it is sufficient to divide the sample into three portions only.

It is the duty of the government analyst[88] to whom a sample has been sent for lest or analysis to furnish the report to the inspector in triplicate. On receipt of

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[86] *Gyanendranath, Mittal v. Darmadas Bhatt*, A.I.R. 1958 All. 163, at p. 164.

[87] Drugs and Cosmetics Act 1940, section 23.

[88] See *Id.*, section 3(c). Under this section a "Government Analyst" means an analyst appointed by the Central Government or State Government under Section 20.

the report the inspector delivers one copy of it to the person from whom the sample had been taken and another to the person, if any, specified in Section 18-A of the Act. The evidence contained in government analyst's report is conclusive unless the person from whom the sample was taken or person mentioned in Section 18A has within 28 days of the receipt of a copy of the report informed the Inspector or the court concerned that he intends to adduce against the content of the report.[89] The court has been given power either on its own motion or at the request of the complainat or accused to cause the sample of the drug to be sent for test or analysis to the central laboratory. If this procedure is followed thenthe report of that laboratory is conclusive evidence of the facts stated therein.[90] The inspector has the power to send a sample to the laboratory direct as well. The government analyst or the laboratory are under a duty to perform the protocol of tests as are mentioned in Pharmacopoeia of India or in other authoritative literature. If this is not done the evidence is not conclusive.[91]

Burden of proof

When any drug is seized from any person in the reasonable belief that such drug is misbranded or adulterated, the burden of proving that such drug is not misbranded or adulterated shall be on the person from whose possession such drug

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[89] *Id.*, section 25(3).

[90] *Id.*, section 23(5).

[91] See *State of Karnataka v. Manoj Drug House and Others*, (1975), 2 Kar. L.J. 171).

was seized. This is contrary to the general principles of procedure. This might have been made keeping in view the difficulties of proving such action.

Penalties for contravention

The Act lays down penalties for contravention of provisions relating to manufacture, sale and distribution of drugs. The penalties for contravention are more stringent for drugs than for cosmetics and ayurvedic medicines.[92] Under Section 27 a person is liable to be punished for not less than five years ;if he manufactures for sale or for distribution and sales or stocks or exhibits or offers for sale any drug deemed to be adulterated or spurious which is likely to cause death or grievous hurt, and in other cases be punished for not less than one year. Although courts have in several cases emphasised that a sentence in respect of offenders under the Act has to be deterrent, the fact remains that the enforcement of law leaves much to be desired.[93]

Provision has been made for initiation of proceedings by the aggrieved person or by a registered consumer association [94]. Further, any person or a registered consumer association is entitled to submit for test or analysis to a

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[92] See Drugs and Cosmetics Act 1940, sections 27A and 31 I for penalties for contravention relating to manufacture, sale and distribution of cosmetics and Ayurvedic drugs respectively.

[93] *Subhas Chandu v. State of Haryana* (1982) 2 FAC 399 (Raj and Haryana), *Inder Mohan v. State of Haryana* (1978) 2 FAC 20 (22) (P & H) Quoted in D.N. Saraf, *Consumer Protection law* N.D. Tripati Pvt.Ltd. (1990) at p. 190.

[94] Drugs and Cosmetics Act 1940, section 32.

government analyst any drug purchased and to receive a report of the same[95]. This is a salutary provision. Consumer organisations must make good of these benevolent provisions particularly against spurious and adulterated drugs sold to government departments or used in hospitals maintained by the state. However, for a consumer organisation to take up this matter, it is considered necessary to grant them on selective basis further powers and immunities as have been given to inspectors under the Act.[96] Involvement of consumer agencies in the enforcement of the law is absolutely necessary in the light of the inadequate staff available for the enforcement machinery.[97]

In addition to this problem, there is a preponderance of small scale industrial units in the country. This results in an increased workload for the drug control machinery in the States, which is inadequately manned in many states.[98] There is also every need to see that these small units be guided by quality control procedures and good manufacturing practices.

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[95] *Id.*, section. 26.

[96] D.N. Saraf, *Consumer Protection Law*, N.D. Tripati Pvt. Ltd., (1990) at p.190.

[97] Critical shortage of Drug Inspectors has been highlighted recently. About 2700 inspectors are needed for the enforcement of the law whereas the actual strength is about 25 per cent of this number. There are 20,000 manufacturing Units and about 2,00,000 sales units in the Country. For details, see Rahul Pathak, "Drugs Controller says he is helpless, No Labs, no staff, no solution," *Indian Express*, Oct 18, 1989.

[98] See V.C. Sane, "Drug Control : India". A Paper presented in World Congress on Law and Medcine, New Delhi, 1985.

Another serious constraint which drug control organisation at the centre and states appear to have been facing is the non-availability of well qualified and trained personnel.[99] Though such personnel is available in India, they are attracted to the industry where remuneration is attractive with opportunities for further advancement. It is necessary that government should adopt a policy which attracts personnel from Industry into drugs control organisation. This will lead to improvement in the technical capabilities of drugs control organisation in the country.

There are various reasons why there is little case law on the subject in India. The claim consciousness among consumer is very low, though financial and procedural obstacles are minimised to some extent by the establishment of consumer forums. Another difficulty stem from the peculiar nature of the product. It is often difficult to prove that one's injuries are due to adverse drug reaction than they have been caused by other reasons. It is still harder to establish negligence. Experience of other countries suggest that a strict product liability approach do not make much difference.[100] Awareness that an injury was drug related or might have been drug related is often long delayed and it may be a

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[99] *Ibid.*

[100] Harvey Jeff, "Regulation under Medicines Act 1968: A continuous prescription for Health," 47 Mod.L.Rev. 303 (1984) at p. 322. The author also quotes US law in this aspect. It seems in most of the US jurisdictions drug design defects have been treated as an exception to strict product liability and in effect, negligence must be proved. See *infra* text.

matter of years after the injury occurs. In such circumstances there is certainly an added temptation for less responsible manufacturers seeking quick profits.[101]

At the same time we can not quantify with precision the benefits of regulation in terms of safer, better quality and more effective drugs. If we take the estimated profits of this industry into account, the present cost of the regulatory requirements is much less. There is every need to strengthen enforcement machinery by allocating more resources. It is an acceptable price for a system to minimise risk of disasters such as thalidomide or J.J. hospital incidents.

Drugs : product liability

The above discussion reveal that a substantail protection is envisaged for pharmaceutical consumers. It relates to the quality and fitness of drugs manufactured for public consumption. The Act is designed to see that drugs are amnufactured as per the standards stipulated in the Act and Rules. It prohibited misbranded, adulterated and spurious drugs from being manufactured for sale to consumers. To achieve the objective of protecting the consumer in all respects, it mainly relies on criminal sanctions. It is generally believed that when the consumer feels agrieved, he often makes complaint to a public authority rather than to take legal proceedings. Of course, the Act provides for the aggrieved person or a recognised consumer association for taking samples to submit for test or analysis and receive reports of such test or analysis and also to institute

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[101] See Rose. Cranston, *Consumers and the Law* (Weidenfield and Nicolson, London), p. 38. (1984)

prosecution[102]. At the same time the Act do not the civil remedy for any injury suffered by the consumer due to the breach of statutory duty.

Remedy under law of Contract

Generally a seller who is sued under the provisions of the Sale of Goods Act is liable irrespective of due care and skill and the seller's strict liability extends to consequential loss caused by the defective drugs. It is not limited to the loss arising under the contract itself[103]. Thus, if the buyer suffers personal injury through use of defective drugs, he can claim damages from the seller under the implied terms in the Sale of Goods Act despite the fact that the seller is not guilty of any negligence.

But the doctrine of privity of contract imposes serious limitations on this form of liability called product liability. Firstly, the buyer's remedy is only available against the actual seller. If the buyer wishes to sue the manufacturer, he can not prima facie invoke the strict liability involved in a breach of warranty, but must still base his case on negligence[104]. However, there are a number of qualifications to this prima facie situation. Strict liability can be effectively

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[102] Drugs and Cosmetic Act 1940, Section 26 and 32 as amended in 1986.. It received the assent of the President on December 24, 1986 and published in the Gazette of India , Extra, Part II Section 1, dated 26th December, 1986, pp. 1-2.

[103] See Chapter VIII of this work which deals with sales and distribution of drugs for detailed discussion on the liability of seller or distributor.

[104] Tort liability for defective product was recognised in *Donogue v. Stevenson*, [1932] A.C. 562.

imposed on the manufacturer through third and even in fourth pary proceedings. If the buyer sues the seller for breach of warranty, the seller may claim an indemnity from his own supplier, and that supplier if not himself the manufacturer may inturn claim an indemnity from the manufacturer. As between each pair of parties, the relationship will be contractual and liability for breach of warranty can be established. For instance, in *Dodd v. Wilson*[105], the plaintiff, a farmer, employed a veterinary surgen to inoculate his cattle with some serum. It proved to be defective and many of the cattle died or became deseased. The plaintiff recovered damages from the surgeon on an implied warranty. The surgeon brought in his suppliers as third parties, and the suppliers brought in the manufacturers as fourth parties. The surgeon obtained an indemnity from the third parties and they inturn obtained an indemnity from the fourth parties. In this way the palintiff effectively obtained damages for breach of implied warranty from the manufacturer through the intermediaries.

This is somewhat a clumsy and costly. Why should not the plaintiff have a direct remedy against the manufacturer for breach of warranty? Moreover the expedient may not always work, for example if one of the intermediaries is insolvent or cannot be found or only carries on business overseas or has gone out of business. A second possible expedient whereby a buyer may be able to hold a manufacturer strictly liable despite the apparent absence of privity is the collateral

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[105] [1946] 2 All E.R. 691.

contract where an express assurance was given by the manufacturers directly to the consumer as in the case of *Carill v. Carbolic Smoke Ball Co.*[106] But apart from this famous case, there are hardly any illustration of this possibility.

The collateral contract, however has serious limitations as a device for holding a manufacturer strictly liable for defective drugs. In particular it only helps a buyer where he can find some express statement or assurance that can be construed as a warranty. There is, as yet, no authority which goes so far as to hold that a manufacturer could be liable for breach of implied warranties on the basis of a collateral contract. A manufacturer market his products through retailors. He advertises directly to the public in respect of some products inviting them to buy. It does not seem unreasonable to hold that he is impliedly offering a warranty of reasonable fitness for ordinary use to a member of the public who buys the product.

The doctrine of privity of contract is also very material in the law of product liability in another major respect. Not only does the doctrine normally restrict liability to the seller but also confines the remedy to the buyer. A donee, a member of the buyer's family, an employee of the buyer none of these can sue the manufacturer for breach of warranty. This will leave the purchaser or user who is injured by a defective product to rely on a claim in tort for negligence.

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[106] [1893] 1 Q.B. 256.

With the advent of consumerism, this privity doctrine is substantially altered. Many developed countries adopted legislation enabling a consumer to sue manufacturer directly[107]. India also followed this in enacting Consumer Protection Act 1986[108].

Remedy under the law of tort

In *Donoghue v. Stevenson*[109], the House of Lords held that the manufacturers of defective product owed a duty of care in negligence to the ultimate consumer of the product, notwithstanding the absence of any contractual relationship between the consumer and the manufacturer. In the course of his speech Lord Atkin expressed the duty in these terms:

> " A manufacturer of products which he sells in such a form as to show that he intends them to reach the ultimate consumer in the form in which they left him, with no reasonable possibility of intermediate examination, and with the knowledge that the absence of reasonable care in the preparation or putting up of the products will result in injury to the consumer's life or property, owes a duty to the consumer to take that reasonable care."[110]

Another judge of the Court said that the defendent who brought himself into a direct relationship with the consumer by placing his product upon the market in a

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[107] See the provisions of Consumer Safety Act 1978 and Consumer Protection Act 1987 (England).
[108] For a discussion on the definition of consumer see Chapter I *supra.*
[109] (1932) A.C.562.
[110] *Id.* at p. 599.

from which excluded any other intermediate examination was liable for the consumer. The manufacturer's duty has been given a broader interpretation by including many products under the definition of the meaning of 'drugs' and 'consumer'[111].

An issue that arises in the context of pharmaceutical products is the possible liability of statutory regulatory agencies. Under the Act of 1940, the manufacture and distribution of medicines in this country is regulated by the licensing authorities of the state and Central Government. The Central Licence Approval Authority assesses manufacturing licence application and renewals and only when satisfied as to the requirements of safety, quality and efficacy, the licences are granted or renewed. The effect is that drugs which are released into the market are being manufactured according to the safety standards monitored by the statutory authority. In such circumstances, if the product is found to have been defective, it is arguable that the licensing authority should be responsible along with the manufacturer, for allowing a defective product to be marketed. The Act grants a general immunity on the authorities from any action arising out of the consequences of their decisions[112]. By such provisions whether the state can skirt its responsibility to the public in granting licence. It has also been argued that the imposition of duty of care on the licensing authorities might lead to conflict of

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[111] See Chapter I of this work for detailed discussion on the definition of 'drug' and 'consumer'.

[112] Drugs and Cosmetics Act 1940, Section 37.

duties, in which the regulatory agencies may adopt an unusually conservative or defensive apporach to its functions because of the fear of liability. This practice may not be in the public interest[113]. Even in a recent case decided in England, the Court maintained restraint and said that "the Courts should proceed with great caution before holding liable in negligence those who have been charged by Parliament with the task of protecting society from the wrong doings of others"[114].

Itis difficult to predict whether, if the matter had to be decided in India, the regulatory bodies established by the Drugs and Cosmetics Act, 1940 would be held to owe a duty of care to individual patients in performing their statutory functions of authorising and reviewing the licences of pharmaceutical units. But it may be argued that in the light of *A.S.Mittal v. State of U.P.*[115] and *Paschim Banga Khet Mazdoor Samity v. State of West Bengal*[116] does provide some support to the proposition of state liability. It is submitted that the regulatory agencies estblished under the Act 1940 is clearly directed to the protection of members of the public from risks to their health. In principle, the regulatory agencies should be held to owe a duty of care to individual patients who suffer injury as a consequence of negligence in discharging their statutory duties.

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[113] Harvey Teff, "Regulation under Medical Act 1968: A Continuing Prescription for Health" 47 Mod. L.Rev.303(1984) at pp.310-311

[114] *X (Minors) v. Bedfordshire Country Council,* [1995] W.L.R.152, at pp. 184-185.

[115] (1989) 3 S.C.C. 223

[116] (1996) 4 S.C.C. 37.

The manufacturers have a duty to exercise reasonable care in the design of a new drug. It includes an obligation to be careful in conducting the research which goes into the design. One of the difficulties is that the defect may not have been apparent before the product is marketed. For liability in neglegence the defect must have been foreseeable at the time of design and manufacture. If the risk was unforeseeable in the light of scientific and technical knowlede at the time of marketing, there is no neglegence. But where there is a graver danger, the greater the need for special care and in some instances the risks may be so great or their elimination may be so difficult to ensure with reasonable certainity that the only reasonable course open to the manufacturer is to abandon the project altogether. The law requires even pioneers to be prudent.

The difficulty with medicinal products is that most of these drugs are recognised as carrying some degree of risk from side effects, allergic reactions, or other unforeseen consequences. The question of what is safe is inevitably a relative concept, particularly in this field. It is a question of fact whether a reasonable person would consider the relative risk acceptable given the objective desired in using the product, and the riskd associated with alternative treatments or nontreatment. The risks that would be acceptable in producing analgesic would be far less than the risks attached to a new drug for the treatment of diseases like cancer or AIDS. Provided that the risk/benefit ratio is acceptibale, and provided

the manufacturer has taken all the care to eliminate risks by proper scientific research, it is not negligent to market the drug.

An adequate warning may be sufficient to discharge the manufacturer's duty of care. It is not necessary that the warning be addressed directly to the consumer where the drug is intended to be purchased on prescription. Prescription drugs are available only on prescription and the prescribing doctor is in a position to take into account the propensities of the drug and the susceptibilities of the patient. In *Buchan v. Ortho Pharmaceuticals (Canada) Ltd.*[117], Robins J. Commented that :

> ".....the manufacturer of drugs, like the manufacturer of other products has a duty to provide consumers with adequate warning of the potentially harmful side-effects that the manufacturer knows or has reason to know may be produced by the drug.....In the case of prescription drugs, the duty of manufacturers to warn consumers is discharged if the manufacturer provides prescribing physicians, rather than consumers, with adequate warning of the potential danger."[118]

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[117] [1986] 25 D.L.R. (4th) 658 (Ont.C.A.) quoted in Michael A. Jones, *Medical Negligence*, Sweet & Maxwell, Tort law library, London, 1986 at prar. 8-033 to 8-041.

[118] *Id.*, at para.8-033

In the absence of a mandatory duty on the manufacturers to supply data sheet to the prescribing doctors, this principle of exempting the manufacturers from liability is not satisfactory. Another question that may be pertinent here is, relating to adequacy of warnings. An adequate warning should be communicated clearly and understandably in a manner calculated to inform the user of the nature of risk and the extent of the danger. It should be in terms commensurate with the gravity of the potential hazard. To be effective, a warning must reach the consumer patient. The rational* for this approach is that in the case of oral contraceptive pill there is greater participation of patients in the decision to use the drug. There may be substantial risks associated with its use. There is frequently limited participation by the physician in the decision to take the pill and there is a real possibility that patients may not be fully informed by their doctors. In such cases the principle of intermediary rule should not be made applicable to the manufacturers.

Where the alleged neglence consists of a failure to warn either the consumer or the doctor about the side-effects or contra-indications of a drug, the plaintiff still has to prove that had the warning been given he would not have taken the drug. In other words he must demonstrate that the negligent omission caused or contributed to the damage. In the case of prescription drugs, where the evidence is that adequate warnings would have had no effect on the decision of the

doctor prescribing the drug, the patients claim againt manufacturers will fail on the ground of lack of causation[119].

If a danger becomes apparent subsequent to marketing the drug, it will be negligent on the part of the manufacturer to continue to produce the same unmodified product or atleast to do so without attaching a warning. In addition, the manufacturer is under a continuing duty in respect of products already in circulation which are known to be defective. The manufacturer must take reasonable steps either to warn users of the danger or recall the defective drug.

But where a manufacturer has complied with the standards normally adopted within industry, this will usually be taken as good evidence that he acted with reasonable care, just as departure from common practice may be evidence of negligence. However, neither is necessarily conclusive of the issue. In the case of drugs, manufacturers must comply with statutory requirements of the law. Compliance will not be conclusive but it will be undoubtedly constitute strong evidence in support of the exercise of reasonable care.

The burden of proving negligence rests with the plaintiff. The effect of this is that in cases of manufacturing defects the plaintiff has to establish negligence by proving the existence of defect. It will be very difficult if the defect is in design. Where a product perform as it was designed and intended, there is no obvious standard to compare it. In addition to this the plaintiff has to prove that

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[119] *Id.*, at para. 8-038

the defective product infact caused the injury of which he complains. This will tend to be more difficult. There may be difficulty in isolating drug-induced harm from the background incidence of such injuries. Merely proving an increased risk of injuriy does not itself establish causation. The question is whether one can infer a casual link by taking a common sense approach to attributing cause. This problem would be multiplied in cases of prescription of a generic drug to identify the defendent among the multiple manufacturers of the same generic drug. It may be impossible for the plaintiff to say which manufacturer was responsible for the drug he took, especially if it was taken over a long period of time.

This issue was addressed by the Supreme Court of California and established a novel theory of liability with far reaching implications. In *Sindel v. Abbott Laboratories*,[120] the issue concerned Diethylstilbestrol normally referred by generic name "DES", a synthetic drug developed to prevent miscarriage. After an estimated three million women had taken it, adenocarcinoma, a rare but fatal form of cancer was found in a small number of daughters exposed to the drug *in utero*. There were as many as three hundred pharmaceutical companies which might have been producing the drug since it was never patented. Furthermore, adenocarcinoma manifests itself only after a minimum latency period of some ten or twelve years and often after twenty years or more. In the circumstances, vast

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[120] 26 Cal. 3d 588 quated in John G. Fleming, "Drug Injury Comensation Plans", 30 Am.J.Com.L. 297 (1982) at p.309.

majority of plaintiffs were unable to identify the specific comapny which manufacturered the pills taken by their mothers.

The plaintiffs argued before the Court to consider the two approaches to overcome the causative factors problem. One such approach was 'alternative liabillity' formula. Under the doctrine of alternative liability, where two or more defendents have committed acts of negligence in circumstances which make it impossible for the plaintiff to prove which of them caused him damage, the burden of proof shifts to the defendents to show that they were not responsible. In default of such proof, the defendents are held jointly and severally liable. But this solution has normally been adopted only where all potentially lliable defendents have been joined in the action. In *Sindell*, only five out of two hundred or more potential defendents who had produced the drug were brought before the Court. Since this created a substantial possibility that none of them made DES which caused the injury, the court refused to apply the doctrine[121].

The plaintiff also sought to rely on another doctrine called 'industry-wide liability'. According to this theory, each manufacturer of a product could, in appropriate circumstances be held jointly and severally liable for all injuries caused by adherence to an industry-wide standard of safety. The Court held that there was delegation of safety functions to a trade association in drug industry.

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[121] It was however alleged by the plaintiff that some half a dozen companies produced 90 percen of DES marketed. See Harvey Jeff, "Market Share" liability-novel approach to causation", 31 1Com.L.Q. 840(1982) pp.841-844.

Moreover, the close regulation of the pharmaceutical industry by FDA means that standards followed by manufacturers are largely imposed by the Government, an additional reason for the reluctance of the Court to apply industry-wide liability doctrine in DES case.

Having examined and found wanting the various theories of liability put forward by the plaintiff, the Court proceeded to construct a novel theory of "market share" liability. It held that it was "..... reasonable....to measure the likelihood that any of the defendents supplied the product which allegedly injured plaintiff by the percentage which the DES sold by each of them for the purpose of preventing miscarriage bears to the entire production of the drug sold by all for that purpose"[122]. The Court held that the principle applies only when the plaintiff joined in the action manufacturer of "substantial share" of the DES which her mother might have taken. Then the burdrn would shift to each company to show that it could not have made the particular substance which injured the plaintiff. In default of such showing, it would be liable for the proportion of the judgement represented by its share of the market.

The primary justification advanced for this bold departure from orthodox causation requirements was that "as between innocent plaintiff and negligent defendents, the latter should bear the cost of the injury"[123] Just as product liability

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[122] See *ibid.*

[123] *Ibid.*

which generally was seen as a means of overcoming defects in traditional common law neglegence, market share liability is viewed as a practical solution to the problems created by harmful products which cannot be traced to any specific producer[124]. Adoption of this "market share" liability principle will herald new horizons in product liability cases especially in pharmaceutical product cases inspite of some practical difficulties like what constitutes "substantial share" of the defendents in the market. It is a breaking point to the causation principle. One might speculate whether Indian legal system would adopt this principle especially in the context in which it has been showing its willingness to depart from strict traditional roles.

Therefore, the traditional tort system suffers from more defects in its appliation to drug injuries. There is vast literature with the writings of law reformers whose studies had convinced that there are severe short comings in the tort law[125]. One claim is that the tort treatment is particularly unjust and is administratively too costly. It was alleged that the combined legal expenses for plaintiff and defendent as well as state's expenses in terms of court's time, the litigation consumed far exceeded the claimant's compensation. Another problem is that tort solution requires unusually difficult determinations of causation as witnessed in cases like *Sindell*. Another problem with the tort of negligence is the

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[124] *Id.* at p.842.

[125] See generally, Fleming, "The Pearson Report : It's Strategy" 42 Mod. L. Rev 249, [1972] Marsh, "The Pearson Report", 95 Law Q. Rev. 513, [1975]

exclusion of 'development risks'. Perhaps it is the most important practical limitation on liability for negligence. Development risks are risks which the manufacturer neither know nor should have known at the time of marketing in the light of existing scientific knowledge. Even under strict liability there is strong support for excluding such risks which, it is feared, would expose the industry to an impossible burden. Other arguments against tort solutions are difficulties of access to evidence particularly in drug defects and possibilities of insolvancy of wrong doer.

Perhaps, the experience of these difficulties in the drug related tort claims, special plans have been devised by some of the advanced countries to address the problem. In Germany, major insurers underwrite individual producer's strict liability at reasonable rates. These exclude non-pecuniary losses. They also limit the liability to amounts within the capacity of the insurance industry. By adhering to the principle of individual liability, it was backed by compulsory insurance on the part of the pharmaceutical industry. The scheme was intended only for personal injury and death resulting from defective drugs. It reaches also to non-negligent manufacturing defects and failures to warn[126]. In Sweden a voluntary group insurance was set up jointly by the Pharmaceutical manufacturers and importers with the major insurance companies[127]. This scheme covered all drug

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[126] See John G. Fleming, "Drug Injury Compensation Plans", 30 Am. J. Comp. L. 297 at p. 300 [1982].

[127] *Id.* at p. 301.

related injuries including injuries due to subsequent change in the composition of a drug and injuries due to misdiagnosis and wrong prescription.

In Scandanavian Countries, these disputes are relegated to a drug injury committee. Compensation includes for pain and suffering, disfigurement and general inconvenience in accordance with prescribed tariffs but in the case of longer-lasting and severe disabillity, the compensation would be in the form of indexed periodical payments[128]. In Japan, a legislative enacted special compensation fund with social security overtones was created. The entitlement is defined on a no-fault basis but the victims remain free to pursue their tort remedity. The fund is financed by manufacturers and importers of drug according to prescribed formula having regard to the number of drugs sold, their price, and their risk rate and finally by discretionary government subsidies.

Such special compensation plans are desired in India in the light of long run, heavy expensive, adversorial system of litigation and difficulties is proving causative factors in the adversary litigation of drug claims. Such plans are not new ideas to our system. Workers compensation and compensation plans for motor accidents etc. are already in vogue. There are also provisions in the Public Liability Insurance Act 1991 to compensate the victims from injuries caused due to handling of hazardous substances. The Act was mainly intended to compensate the victims of industrial hazards like Bhopal gas tragedy. Such intention is evident

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[128] *Id.* at p. 302.

when the Act defines hazardous substance[129] to mean that which has been defined under Environmental Protection Act 1986. It may be submitted that these provisions can be extended to cover the injuries caused by hazardous drugs by a strained interpretation of the provisions. But it will be safe to have a separate compensation plan to cover the victims of pharmaceutical products.

[129] Public Liability Insurance Act 1991., Section 2(d).

CHAPTER VI

DRUG PRICE REGULATIONS

The price of any commodity is central to the concern of any consumer. Effective protection of human health demands that drugs be sold at reasonable prices. Pricing of drugs has always been very sensitive subject. The policy objective in this area should be to ensure that prices are fair and reasonable to the producer and consumer. The best guarantee of consumer protection is considered to be a competitive production and market structure. As long as market is characterised by more or less free competition, the consumer is guaranteed that the price paid for the product does not imply a monopolistic profit accruing to any specific firm producing the product. However, through their control over manufacturing technology and distribution channels, these firms often have the possibility of affecting the price of their product without regard to the general economic principle of demand and supply and thereby realise huge profits. Hence the problem is high prices bearing little relation to the cost of production. Therefore it may be pointed out that no country leaves price-fixing of drugs entirely to free market forces[1].

Price regulation is a very complex issue. Many factors influence the price of commodities. Cost of the raw materials used, cost of power utilised, salaries of the employees and other conversion costs, packaging materials used and packing costs and advertisement costs go into the total cost of production

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[1] See L.Krames, *EEC Consumer Law*, Droit Ed. Consommation, (1986) at.p. 83.

of a drug and add up to the ultimate price payable by the consumer. In addition to this various duties and taxes payable to government also form part of the ultimate price payable by the consumer. Irrational combinations in the formulation activity is considered another aspect which needlessly enhance the cost of a drug. A sound price control system may have to take all these factors into account and take all the possible steps to reduce the cost of all these items and ensure a fair price to the consumer. This require a very comprehensive price control machanism which should not leave any of these elements to play havoc on the economic interest of the consumer.

It is in this background an analyse of the provisions of the Drug (Price Control) Orders framed for this purpose is undertaken. It is also examined whether these are adequate to provide drugs at fair price to the consumer. The study also intends to look for other alternatives, if any, available which can provide a satisfactory solution to this problem.

Objectives of regulation on prices of drugs

At present the prices of drugs are controlled under the provisions of the Essential Commodities Act 1955. One of the principal objectives of the Essential Commodities Act is to fetter and curb the profiteering in the scarce resources of the community which are needed for life sustaining food and life-saving drugs. The law considers profiteering in this area as an evil and diabolic. The object of the Act and Orders framed under it appeares to have been designed to fulfil the mandate of Article 39(b) of the Constituion. It must be remembered that Art 39(b) enjoins a duty on the State towards securing "that

the ownership and control of the material resources of the community are so distributed as best to subserve the common good "[2]. The Essential Commodities Act enables the Central Government to regulate production, supply and distribution of essential commodities for the purpose of maintaining and increasing the supply of such commodities[3]. It enables the Central Government to make an order-providing for controlling price at which any essential commodity may be bought or sold. It is in pursuance of the powers granted to the Central Government by the Essential Commodities Act, that first the Drugs (Price Control) Order, 1970 and later the Drugs (Price Control) Orders 1979, and 1987 were made. Now DPCO, 1995 is in force[4]. These orders are issued from time to time to give effect to the drug policy formulated from time to time. DPCO, 1995 is issued in pursuance of the new drug policy guidelines framed in 1994[5].

Before we turn our attention to the terms of the Drugs (Price Contol) Order 1995, it may be appropriate to make certain general observations of the legality of these price regulating provisions.

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[2] See *The Constitution of India*, Part IV "Directive Principles of State Policy"

[3] Essential Commodities Act 1955, section 3(1) reads: "3. Powers to control production, supply, distribution, etc. Of essential commodities-

(I) If the Central Government is of the opinion that it is necessary or expedient so to do for maintaining or increasing supplies of any essential commodities or for securing their equitable distribution and availability at fair oprices, or for securing any essential commodity for the defence of India or the efficient conduct of military operations it may, by order, provide for regulating or prohibiting the production, supply and distribution thereof and trade and commerce therein."

[4] For the text of the Order see *Gazette of India* , Extra ordinary, part II section 3(ii) dated 6-1-95. See also 1995 C.I.S. 112 (Central notifications).

[5] Modifications to Drug Policy 1986, see for text (1994) 4 Comp.L.J. (Statutes) 49.

Legality of price control orders

The notification issued under the Essential Commodities Act relating to Sugar Contol Orders were challenged in *D.S.G. Mills v. Union of India*[6]. In this case the legality of the order was challanged on the ground that it imposed an unreasonable restriction on the right to trade under Article 19(1) (g) of the Constitution because it compells the factories to sell sugar at a loss, it fixes the price arbitrarily and there is no resonable safeguard against the abuse of power. Answering these issues the Supreme Court observed that since the order provides for factors that the Government will have to take into account before fixing the prices like minimum price fixed for sugarcane manufacturing cost, taxes and reasonable margin of profit for producers, it cannot be said that the Order gives uncontrolled, unguided and unfettered power to the executive to fix the prices arbitrarily[7].

On the question whether it is beyond the authority conferred on the Central Government the Court, said:

> "the object of the Act and rules is to provide for controls of production, supply and distribution of trade and commerce in essential commodities in the interest of the general public so that the supplies of such commodities may be maintained or increased, their equitable distribution secured and they may be available to the general public at fair price"[8].

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[6] A.I.R. 1959 S.C. 627.

[7] *Id.*, p. 630.

[8] *Ibid.*

Hence the Court held that the Order would subserve the purposes of the Act and so it is within authority of the law. The Court dismissed the petetion by holding that so long as the Central Government excercises the power to fix prices in the manner provided by the Act and the Order and the prices fixed were not below the cost of production it cannot be said that any further safefuards are necessary and held that the excercise of power cannot be said to be arbitrtary[9].

In *Shree Meenakshi Mills v. Union of India*[10] , the petetioners challenged the Cotton, Textile (Control) Order on similar grounds. They argued that these orders conferred arbitrary powers on the executive to fix prices of essential commodities unrelated to the cost of production and reasonable margins of profit. According to them the fluctuation in the price of cotton is not taken into consideration. Raw materials, wages and profits were not condisered. Nothing had been done with regard to those who suffered electricity cut in some States. Hence according to the petetioner, these regulations become void by reason of infringement of Fundamental Rights.

The Court while answering these arguments underlined the need to maintain equilibrium between the intereste of consumer and the trader. The Court cautioned that the control of prices may have effect on the supply of the commodity and stressed the need to maintain increasing supply of commodity. For this purpose the Court recognised the need to take into account the cost of

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[9] *Id.*, 632.

[10] A.I.R. 1974 S.C. 367.

production and a reasonable return to the producer of the commodity. It observed that the producer must have an incentive to produce. The fair price must be fair not only from the point of view of consumer but also from the point of view of producer. At the same time the Court said:

> "In fixing the prices, the price line has to be held in order to give preference or predominant consideration to the interest of the consumer or the general public over that of the producer in respect of essential commodities. The aspect of ensuring availability of the essential commodities to the consumer equitably and at fair price is the most improtant considerstion"[11].

Simultaneously, the Court struck a note of caution that the producers should not be driven out of his producing business because of these controls. That would lead to short suppy of essential goods. Therefore, the Court said:

> "any restriction in excess of what would be necessary in the interest of general public or to remedy the evil has to be very carefully considered so that the producer does not perish and the consumer is not crippled."[12]

However the Court held that the mere suggestion that no provision was made for adjustment on account of changes in the cost of production did not amount to infringement of Fundamental Right to carry on business and hold and dispose of property. According to the Court the fixing of controlled price

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[11] *Id.*, 383.

[12] *Ibid.*

of yarn was much more than a fair price to the producer on the date when it was fixed[13].

Realising that they may not succeed in their traditional mode of attack, the petetioners in *Union of India v. Cynamide India Ltd.*[14], adopted a different device to challenge the provisions of the Drugs (Price Control) Orders 1979.

In this case they contended that the excercise of power of price fixation under DPCO 1979 was a quasi-judicial activity and should comply with the rules of natural justice. According to the petetioner the provisions of DPCO unlike other price regulations, were designed to induce better production by providing for fair return to the manufacturer. In course of their argument references were also made to the Hathi Committee report and Statement on Drug Policy 1979 which had recommended a retun of 12 to 14 percent post tax return on equity and that ceiling prices may be determined by taking into account production costs and reasonable retun. In their argument emphasis was laid on second clause of paragraph 3 of 1979 Order.[15] This provided that in fixing the price of a bulk drug, the government may take into account the average cost of production of such bulk drug manufactured by an efficient manufacturer and allow a reasonable return on net worth. It was also submitted that the provision for an enquiry preceding the determination of the price of the

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[13] *Id.*, p. 384.

[14] A.I.R. 1987 S.C. 1802.

[15] Drug (Price Control) Order 1979 Para 3 reads: " 3(2) while fixing the price of a bulk drug under sub-paragraph (1), the Government may take into account the average cost of production of such bulk drug manufactured by an efficient manufacturer and allow a reasonable return of networth."

bulk drug, and provision for a review of the order determining the price would become futile if they were not heard before the determination of the price and were not disclosed the grounds on which the decision was based and therefore violated the principles of natural justice.

To counter the argument that price fixing activity is a quasi judicial activity, the Court elaborated the distinction between legislative activity and administrative or quasi-judicial activity. The Court made the observation that price fixation is more in the nature of legislative activity and hence the question of hearing the prospectively affected persons will not arise before venturing in such legislative activity. The Court observed that though it is difficult to draw a distinctive line between legislative and administrative function because of the proliferation of delegated legislation, the line must sometimes be drawn as different legal rights and consequences may ensure out of such distinction. According to the Court the distinction between the two is one as between the general and the particular. A legislative act is the creation and promulgation of general rule of conduct without reference to particular cases and an administrative act is the making and issue of a specific direction or the application of general rule to a particular case in accordance with the requirements of the policy[16]. The Court, accordingly, held;

> "A price fixation measure does not concern itself with interests of an individual manufacturer or producer. It is generally in relation to a particular commodity or class of commodities or

[16] *Id.*, p.1806.

> transctions. It is a direction of a general character, not directed aginst a particular situation. It is intended to operate in the future. It is concieved in the interest of the general publlic."[17]

The right of the citizen to obtain essential articles at fair prices and the duty of the State to provide them are transformed, as observed by the Court, into the power of the State to fix prices and the obligation of the producer to charge not more than the price fixed. The Court refused to agree with the premise that the price fixation primarily affects manufacturers and producers. It held that those who are most vitally affected are consumer public. It is for their protection that price fixation is resorted to and any increase in price affects them as seriously as any decrease does a manufacturer[18]. The Supreme Court categorically said:

> "Nothing in the scheme of the Drugs (Price Control) Order induces us to hold that price fixation under the Drugs (Price Control)Order is not a legislative activity, but a quasi-judicial activity which would attract the observance of the principles of natural justice. Nor is there anything in the scheme or provisions of the Drugs(Price Control) Order which otherwise contemplates the observance of any principle of natural justice....."[19]

According to the Court the enquiry contemplated by paragraph 3 of the Drugs (Price Control)Order was intended for the purposes of fixing the maximum price at which a bulk drug may be sold with a view to regulating its

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[17] *Ibid.*

[18] *Id.*, p. 1807.

[19] *Id.*, p. 1816.

equitable distribution and making it available at fair price. This enquiry need not be confined to obtaining information from manufacturers in general or 'an efficient manufacturer' but it may go beyond that if it thinks fit. Hence the Court held that no implications of natural justice can be read into it unless it is a statutory condition[20].

With respect to the true nature of the review power provided by paragrph 27 of the Order in relation to fixation of the price of the bulk drug, the Court observed that the reviewing authority has the fullest freedom and discretion to prescribe its own procedure and consider the matter brought before it so long as it does not travel beyond the parameters prescribed by paragrph3 [21].

On the issue of factors that are to be taken into account and the items that are to be excluded before the determination of the price of a bulk drug, the Court observed that 'price fixation is neither the function nor the forte of the Court'. It said.

> "The assembling of the raw materials and the mechanics of price fixation are the concern of the executive and we leave it to them. And we will not re-evaluate the considerations even if the prices are demonstrably injurious to some manufacturers or producers."[22]

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[20] *Id.*, p. 1817.

[21] *Id.*, p. 1817.

[22] *Id.*, p. 1805.

Therefore, it is beyond any doubt that the authority to fix the price of any essential commodity including drugs is perfectly legal and constitutional.

Drug price control orders : An evaluation

Nature of control of a drug under the 1987 Orders varied depending on the Shedule in which the drug was included and category of formulation. Some aberrations have also been noticed in the listing of drugs and their categories for the purpose of price control, under DPCO 1987[23] which resulted in acute market shortage of some vital drugs of which India is a largest consumer in the world.[24] The new Drug Policy has changed the Price Control system substantially. Keeping in view of the changes in the national and international level, price control provisions have been liberalised to a great extent. Now the system of price control operate through a single list of price controlled drugs based thereon with a Maximum Allowable Post Manufacturing Expenses (MAPE) of 100 per cent on all the drugs.[25] The categorisation of drugs into two list with different MAPE were allowed in 1987 Order. A lower MAPE of 75 per cent for the drug required for National Health Programmer (NHP)[26] and a grant 100 per cent for others. Because of this there were reports of inadequate supply of drugs required for N H.P[27]. Perhaps it is to encourage

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[23] Editorial, *The Economic Times*, May 10, 1989.

[24] *Ibid.* and also see *Times of India*, January 28, 1990.

[25] *Supra* n.5 para 27.7.1.

[26] DPCO 1987, Category I drugs .

[27] *Id.*, Category II drugs.

production and availability of these drugs, it was thought necessary to allow a uniform MAPE in all cases of drugs under price control. The criteria of including drugs under price control will be the minimum annual turnover stipulated in the Orders[28]. High turnover of a drug is considered as an index of its extent of usage and considered to meet requirements of objectivity justifiable on economic consideration.

We may have a look at some of the important phrases used and their meanings before going to summarise some of the essential features of the DPCO 1995. The expressions, 'bulk drug', 'formulation', ' Sheduled formulation', 'non-sheduled formulation','free reserve', 'networth', 'pretax return'and 'sale turn over' have been defined under the Order. 'Bulk drug' is defined to mean any pharmaceutical, chemical, biological or plant product. It includes the components and derivatives which conform to pharmocoepoeial or other standards specified in the Drugs and Cosmetics Act[29]. 'Formulation'[30] to mean a medicine processed out of one or more bulk drugs with or without the use of pharmaceutical aids and which is used for internal or external use for diagnosis, treatment or prevention of disease in human beings or animals. It expressly excludes any medicine included in the ayurvedic, sidha, unani and homeopathic system of medicine. 'Scheduled formulation' means[31] a formulation containing any bulk drug specified in the First Schedule eithre

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[28] *Supra* n.5 para 27.7.2(I)

[29] *Supra* n.4 para 2(a).

[30] *Id.*, para 2(h).

[31] *Id.*, para 2(v).

individually or in combination with other drugs which may include one or more drugs not specified in the first shedule. It does not include a single ingredient formulation based on bulk drugs, specified in the First Schedule and sold under generic name. 'Non-sheduled formulation' means[32] a formulation not containing any bulk drug specified in the First Schedule.

'Free reserve' means[33] a reserve created by appreciation of profits, but does not include reserves provided for contigent liability, disputed claims, goodwill, revalution and other similar reserves. 'Net worth' means the paid up share capital of a company plus free reserve and surpluses. It excludes outside investments which are not readily available for operational activity[34]. 'Pretax return' means profits before payment of income tax and surtax and includes such other expenses which do not form part of the cost of formulation[35]. 'Sale turn over' means the product of unit of formulations sold by a manufacturer or an importer, as the case may be, in an accounting year multiplied by retail price which includes sales tax paid directly by the manufacturer or importer but does not include excise duty and local taxes[36].

In DPCO 1995, there are three shedules. The First Shedule lists bulk drugs which are used in formulations. Most of the Shedule I drugs are considered to be relatively important drugs. Second Schedule consists of forms

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[32] *Id.*, para 2(p).

[33] *Id.*, para 2(i).

[34] *Id.*, para 2(n).

[35] *Id.*, para 2(q).

[36] *Id.*, para 2(w).

which are to be submitted by the manufacturers or importers. It provide for three kinds of forms and an annexure. Form I is meant for application by the manufacturer or importer for fixation or revision of prices of Scheduled bulk drugs. Form II is intended to be used as an application by the manufacturer or importer to furnish information for enabling the Government to fix the price in respect of non-Scheduled bulk drugs. Form III is an application for approval or revision of rhe price of Sheduled formulations . Annexure indends to obtain information of cost of production of Scheduled bulk drugs. The Third Schedule gives details about the maxumum pre-tax returns on sales of manufacturers or importers of formulations depending upon the category to which the manufacturer belong under this Shedule. Categorisation was based on the maximum sale turnover in a financial yrar.

With a view to regulate equitable distribution and increase in supply of bulk drugs specified in first Shedule and making them available at fair prices from different manufacturers the Government was empowered under the rules to fix from time to time, after making an enquiry, a maximum sale price at which a bulk drug is to be sold[37]. It is mandatory on every manufacturer producing a Sheduled bulk drug to furnish the details of cost of each bulk drug in a separate form within 30 days of the commencement of the order and before end of September every year[38]. For the purpose fixing the price under this paragraph the Government is empowered to inspect the manufacturing

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[37] *Id.*, para 3(1)

[38] *Id.*, para. 4.

process, facilities and records to enable itself to obtain information in addition to what has already been furnished by the manufacturer[39]. While fixing the price of a bulk drug the consideration must be given to the post-tax returns of fourteen percent on net worth or retun of twenty two percent on capital employed or in respect of new plant an interest rate of twelve percent based on long term marginal cost depending upon the option of the manufacturer[40]. The Government will take into consideration a post-tax return of eighteen percent on net worth or return of twenty six percent on capital employed if the production of such bulk drug is from basic stage. But the option with regard to rate of return once exercised by the manufacturer will be final and change of rates can be made only with the prior approval of the Government. Once the maximum sale price of Sheduled bulk drug is fixed by the Government, any sale in excess of the price fixed is prohibited. But until the price of a bulk drug is fixed, the price of such drug would be the price which prevailed immediately before the commencement of this order and it should not be sold in excess of such price[41]. If any manufacturer commences production of any sheduled bulk drug after the commencement of the Order he has to furnishe the details of costs and other information to the Government within a stipulated period. Basing on the information furnished by the manufacturers or after obtaining

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[39] *Ibid.*

[40] *Id.*, para. 3(2).

[41] See *id.*, para. 3(3).

any additional information the Government may fix the maximum price for such bulk drug[42].

Any manufacturer who is agrieved by the decision of the government in fixing the maximum price may make an application to the government. The government after making necessary enquiry may either revise or reject such application. But any such decision must be taken within a period of our months and the order must be a speaking order[43].

There is a different procedure for fixing the price of bulk drugs not listed in the First Shedule[44]. Manufacturer who is producing a non-Sheduled bulk drug has to furnish a list of such drugs. He has to furnish the details of the cost of each such drug to the government within a stipulated period. Basing on the details of cost submitted by such manufacturer or importer the government may in the interest of public fix or revise the price of such drug within fifteen days of the receipt of such information[45].

The provisions of DPCO also empowers government to fix the retail price of any formulation in accordance with the formula laid down in the Order[46]. The formula for calculating the retail price of such formulations is provided under paragraph 7 of the DPCO[47]. If any manufacturers utilises a

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[42] See *id.*, para. 4(4).

[43] See *id.*, para. 4(5).

[44] See *id.*, para 5.

[45] *Ibid.*

[46] See *id.*, para. 8

[47] *Id.*, para 7 states, R.P. = (M.C.+ C.C. + P.M. + P.C.) x (1 + MAPE / 100) +ED).
"R.P." means retail price.

bulk drug, for which the price has been fixed by the government under these provisions, in his formulations he has to make an application to the government within thirty days of such fixation for price revision of all such formulations. The retail price of formulation once fixed by the government cannot be increased by the manufactures without prior approval of the government. If an application is filed by any manufacturer for revision of retail price the government has to take a decision either to revise or reject the application within two months from the date of reciept of application. The government has to record reasons for its decision.

Under paragroh 7 the maximum allowable post manufacturing expenses (MAPE) for indigenously manufactured formulation should not exceed hundred percent. However in the case of imported formulations landed cost is to be the

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"M.C." means Material cost and includes cost of drugs and other pharmaceutical aids used including averages, if any, plus process loss thereon specified as a norm from time to time by notification in the official Gazette in this behalf.

"C.C." means conversion cost worked out in accordance with established procedures of costing and may be fixed as a norm every year by notification in the official Gazette in this behalf.

"P.M." means cost of the packing material used in the packing of concerned formulation and includes process loss, and shall be fixed as a norm every year by notification in the Official Gazette in this behalf.

"P.C." means packing charges worked out in accordance with established procedures of costing and shall be fixed as a norm evey year by notification in the official Gazette in this behalf.

"M.A.P.E." (Maximum Allowable Post-Manufacturing Expenses) means all costs incured by a a manufacturer from the stage of ex-factory cost to retaining and includes trade margin and margin for the manufacturer and it shall not exceed one hundred percent for indigenously manufactued formulations.

"E.D." Means excise duty...

basis for fixing its price with a margin to cover selling and disribution expenses including interest and importer's profits which together should not excced fifty percent of the landed cost. For this purpose landed cost means cost of import of the formulation including customs duty and clearing charges[48].

No manufacturer or importer may market a new formulation or a new dosage form of his existing Sheduled formulation without obtaining the prior approval of its price from the government[49]. The government has also taken the power to fix a ceiling price of Sheduled formulation in accordance with formula provided in para.7[50]. Ceiling price is to be fixed by keeping in view of the cost of major manufacturers of such formulation. Such ceiling prices operate for all packs including those sold under generic name. And such price is applicable even to small scale manufacturers. If a manufacturer desires to sell those formulation in pack size different to the pack size for which ceiling price has been notified, he has to work out the price for such pack size and intimate the same to the government. He is not permitted to release such formulation packs for sale until the expiry of sixty days from such intimation[51].

Power to Revise the price

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[48] See *id.*, explantion to para. 7.

[49] *Id.*, para. 8(7).

[50] *Id.*, para. 9.

[51] *Id.*, para. 9(3).

The Government may revise the price of any bulk drug or formulation including non-sheduled formulation if it considers necessary in the interest of public. This power is to be exercised in the manner provided under the Order. It has to take into account the pre-tax return on the sale turnover of the manufacturer. It has to ensure that the pre-tax return on the sale turnover of any manufacturer does not exceed the maximum pre-tax return specified in the Third Schedule[52].

If the government considers necessary in the public interest, it may include any bulk drug in the First Schedule and fix the price of such bulk drug and formulation containing such bulk drug[53].

Power to exempt

Any manufacturer may be exempted from the operation of the provisions of all or any of the provisions of the Order. Before exempting any such manufacturer, regard must be had to factors like number of workers employed, the amount of capital invested, range or type of products manufactured and sales turnover. Another factor to be taken into account is the production of bulk drugs from basic stage by a process developed through indigenous research and development and production of new drug which has not been produced elsewhere[54].

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[52] See *id.*, para. 10.

[53] *Id.*, para. 10(c).

[54] *Id.*, para. 25.

A special power is conferred on the government to fix price in respect of any bulk drug or formulation for which manufacturer or importer fails to furnish the information required by it under these provisions.[55] Every manufacturer or importer has to implement the price fixed by the government within the stipulated time. Likewise, every manufacturer, importer or distributor of a formulation is required to display on the label of the container the retail price with the words "retail price not to exceed" preceding and "Local Taxes Extra" succeeding it.[56] But a manufacturer or importer or distributor of a non-Sheduled formulation has to display in indelible mark on the label of container of the formulation and on the minimum pack offered for sale, the retail price of that formulation with words "maximum retail price" preceding it and words "inclusive of all taxes" succeeding it[57]. The manufacturer or importer has to issue a price list to the retailer or dealer and every such retailer or dealer is duty bound to display the price list on a conspicious part of the premises where he carries on his business. This display is to be easily accesible to any person who wish to consult it[58]. This rule applies to prices of non-Scheduled formulations also.

A reference should also be made to some of the items included and excluded in the forms provided under the schedules and the annexure to be attached to Form I. As already pointed out Form I is meant for an application

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[55] *Id.*, para 11.

[56] *Id.*, para 14(2).

[57] *Id.*, para. 15(1).

[58] *Id.*, para. 14(4).

for fixation or revision of the scheduled bulk drug. The contents of the form are intended to enable the government to obtain information relating to, among other things, capital employed, manufacturing process, rate of production, cost of raw materials used and number of persons employed, their grades and emoluments and cost of production. For furnishing the details of cost of production, an annexure is to be attached to this Form. Annexure includes, among other things, contents like details of cost, cost of raw materials, power, converion cost, packing materials and expenses, transport charges and selling expences. It also specifically provides items of expences which are not to be included in the cost. The items of expences excluded from cost are bonus in excess of statutory mimimun, bad debts, donations and charities, loss on sale of assets, brokerage and commission and other expences not recognised by income tax authorities[59].

Some of these provisions including the phrases defined under the Orders have been contentious issues between the government and the drug manufacturers. For example it was argued that in calculating "net worth" the exclusion of the cost of new works in progress and the amount invested outside the business could not be justified on any known principle of accountancy[60]. Attacks were also made in respect of items of expences to be excluded in ascertaining the cost. They argue that 'bonus in excess of statutory minimum' should not have been excluded. So also other item of expenditure excluded.

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[59] See *id.*, item 17 of Annexure.

[60] The arguments of manufacturers are reproduced from the *Cynamide* case, *supra* n.14 at p.1819.

Their contention is that where bonus in excess of statutory minimum was payable under the provisions of the Bonus Act, there was no option left to the manufacturer not to pay the bonus in excess[61].

Another contention of the manufacturers was relating to the norms for conversion costs, packing charges, process loss of materials and packing material required to be notified for the purpose of calculating retail price of formulation. The argument was that the formula in regard to conversion cost as provided under the Order is not scientific. According to them, the same can be done in a more scientific manner[62]. But these arguments were rejected by the Supreme Court on the ground that it was sufficient to adopt a rough and ready but otherwise not unreasonable formula rather than going for a needlessly intricate one[63].

Measures needed for a better price control system

The rules relating to display of price on the label appears to conflict with some provisions of the Standards of Weights and Measures Act 1976.. This controversy assumes importance because of strict enforcement of the Packaged Commodities Rules1977 framed under the above Act in some states. It has created problems for producers and sellers of drugs. Such problem may not arise after DPCO 1995 in case of non-Scheduled formulations. But the problem may persist with regard to scheduled formulations. For example,

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[61] *Id.* at 1820..

[62] *Ibid.*

[63] *Ibid.*

maximum retail prices of drugs are fixed under the DPCO. The prices of scheduled formulations are exclusive of local taxes and the local taxes vary from place to place and time to time. Under the Packaged Commodities Rules, however the maximum retail price of a drug package must be inclusive of all local taxes. The government ought to suitably amend the relevant rules to avoid disputes and litigation caused by these conflicting provisions.

It was suggested that the drug industry may be exempted from the relevant provisions of the Standards of Weights and Measures Act and the rules framed thereunder.[64] Significantly the Act itself provides that "the Central Government may, by rules, specify the classes of commodities or packages in relation to which all or any of the provisions shall not apply or shall apply with such exceptions or modifications as may be specified therein"[65]. It is nobody's case that the Standards Act should not be made applicable to the drug industry. It must, however, be ensured that there is no conflict between the two sets of rules required to be observed by the industry and avoid confusion in the minds of consumers. If the maximum retail price fixed under DPCO is exclusive of local taxes, retailer gets an opportunity to defraud consumers by inflating local taxes. There is every need to levy local taxes at uniform rates through- out the country for protecting consumers.

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[64] Editorial, "Available Conflict", *Financial Express,* October 19, 1989.

[65] Standards of Weights and Measures Act 1976, section 39(9).

There are allegations that industry has been adopting devises to minimise even these limited controls.[66] Many big companies get certain products manufactured by small scale units through loan licensing system[67] and market them under their brand names. The large companies decide from where and at what price the small scale units should import intermediates and penultimates for formulations to be marketed by them. Drugs of popular use, in which there is a monopoly situation are to be kept under price control. As an experimental measure, drugs having adequate competition are kept away from price control. The idea is that if this proves successful, it may pave the way for further liberalisation. However, strict watch on the movement of prices of these products is required.

The government may determine the ceiling levels beyond which increase in prices would not be permissible. The ceiling price will be determined by taking into account the production costs and reasonable returns for the units which are market leaders. It intends to keep close watch on the prices of medicines which are taken out of price control. In case, the prices of these medicines rise unreasonably, appropriate measures, including reclamping of price control would be initiated. The genetically engineered drugs produced by recombinant DNA technology and specific cell or tissue targeted drug

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[66] Sasankan, "Wrong drug policy has made medicines expensive," *Times of India*, January 31, 1990.

[67] A Bombay based non FERA Company has as many as 23 drugs manufactured under the loan licensing system.

formulations are to kept away from price control for five years from the date of manufacture in India[68].

As an answer to the allegations that there is an unreasonable delay in fixing the prices of the drugs,[69] a time frame for granting price approvals has been fixed as 2 months for formulation and 4 months for bulk drugs from the date of receipt of the complete information. To encourage the production from basic stage the rate of return has been enhanced to 18 per cent on net worth or 22 per cent on capital employed.

All these measures of direct controls on the pharmaceutical industry failed to yield the intended results for various reasons. The machinery created under the provision is inadequate to monitor these controls apart from its reluctance to antagonise the industry. It is compounded by the difficulty of obtaining an accurate information of the cost of materials used and the actual turnover of the respective industries because of the ability of multinationals who engage in many devices like over invoicing of imported materials and transfer pricing methods[70] However there are serious copmplains that

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[68] Though the new drug policy 1994 makes such proposal, the same has not been provided under DPCO 1995. It only allows excemption of new drugs produced through indigenous research and which has not been produced elsewhere. Perhaps drugs produced by DNA technology may be covered impliedly, see DPCO 1995 para 25.2(f)

[69] See *Indian Express*, January 20, 1990.

[70] Even in England where the laws are more rigorous this practice is followed. For details see Hoff mann La Roche affairs. Here the company held a patent for two very widely used tranquillisers, Librium and Valium. Following a reference from the Government, the monopolise Commission reported that profits on drugs were too high - profits on sales upto 60 per cent and 70 per cent on capital in a year. A salient piece of evidence was that although the price of drugs falls from the time they are patented, the price of Librium and Valium had remained stable. Moreover, the active

manufacturer and importers have been over invoicing imports. The power to revise the prices of drugs has been constantly invoked by the drug companies on the pretext of hike in the cost of imports and on account of devaluation of the rupee. The Department of Chemicals did not bother to find out either the prevailing international price of the concerned items or the imported stocks with the manufacturers.

It is doubtful whether any other price fixing agency could have been assigned a more thankless job than the Bureau of Industrial Cost and Prices (BICP) which had to examine the cost data from the stage of basic production, work out the 'mark-up' consisting of several components at the final stage of formulations and sale prices of several hundreds of items.

The constitution of an independent body to implement the provisions of DPCO is also envisaged under new drug policy[71] As per these provisions, an independent body of experts, to be called National Pharmaceutical Pricing Authority, will be entrusted with the task of price-fixation or revision and other related matters. It will also update the list of drugs under price control regime by inclusion and exclusion on the basis of established criteria or guidelines. It would be empowered to take all final decisions.[72] But the government would

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;ingredients for Librium and value cost £9 and £20 per kilo in Italy, but the cost of manufacture was said by the company to be £437 and £979 for the same amounts. Acting on the Monopolies Commissioner's report, the Government fixed maximum prices for drugs under the Fair Trading Act, 1973. See Harvey Teff, "Regulation under the Medicine Act 1968: A continuing prescription" 47 Mod.L.Rev. 303 at p.319.

[71] *Supra* n.5 para 27.7.4.

[72] Ibid.

have power of review. It would also monitor the prices of decontrolled drugs and formulations and oversee the implementation of the provisions of DPCO.

Need for use of brand names

With the introduction of new drug policy most of the basic drugs and formulations were excluded from price control regime on the ground that the operation of market forces would reduce the prices. These excluded drugs constitute large chunk of the total consumption. But the order of the day between drug companies is product competition, rather than price competition. Thus, different brand name drugs are promoted which are therapeutically similar. With product competition there is little incentive for companies to reduce their prices. It may even increase the cost of drugs by encouraging the search for unnecessary variations of existing products.

The use of brand names as opposed to generic names enables the drug industry to sell essentially similar drug formulations at widely varying prices. Quite often it is difficult for the doctor and almost impossible for the patient to have at their disposal information which would enable them to compare prices of drugs which are virtually identical. Advertisements rarely mention prices and in general the medical representatives canvass the superiority of their particular brands of medicine with the doctor not on grounds of prices but on other grounds such as therapeutic effectiveness or advantages of the new and improved drug.

The concern about drug prices really arises from the fact that many of them are essential to health of the community and that there is no justification

for the drug industry changing prices and having a production pattern which is based not upon the needs of the community but on aggressive marketing tactics and created demand.

At the same time the proposals to introduce essential drugs list or generic drugs available for prescription seems unlikely to prevail over the objections that it would constitute an unacceptable interference with the clinical freedom of the doctors, though several countries do have such list.[73] Moreover, many doctors would see such a move as depriving patients of higher quality and more suitable drugs. But for these objections introduction of generic substitution is a potential source of price control.[74] These generic products marketed under the name of their chemical components are offered at much lower prices than the same products marketed under their brand names. The generic and brand name controversy has acquired the notoriety of international status. Therefore, it has been suggested that the brand name of the product be followed by the international non-proprietary name recommended by the World Health Organisation, where such names exist.[75]

By fiscal or legal measures the production of irrational and hazardous drugs are to be made unattractive. Indirect constraints on the doctor may also be imposed to reduce the burden of cost of the prescription drugs on the

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[73] For example Bangladesh and some other countries have such list.

[74] Brand name prescription constitute 80 per cent of the total consumption. In 1983 British Government acknowledged that, if introduced for nine commonly taken drugs alone, it would save some £30 million a year. See Teff (1984) *of.cit.* at p.320.

[75] See L. Krames, *EEC Consumer Law, of.cit.* at p.86.

consumer. One such move, which has already been in vogue elsewhere, is to make physician responsible to meet the additional cost if he prescribes beyond a fixed per capita limit.[76] It will certainly enable physicians to prescribe the less expensive products among the available brand name products having equal pharmaceutical properties. A magnificent effort was also made by some voluntary organisations to overcome widespread irrational prescription practices.[77] They manufacture solely generic drugs and opened a chemist's shop only to sell generic drugs. The consumers are free to choose between costlier brand name drugs and the cheaper generic drugs. That the prices are cheap can be seen from a comparison of some of the more common and often used medications people normally need. Such organisations are to be encouraged with proper tax incentives.

Use of Patent System

Apart from direct price control, another avenue for lowering drug prices is through preventing the abuse of the patent system. Section 97 and 99 of the Patents Act1970 enables the government to grant a licence to persons other than the patent holder "if it is necessary or expedient in the public interest.'[78] The Patents Act also provides that a patent could be compulsorily

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[76] Germany has introduced such laws, though it has no direct Price Control on drugs. See Ross Canston, *Consumer and the Law of.cit.* at p. 408.

[77] SEWA a drug manufacturing voluntary agency was set-up at Baroda. See Andrew J. Rebello, "Effort to make popular generic drugs," Indian Express, July 28, 1989.

[78] Similar provisions were invoked in Britain in early 1970s to permit the importation of tetracycline for hospitals from countries such as Italy which did not grant drug patents. The House of Lords

licensed to another drug company, "if the demand for a patented article in India is not being met to an adequate extent and on reasonable terms." But survival of these provisions is doubtful in the light of the impending Patents Bill 1995 which, if enacted, would take away the spirit of the compulsory licensing philosophy under patent system.[79]

Rational packing of drugs

Another important element in the prices of drugs which needs particular attention is the cost of packing. It has been noticed that the cost of packing materials constitute fairly high proportion of the costs of pharmaceutical products.[80] In some preparations the costs of the packing materials could be much higher than the cost of ingredients used.[81] The Hathi Committee felt that greater attention should be paid to the standardisation and economy in the use of packing materials consistent with the protection of consumer interest.[82] It should be assured that competitive packing is not resorted to as a sales promotion measure.

Rationalisation of taxes on drugs

The issue of bringing down drug prices is also directly related to the problem of taxes and duties on medicines, at the manufacturing and distribution stages. The excise duties, customs duties, sales tax and other imposts on raw

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upheld its use and the outcome was a drastic fall in the price of the drug from £60 per 1000 tablets to £6.10. See Teff, (1984) *of.cit.* at p.319.

[79] For a detailed discussion on this aspect see Chapter IV *supra*.

[80] Hathi Committee Report, (1975), para 23-179.

[81] *Ibid.*

[82] *Ibid.*

materials and intermediates are imposed on drugs. It is disconcerting that the Union and state governments treat medicines as a source of revenue. It has been noted that these taxes together account for nearly 35 per cent of the price paid by the consumers.[83]

It is bad enough that the government is tardy in lowering the incidence of taxes on medicines. What is worse is that state governments are still to aim for uniformity in the rates of sales tax and Octroi. There are indications that some states are imposing turnover tax or 'basic tax' on medicines.[84] On the whole, by all these means consumer is exploited. If the government is genuinely interested in protecting consumers it will do well by significantly lowering down the burden of taxes and duties on medicines. There are reports that some of the customs duty concessions announced to the industry to help the consumer did not percolate down to the consumer because of the failure to monitor its impact on production of drugs.[85] But the concession was not withdrawn. Therefore, the loss to the exchequer has gone to the pockets of the drug manufacturers and not to the consumers.

A satisfactory solution regarding the pricing of the drugs has not yet been devised. Though the existing regulations have helped to control price escalation to some extent, there are deficiencies in its approach. The operation

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[83] Assocham, "Drugs and Pharmaceuticals : Protection of Consumer Interest". A paper presented at a workshop organised by Associate Chambers of Commerce and Industry of India in association with the Council of Fair Business Practices in Bombay reported in *Financial Express*, Sept. 9, 1989.

[84] *Enadu*, November 9, 1993.

[85] See Sasankan, "Tardy implementation of DPCO hits poor", *Indian Express* Economic Bureau, New Delhi, October 24, 1991.

of price control so far certainly helped in preventing very large profits by pharmaceutical industry. But it does not appear to have contributed materially to the emergence of a product or price pattern which is more consistent with the social needs and national objectives.[86]

[86] See B. Ekbal, *A Decade of After Hathi Committee*, Kerala Sasthra Sahithya Parishad, Trivandrum(1988), at p. 101.

CHAPTER- VII

DRUG ADVERTISMENT AND LAW

The dictionary defines the word 'advert' as "to draw attention to, to refer to," and this is exactly what advertising did mean originally. The Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 defines advertisement as "any notice, circular, label, wrapper, or other document, and any announcement made orally or by any means of producing or transmitting light, sound or smoke."[1] The definition is only inclusive and not exhaustive. It is intended to make known to the public through any of the media of something for promoting sale. In the Commercial advertising is the business which concerns itself with making known to the public of what is for sale and encouraging them to buy by any means of communication which the seller deems to be effective.

The need to regulate commercial advertisemtns in general and pharmaceutical advertisements in particular is necessary to prevent exploitation of consumers by misleading informations. The various legal provisions dealing with drug advertisement, its background and constitutionality are analysed here. The cases decided under these provisions are examined to see how far these provisions are effective in protecting the interest of pharmaceutical consumer.

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[1] Drugs and Magic Remedies (Objectionable Advertisements0 Act 1954, S.2(a)

The legal provisions dealing with pharmaceutical advertisement are spread over many legislation and rules framed under these legislation. The main legislation dealing with pharmaceutical advertisements is the Drugs and Magic Remedies (Obligationable Advertisements) Act 1954 and Rules framed under it. Since 'advertisement', by definition, also includes 'labelling', the study of the provisions in the Drugs and Cosmetics Rules dealing with the information to be furnished through 'labelling' may also become relevant here. In addition to these provisions the Monopolies and Restrictive Trade Practices (MRTP) Act 1969 and the Consumer Protection Act 1986 regulate advertisements in general.

It may be appropriate at the outset to deal with some of the aspects of advertisements and the importance of advertisement in general from the point of view of both manufacturer and as well as consumer.

Importance of commercial advertising

When a manufacturer wants to sell a product, he has to reach out, and establish contact with the mass market. The best way of reaching these potential buyers is through mass communication by way of advertising. Advertising is a forceful communication which promotes the sale of goods, services through use of information and production. It is perhaps the best known mass communication channel. Marketers and firms engaged in selling their products throughout the world are fully aware of the necessity and importance of advertising.

Advertising is important because it is supposed to provide the consumer with facts he needs to make an intelligent choice. In a market flooded with a variety of brands, he can differentiate and compare the features of various products, and can know their plus and minus points. He can differentiate between competing brands in the matter of price and other advantages and disadvantages. He can also save his time. In this context, advertising is supposed to help in creating a competetive environment which promotes better quality and fair pricing.

From the point of view of the manufacturer or marketer, the equation is simple. The aim of any business is survival and growth. In order to survive, one has to sell. In order to sell, he has to advertise. Even the Supreme Court appeared to have recognised the importance of the advertisements when it observed that "low prices to consumers are dependent on mass production, mass production is dependent on volumesales and volume sales are dependent on advertisement."[2] The Court viewed it as a life blood of free media.

Some aberrations in advertisement

Unfortunately, with the growth in the number of goods and services available to society, advertising has become an instrument to draw our attention away from the product and focus our attention on factors that in no way benefit its utility. For example, in promoting the sale of a particular brand of a washing

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[2] *TATA Press Ltd.v. Mahanagar Telephone Nigam Ltd.*, A.I.R. 1995 S.C.2438 at p.2447.

soap or detergent, the advertiser draws the consumers' attention to 'free with the package' soap tray or brush or even a plastic pail. The buyer's attention is drawn away from the actual commodity and its quality and is focused on the 'free' article supplied with the product to the extent that the buyer considers it a good 'buy' if he can obtain the pail together with the soap. In other words, the main consideration in such a purchase is not the efficiency of the soap. Such an advertisement, therefore, does not 'advert' but 'diverts' the attention of the buyer. In the present day business scenario, where a consumer is supposed to be the 'king', the businessmen by means of glossy and hypertech advertisements swarmed all segments of consumerism to leave an enchanting impact on the'kings' and have also devastated to some extent the principle of 'free and fair business practices'. Advertisements today instead of being an expression of 'creative means of the need' are simply 'creating the need' for buying a product. The lure of a glossy advertisement depicting a facourite film star or sports star promoting a product is too tempting to avoid. Unfortunately the present day Indian consumer is far more illiterate and ignorant of realities and surroundings. He is easily given to hype and is fascinated by hypertech depictions.

Advertising had its beginning as a means of communication between a seller and buyer. It is supposed to be factual and informative, honest in content and clear in presentation. The explosion of the commodity market introduced not only innumerable items of daily use and consumption but many manufacturers of

the same commodities which in turn resulted in keen competition for sales and gave birth to the phenomenon known as 'high pressure' sales advertising. The implication of advertising can only be appreciated when we consider that the advertising business has grown into a leviathan today with an annual turnover into hundreds of crores of rupees.[3] The common man can not condone this enormous growth especially when he knows that this astronomical increase is at his expense because it is he who pays for all advertising. Further, this phenomenal rise in advertising business has occurred during a decade when the National Growth Rate had gone down and the purchasing value for the rupee has plummeted to an all times low.[4] It is obvious, in these circumstances, that advertising today is both wasteful and contrary to the interests of the national economy.

Advertising has lost its educative value. The advertising process itself makes little or no pretence of being educational or unbiased. The consumer education by definition has the welfare of the consumer as its ultimate goal, where as the main purpose of advertising is to stimulate in consumers a desire to buy a certain product or patronise a particular business. Such an action may or may not be in the interest of the consumers who come into contact with the advertisement. The seller controls the content and emphasis of advertisements

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[3] Jojie Mandana, *The Indian Market Place* W.Q. Press, Bangalore, (1977), at p. 53.

[4] *Ibid.*

and the interest of the seller are naturally primary. It compels people to buy things which they do not need. It multiplies our needs by playing upon our sentiments and weaknesses and makes us spend beyond our means. It also raises the prices of goods. Advertiser spends huge amounts to promote sales, and pass on the expense to the consumers who pay through the nose of products which have absorbed the cost of advertising. Then again we have the tall and unbelievable claims of manufacturers. It is not possible to become as beautiful as an actress by use of a particular beauty cream. Psychological and emotive appeals are also cleverly used to mislead the public. Sometimes a false claim for a product is made. It is advertised as "the largest selling" brand when, infact, it barely manges one to two percent of the total sales of the product. It can also be vulgar. The body of woman is exploited to promote products. But what is disturbing is that it tends to develop monopolies. Advertising creates a brand image and puts the product in a class by itself. This brand image is like a protective wall around the products which it is difficult for other brands who are new to the market to compete with. Thus advertisement gives tremendous coverage to established market leaders and enables them to monopolise the market. These are some of the disadvantages crept into the advertising. While the informational needs of consumers may at times correlate with the goals of the seller, the consumer's needs are only incidental to the advertising business.

Need to regulate advertising

Advertising remains as a vital source of information. It is hard to imagine any business functioning effectively if one were deprived of commercial advertising. The total prohibition of advertising would not solve current information deficiencies. Major alternative sources of information from government or private consumer groups are not now available substitute. Product testing magazines reach relatively few people. Alternative information sources like television and news papers provide relatively little information.

The current information system, with commercial advertising playing a central role, is likely to remain. On one side advertising has been justified as a boon to consumers[5] and on the other it has been criticised as a deterrent to the free market which is considered ideal to the consumer sovereignty based on rational choices.[6] Whichever description is closest to the truth, the practical impact of the role of advertising on consumers is to leave them with little control over a major information source on which they base many consumer decisions.

Therefore, the major concern to consumers are the reliability and accuracy of advertising content. Although advertising in its current form does not provide full information, can consumers be protected from inaccurate and deceptive appeals? What regulatory mechanisms are most appropriate to this goal?

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[5] American Advertising Federation, *Questions and Answers About Advertising*, (Washington. D.C. 1974). Brochure.

[6] Zena Cook, Allen R. Ferguson and Garth Trenkl, *Impact of Advertising: Implications for Consumer Education*, Washington, D.C.: U.S. Office of Consumers' Education, pp. 2ff.

In many countries of the world, advertising has been restricted in many forms either by consent of Advertisers' Associations or in some cases by government authority. It is significant that in Britain they have what is known as the Advertising Standards Authority.[7] The function of this body is to infuse ethics into advertising and to ensure that all advertisements are legal, decent, honest and truthful.[8] In India, guidelines have been provided for advertisers, agencies and media owners. The Advertising Agencies Association of India has laid down a code of 'Standard Practices' which seeks to protect the interest of the public and to discourage advertising that may impair public confidence.[9] To this end, it lays down that advertising should conform not only to the laws but also to the normal and aesthetic sentiments of the general public. It should not exploit superstition and credulity and should avoid distortion and exaggeration. The Indian Society of Advertisers and Indian and Eastern Newspapers Society also seek to prevent advertising that is untruthful and misleading.[10] They rule that advertising should not mislead public with false statements with regard to the character and prices of the merchandise with personal recommendations and testimonials which are untrue and fictitious, or by creating misgivings in the mind of the public about the trustworthiness of competitive products. Advertising is not supposed to create

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[7] See O' Keefe, *The Law Relating to Trade Descriptions*, Vol. 2, Butterworths. (1988), pp.5/54 - 5/80.

[8] See generally, international chambers of Commerce, *International Code of Advertising Practice*, (1937)

[9] *Supra* n.3 at p. 54.

[10] *Ibid.*

confusion in the public mind between the products of one manufacturer and another. Indecent, vulgar, suggestive of offensive themes or treatments should be avoided. In addition to these guidelines of professional bodies, there are also other voluntary self regulating bodies like Professional Advertisement Council and Council for Fair Business Practices. But all these bodies appears to be existing for name sake and as perfect paper tigers[11].

Advertisements containging health claims made for medicinal products

In recent years there has been a great increase in the number of objectionable advertisements published in newspapers and magazines relating to alleged cures for various diseases.[12] These advertisements tend to cause the ignorant and unwary to resort to self-medication with harmful drugs and appliances or to resort to quacks who indulge in such treatments which cause harm. The Drugs and Magic Remedies (Objectionalble Advertisements) Act 1954 has been enacted and rules were framed[13] under it to control the advertisement of drugs in certain cases, to prohibit the advertisement of remedies alleged to posses magic qualities.[14] It is clear from the preamble that the purpose of the Act is to

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[11] See Amit K. Vyas, "Misleading Advertisements are Injurious to Public Interest : An Overview of Related MRTP Provisions", (1998) *Chartered Secretary*, A77.305 (April).

[12] See *Indian Express*, January 27, 1990.

[13] Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955.

[14] See *supra* n.1, Preamble.

prevent objectionable and unethical advertisements in order to discourage self-medication and self treatment.

It may be appropriate to study in brief the background of this legislation, the surrounding circumstances and conditions under which the legislation was enacted and the mischief which it intended to suppress. This may also enable us to examine the issues of constitutionality of these provisions and the right of commercial advertisement as part of freedom of speech guaranteed under Article 19(1) of the Constitution.

The context which warranted the legislation of the kind that was enacted in 1954 was made clear from the report of the Chopra Committe[15]. Committee noticed the ingenious propaganda, clever and attractive dissemination of the supposed virtues and wide and alluring advertisements of patent and proprietary medicines. The Committee realised the credulity and gullibility of the masses, especially when certain cures are assured in utterly hopeless cases and the probable impact on patients who have tried treatment by medical men without success. Such patients resort to any and every drug that comes in their way. Widest publicity is given to these and the preparations became invested with miraculous virtues. The re-assurances of cure, the force of argument advanced to guarantee it and certificates of persons said to have been cured which are all set

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[15] In August 1930, the Government of India appointed the Drugs Enquiry Committee with Sir. R.N. Chopra as its Chairman to enquire into the extent of controls on drugs. Report is quoted here from *Hamdard Dawakhana v Union of India*, A.I.R. 1960 S.C. 554 at p. 560.

out in advertisemtns make a deep impression, especially on those with weak nerves. The report pointed out that "the love of mystery and secrecy inherent in human nature, the natural disinclination and shyness to disclose details of one's illness especially those involving moral turpitude, the peculiar temperament of the people who, high or low, rich or poor, demand 'something in a bottle' for the treatment of every ailment and poverty of the people who cannot afford to pay the doctor's bills or the high prices current for dispensed medicines, have all been enlarged upon as tending to self diagnosis and self medication by patent or proprietary medicine."[16]

This was considered to be very apt comment on the existing situation and mischief which needed to be curbed. Therefore, the evil of self-medication and consequences of unethical advertisements relating to medicine are the targets of the legislation.

Constitutionality of the provisions of the Act

The Act was challenged in *Hamdard Dawakhana v. Union of India*[17], on the ground that it is an infringement of the right to free speech under Article 19(1) (a) and the right carry on trade and business under Article 19(1) (f) and (g). Objection was also taken under Articles 14, 21 and 31. In this case the Drug Controller stopped the sale of forty of the petetioner's products. An objection

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[16] *Ibid.*

[17] A.I.R. 1960 S.C. 554.

was taken to the advertisements in regard to drugs. In the counter affidavit, the respondents justified the necessity of the Act and its rigorous enforcement. It stated that the restriction is about the advertisements to the people in general. It said that the main object and purpose of the Act is to prevent people from self medicating with regard to serious diseases. It was argued on behalf of the respondents that self medication in respect of diseases of serious nature mentioned in the Act and Rules has a deleterious effect on the health of the people. Having thus found that some medicines have tendency to induce people to resort to self-medication by reason of elated advertisments; it was thought necessary in the interest of public health to put a complete check. The manufacturers are required to route their products through recognised sources so that products of these manufacturers could be put to valid and proper test and consideration of expert.

The Supreme Court considered the circumstances in which the legislation was enacted and the need to curb the mischief of self-medication. It held that an advertisement was no doubt a form of speech but its true character is reflected by the object for the promotion of which it was employed. The Court opined that advertisement assumed the attributes and elements of the activity under Article 19(1). But it held that "when it takes the form of the commercial advertisement which has an element of trade or commerce, it no longer falls within the concept

of freedom of speech for the object is not propagation of ideas - social, political and economic or furtherance of literature or human thought"[18].

On the question of freedom of trade and business the Court opined that it was not shown in the present case that under the guise of protecting public interest the Act arbitrarily interferes with private business or imposes unreasonable restrictions[19].

Another point raised by the petitioner was that the words ' or any other disease or condition which may be specified in rules made under the Act surrender unguided un canalised legislative power to the executive to add any diseases in the Schedule. The consitutionality of powers of search and seizure provided under section 8 of the Act was also challenged by the petitioners. The Court accepted these two arguments of the petitioners and held "a portion of clause (d) of Section 3 and the whole of Section 8 as unconstitutional and since these are severable from the rest of the Act, it would remain unimpaired"[20].

The Supreme Court has to deal with simiar issue in *TATA Press Ltd.v Mahanagar Telephone Nigam Ltd.*[21] In this case, the issue before the court was whether 'commercial advertisement' comes within the purview of the concept of "freedom of speech and expression" guaranteed under Article 19(1)(a) of the

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[18] *Id.*, p. 563.

[19] *Id.*, p. 566.

[20] *Id.*, p. 568.

[21] A.I.R.1995 S.C.2438.

Constitution of India. Here, an objection was taken by the Nigam Ltd. against the publication of telephone numbers of the business persons and professions on payment in the Tata Press yellow pages as it is violation of the Telegraph Act 1885 and rules. The Supreme Court speaking on the importance of the advertisements held the view that general society also may have a strong interest in the free flow of commercial information[22]. According to the Court the recipient of commercial speech may have deeper interest in the advertisement than the businessman who is behind the publication. In the process Court referred to the importance of an advertisement giving information regarding life saving drug to the general public than to the advertiser who may be having purely a trade consideration[23].

The Court also refused to distinguish between public interested commercial advertisements and the opposite kind. It held that "advertising, however tasteless and excessive it sometimes may seem, is nonetheless dissemination of information as to who is producing and selling what product, for what reasons and at what price"[24].

The Court, ultimately, held that "commercial speech" is a part of the freedom of speech and expression guaranteed under Article 19(1)(a) of the Constitution. Accordingly, the Court speaking through Kuldip Sing.J. opined that

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[22] *Id.*, p. 2445.

[23] *Id.*, p. 2448.

[24] *Id.*, p. 2445.

"right to freedom of speech and expression guaranteed under Article 19 (1) (a) of the Constitution can only be restricted under Article 19(2). The right cannot be denied by creating a monopoly in favour of the Government or any other authority"[25].

Hence, by this judgement, the Supreme Court impliedly overruled *Hamdard* decision and recognised the right of advertisement as part of freedom of speech. The change in the attitude of the Court might have been due to the winds of liberalisation blowing across the world and also India.

Provisions of the Act

The Act explicitly prohibits the publication of any advertisement referring to any drug in terms which suggest or are calculated to lead to the use of that drug for ---

(a) the procurement of miscarriage in women or prevention of conception in women; or

(b) the maintenance or improvement of the capacity of human beings for sexual pleasure; or

(c) the correction of menstrual disorder in women; or

(d) the diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the Schedule, or any other disease,

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[25] *Id.*, p. 2448.

disorder or conditions (by whatsoever name called) which may be specified in rules under the Act. [26]

In fact the above provision is the heart of the Act. There are many phrases which needs brief explanation. The words "taking part in the publication of any advertisement" includes the printing of any advertisement and the publication of any advertisement outside the territories by a person residing within the territories or at the instance of a person residing within the territory.[27] Hence sending the advertisement outside India is brought within the purview of the provision.

The word 'drug' under this Act means more or less the same as has been stated in the Drugs and Cosmetics Act 1940. It has been held that "machines of science" and "electric treatment" advertised in newspapers having ability to cure nervous diseases were considered as 'articles' within the meaning of section 2(b) (iii) and therefore was considered as a 'drug' for the purpose of the Act.[28] It is to be noted that the word "article" is used in the Act of 1954 in place of and in addition to the word "substance" used in the Act of 1940. The Court held that 'machines of science' whose magically curative properties which were advertised by the appellant were articles intended to influence the organic function of the human body[29].

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[26] *Supra* n.1, section 3.

[27] See *id.*, sub-section (d) of Section 2.

[28] *Zaffar Mohammad v. State of West Benga,l* A.I.R. 1976 S.C. 171 at p.172.

[29] *Ibid.*

The word 'advertisement' is comprehensively defined in section 2(a) of the Act.[30] It includes every form of advertising, whether in a publication, or by display of any notice or by means of any catalogue or price list. It may be a circular or letter or other document. It may be a label which means words inscribed on any wrapper or article. It may be by way of sound recording, sound broadcasting or in any other way. As the purpose of the Act is to prevent objectionable and unethical advertisements in order to discourage self medication and self treatment, the Court held that the definition of advertisement' is not too wide.[31]

The words, "or any other disease or condition which may be specified in the rules made under this Act", according to the Supreme Court are vague. This according to the Court, confer uncanalysed and uncontrolled power to the executive and therefore held *ultra vires*.[32] The Court also held that by taking that part of clause (d) of section 3 out of the Act, it will not affect the constitutionality of the remaining part of the section or the Act.

Under the Act, the following ingredients are required to be present so as to make a person liable:

(i) The accused should have taken part in the publication of an advertisement;

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[30] *Supra* n. 1.

[31] See *Hamdard Dawa Khana V. Union of India*, A.I.R 1960 S.C. 554 at p.565.

[32] *Id.* at p.568.

(ii) that advertisement should relate to or should have reference to a drug;

(iii) that drug is suggested as a cure for any one of the purposes mentioned in sub clauses (a) to (d) of section 3 of the Act.

Since the contravention of the section is punishable under the Act,[33] courts have construed the section strictly. This will be evident from an analysis of the few cases decided under this Act. The Court in one case was very eloquent in making known the objectives of the Act. In *Yashpal Sahi v. Delhi Administration*[34], it stated that "the whole object of the Act is to save ignorant people from being duped to purchase medicines just because their effect is advertised in eloquent terms.[35] But in two other cases it refused to interfere. In *State of Karnataka v. R.M.K Sivasubramany Om*[36] and *S.K. Saini v. Union of India*,[37] the court interpreted the section strictly. It held in the former case that to bring the act of an accused within the mischief of law, all the ingredients of the offence will have to be strictly proved by the prosecution.[38] In the latter case, the court observed that "if some one says that I undertake the treatment of an ailing person by

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[33] See supra n.1, section 7.

[34] A.I.R. 1964 S.C. 784.

[35] *Id.* at p.787

[36] 1978. Cri. L.J. 853.

[37] A.I.R. 1967. Punj. 322.

[38] *Supra* n. 36 at . p.855

scientific methods with the aid of electricity, it can not amount to a suggestion for the use of any drug."[39]

From a casual reading of the section one can understand the legislative policy behind the enactment of the provision. Sub-sections (a) and (c) of section 3 intends to protect the health of women by preventing self medication in serious aspects of their health like miscarriages, use of contraceptives and matters relating to menstrual disorders. This affect the health of the women in a very serious manner. Unfortunately it is in these aspects for which most of the women hesitate to approach the doctor and to even to disclose to their nearest relatives. Advertisements by unscrupulous quacks come handy to such people who will be tempted to self-medication. This reason also holds good even for the purpose mentioned in sub-section (b) of section 3. The common weakness of the human being in such matters is being exploited. In fact there exists no such scientific formula which can improve the capacity of the human being for sexual pleasure.

Sub clause (d) of section 4 prohibits any adverisement suggesting the use of any drug for diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the Schedule. There are 54 diseases specified in the list[40]. From the perusal of the list, it is very clear that all these ailments are of very serious nature. Therefore, the policy of the law is to discourage the people

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[39] *Supra* n. 37 at p.324

[40] See Annexure IV for the list of diseases included in the Shedule.

to use the medicine on their own for treatment of such diseases.. These ailments require the people to approach recognised medical practitioners and take a better advise before using any medicine.

As far as the use medicine for prevention, cure or treatment of any such disease or disorder is concerned, the manufacturers can advertise the same to the medical practitioner or to a pharmacist as per the procedure laid down in the Act and Rules.[41]

The Central Government is empowered to make rules providing the manner of advertisements relating to any drug or article.[42]

Rule 5 lays down the procedure to send such advertisement or documents containing such advertisement[43] Accordingly, such documents containing advertisements

relating to drugs shall be sent by post to registered medical practitioners by name or to a wholesale or retail chemist. Such documents shall bear at the top, printed

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[41] See Drugs and Magic Remedies (Objectionable Advertisement) Act 1954 section 16 and Drugs and Magic Remedies (Objectionable Advertisements) Rule, 1955. Rule 5 . Section 14 reads "Nothing in the Act shall apply to any advertisement relating to any drug sent confidentially in the manner prescribed under section 16 only to a registered medical practioner.

[42] *Id.*, S.16. It reads " The Central Government may by notification in the official Gazette. make rules for carrying out the purposes of the Act. 2) In particular and without prejudice to the generality of the foregoing power, such rules may Prescribe the manner in which advertisements of article or things referred to in clause (c) of Section 14 may be sent confidentially".

[43] See Drugs and Magic Remedies (Objectionable Advertisements) Rules1955, Rule 5 .

in indelible ink in a conspicuous manner, the words "for the use only of registered medical practitioners or a hospital or a laboratory.[44]

Hence, the Act ideally reposes trust on the doctors so that they would prescribe appropriate dose of the right medicine. But studies show that most pharmaceutical advertisements directed at physicians are false or misleading and can cause doctor to prescribe drug improperly, thus endangering patients' health.[45] It was found that virtually every medical journal contains advertisements that violate regulations. Astonishing disclosures were made by the studies.[46] It was found that 92 per cent of the advertisements potentially violated at least one regulation. 38 per cent of advertisements potentially violated at least five regulations. 50 per cent of the advertisements had little or no educational value. 59 per cent would not lead physicians to proper prescribing. 47 per cent of the advertisements that addressed issues of side effects and contra-indications" did not appropriately highlight the side effects.[47]

What makes these findings especially troubling is the fact that many doctors rely on advertisements and handouts of pharmaceutical companies for information about drugs. Whether they should or should not is another aspect.

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[44] *Ibid.*

[45] See *Health letter*, August, 1992.

[46] *Id.*, P.1

[47] *Ibid.*

But when information is false and misleading and swallowed by doctors, patients can be harmed. This happens in spite of the prohibition by the Act.[48]

It clearly provides that "no person shall take any part in the publication of any advertisement relating to a drug if the advertisement contains any matter which –

(a) directly or indirectly gives a false impression regarding true character of the drug; or

(b)makes false claim for the drug; or

(c)is otherwise false or misleading in any material particular".[49]

It is not necessary that there must be some evidence of mischief before prohibiting an advertisement. It is sufficient if in the opinion of the authorities it is likely to mislead or deceive. The tendency of a particular advertisement to mislead is to be determined by the net impression it is likely to make upon the public.

Unfortunately these provisions are considered to be ineffective in controlling false or misleading advertisements. Consumer education through advertisements remained a distant dream and mirage. To meet the growing menace, some provisions were incorporated in the Monopolies and Restrictive Trade Practices Act 1969 and the Consumer Protection Act 1986. Since the

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[48] *Supra* n.1, section 4.

[49] *Ibid.*.

provisions in these two enactments are identical, it may be sufficient to study the provisions in any of these Acts. These provisions are envisaged as an effective means to combat the terrarism of unfair trade practices.

Provisions of MRTP Act dealing with advertisements

MRTP Act was enacted in 1969 with an object to prevent concentration of economic power to the common detriment, for the control of monopolies and restrictive trade practices and for matters connected or incidental to these. Since the present analysis pertains to misleading advertisements, the scope of this part of the study is confined to the aspects of unfair trade practices under MRTP Act and their impact on pharmaceutical product advertisements.

Section 36 A of the Act defines an unfair trade practice [50] to mean a trade practice which adopts any unfair method or deceptice practice for the purpose of promoting the sale or supply of any goods or services. Among other things, these unfair trade practices include the practice of making any statements whether orally or in writing or by visible representation which (1) falsely represents that the goods are of a particular standard, quality, grade, composition, style or model, (2) represents that the goods or services have sponsorship, approval, performance, characteristics, accessaries, uses or benefits which such goods or services do not

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[50] Consumer Protection Act 1986, sub-clause (r) of Section 2(1) also conveys the same meaning as provided under MRTP Act 1969.. This provision was substituted by Consumer Protection (Amendment) Act 1993.

have (3) makes a false or misleading representation concerning the need for, or the usefulness of any goods or services.

Further, section 36 B has empowered the MRTP Commission to enquire into an unfair trade practice upon receiving a complaint of facts which constitutes such practice from any trade association or from any consumer or a registered consumer association whether such consumer is a member of that consumer association or not. It is also empowered to enquire into any such practice upon an application made to it by the Director General or upon its own knowledge or information. Section 36 D provides that the MRTP Commission may enquire into any unfair trade practices which may come before it for enquiry, and, if after such enquiry, it is of the opinion that practice is prejudicial to public interest or in the interest of any consumer or consumers generally, it may pass a cease and desist order directing that the practice shall be discontinued or shall not be repeated.

Under section 12 A of the Act, the Commission is empowered to issue temporary injunction in the course of enquiry into any monopolistic, restrictive or unfair trade practice, restraining the carrying on of such trade practice untill the conclusion of such enquiry, if found prejudicial to public interest or interest of any trader or of consumers generally. Section 12 B of the Act also empowered the MRTP Commission to award compensation on account of any monopolistic, restrictive or unfair trade practices, to the aggrieved person.

Failure to warn

In re *Zandu Pharmaceutical Works Ltd.*[51], the manufacturer of ayurvedic medicine, while advertising its medicine 'Trishun' failed to give the caution that the medicine should be taken under the advice of a physician. Accepting that it was an unfair trade practice, the manufacturer gave the undertaking that in all future advertisements for sale of this product the words, " Read the instruction on the pack carefully before use " would be incorporated.

Again in *re Boots Company Ltd.*[52], the respondent engaged in the manufacture of pharmaceutical products. In its advertisements on TV network it failed to state the warning that 'Coldarin' should not be used by children below 12 years of age, except under medical advise as per the requirements laid down by the Director General of Health Services. Holding it to be an unfair trade practice, the Commission disposed of the case on the basis of an undertaking given by the respondent.

Unsubstantiated claims

If a company producing a drug makes an advertisement consisting of certain claim of cure, it must be in a position to substantiate the same with the scientific data available with them. Otherwise such claim can be called as misleading or false claims covered by the sweep of unfair trade practices. The

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[51] UTP Enquiry No. 164/1986, Order dated 14-6-1988.

[52] UTP Enquiry No 401/1987, Order dated 17-11-1988.

basis for the orders passed by the Commission in most of the cases decided by it appeared to be the principle enunciated in the United States in a celebrated case *Charles of the Ritz Distributor Corp. v. FTC*[53]. Facts of this case are very interesting. In this case there was a petetion to review a cease and desist order issued pursuant to a complaint charging the petitioner with having violated Section 5 of the FTC Act (U.S) by falsely advertising its cosmetic preparation by name 'Charles of Ritz Rajuvenescence cream'. The advertisement typically referred to 'a vital organic ingredient' and certain 'essences and compounds' which Rajuvenescence cream allegedly contained and stated that the preparation brings to the user's skin quickly " the clear radiance... the petal-like quality texture of youth" and that it "restores natural moisture necessary for a live, healthy skin", with the result that "your face need know no draught years" and that it gives to the skin "a bloom which is wonderfully rejuvenating" and is constantly "active in keeping your skin clean, radiant and young looking".

The Commission found that such advertising falsely represented that Rejuvenescence cream would rejuvenate and restore youth or the appearance of the age of the user. It, therefore, ordered petetioner to cease and desist disseminating in commerce any advertisement of Charles of the Ritz Rajuvenescence cream in which the word "Rejuvenescence' or any other word or

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[53] (1944) U.S. Court of Appeal, Second Circuit, 143 f 2d 676, quoted in Mc Call, *Consumer Protections: Cases, Notes and Materials*, West Publishing Co. (1997), p.166.

term of similar import or meaning is used to designate, describe or refer to the petetioner's cosmetic preparation. FTC also ordered to desist from advertising the product in a manner in which it represents directly or by inference that the said product will rejuvenate the skin of the user. Regarding the non production of evidence of consumers actual deceit by such advertisement the Court held that it did not make the order improper, since actual deception of the public need not be shown in Federal Trade Commission proceedings. Representation merely having a 'capacity to deceive' are unlawful[54].

Similarly in *re Dr. Yadgir*,[55] the respondent gave various advertisements claiming that white patches appearing on the body of the person could be cured by his medicine and said that the treatment was so effective that the patches start fading from the very commencement of the treatment. According to medical opinion obtained by the Commission such claims were false and as such constituted unfair trade practice. The enquiry was concluded on the respondent agreeing to modify the advertisement in future which would merely indicate the possibility of treatment being successful.

In yet another case *re Manne Quin's*,[56] the respondent and manufacturer and seller of hair massage oil, in advertisement for promoting the sale of its product made tall claims that it's formulation is 'world famous' and has been

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[54] *Id.*, p.169

[55] UTP Enquiry No 1/1989. Order dated 31-12-1990.

[56] UTP Enquiry No 167/1986. Order dated 20-7-1989.

introduced for the first time in India and its use prevents hair loss. It also claimed that it contains several imported ingredients and damaged hair would come back to life again with the use of this formulation. The Commission passed a cease and desist order by holding that theclaim that the product is world famous because its ingredients are the same as used worldwide and in all western countries, is baseless in as much as the expression 'world famous' rightly speaking signifies that the product is wellknown through out the world. The Commission also said that the claim that the product has been introduced for the first time in India is not justified in the absence of any market survey or other evidence in this regard. With respect to the claim that hair got strength and electricity with the use of the formulation, the Commsion held the view that it only means that live hair and not the dead one get the strength and hence the claim that damaged hair come back to life is again false.

Any claim of clinical superiority over the existing drugs for similar ailments, if unsubstantiated, the Commission may hold that such claim is misleading and therefore unfair. In *re Burrough Welcome (India) Ltd.*,[57] the respondent was manufacturing and marketting a medicine under the name of 'Ridake Paracetamol Tablets' for clearing headaches. In the advertisements issued by it, it was claimed that this medicine was the safest way to clear headaches and did not have the side effects as in the case of Aspirin, which

[57] UTP Enquiry No. 78/1986. Order dated 28-11-1986.

caused erosive gastritis with occult and overt gastro intestinal bleedings and gastric ulcer. It was contended that it is based on an editorial which appeared in the British Medical Journal known as 'The Lancet', reproduced in Deccan Herald. Against the respondent, it was alleged that while suppressing the view expressed in the said juornal that paracetamol adversely affected liver, attract clause (1) of Section 36 A. It was also alleged that he is guilty of disparaging 'Aspirin' regarding its side effects and extolling the quality of 'Ridake'. The Commission held that the impugned trade practice was unfair and ordered the respondent not to include the same in future.

At the same time the Commission in re *Hamdard Wakf Laboratories*,[58] held that a claim about efficacy and usefulness of a product which is based on actual research work is not an unfair trade practice. But contrary to the sequence of decisions in all the above cases the Commission insisted the proof of injury to restrain an otherwise unfair trade practice in re *Glaxo Laboratories (P) Ltd.*[59]. In this case the allegation was that Glaxo marketed a drug "phexin" manufactured by Capsulation, showing logo of Glaxo prominently on the packing strip and name of Capsulation written in small print , thereby giving the impression that 'phexin' was manufactured by Glaxo. In the course of enguiry it was brought out that the said drug was being manufactured and packed by Capsulation on the basis

[58] UTP Enquiry No. 194/1986. Order dated 11-3-1987.

[59] UTP Enquiry No. 22/1985. Order dated 20-10-1987.

of technical knowhow supplied by Glaxo and under its supervision as per its quality control standard. The Commission therefore held that the said practice was not unfair practice. It was also brought to the notice during the enquiry that the price of the drug compared well with similar products manufactured and marketed by other leading pharmaceutical manufacturers. The commission held that the ingredient of loss of injury being absent, eventhough the impugned practice may fall under one or more clauses of Section 36 A of the Act, it was not an unfair trade practice.

In re *Indo-German Pharmaceuticals*,[60] the enquiry before the Commission was relating to an advertisement about medicine named "Energy Forte". A claim was made that it cured many diseases including sex disorders. The Commission held that the advertisement merely indicated that the medicine was useful for improving vigour and vitality and there was no claim for cure of such disorder. The Commission observed,

> "It is generally known that the contents of this medicine "Energy forte" according to the Ayurvedic system of treatment, do have tonic value and Ayurvedic physicians freely prescribe these drugs for curing physical and mental weakness. It is needless to say that one's sexual potency, by and large, will depend upon physical health. Therefore, so far as the efficacy of the medicine, in the

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[60] (1987) 61 Comp. cases 432 quoted in S.M.Dugar, *Law of Monopolistic Restrictive & Unfair Trade Practices*, Wadhwa Co., Nagpur, (1997) at p.407.

treatment of ailments, it is generally prescribed for, is concerned, there cannot be any misrepresentation."[61]

A more deceptive trade practice was noticed by the Commission in an enquiry in re *Iveon Laboratories.*[62] In this case a company producing a particular bottle of medicine gave a make-belief advertisemt showing on the label that the medicine was prepared with 'knowhow' of a foreign company. The Commission passed a cease and desist order with an observation that simply because the medicine in question had been packed with the help of the machine purchased from M/s Rommelog Switzerland, it will not enable the respondent in any way to represent that there was an association with the foreign company in the formulation. Such an assertion on the label of the medicine would definitely mislead the consuming public into believing that there is a technical collaboration with the Switzerland company for the manufacture of medicine, while the fact is that the medicine has simply packed in the bottle with the help of a machine manufactured by the foreiwgn company. There is a clear distinction between the contents, that is, medicine and the container that is bottle. The respondent had got nothing to do with the medicine , i.e. the contents. As such it is deliberate misrepresentation to make the consumer get erroneous impression about the knowhow.

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[61] *Id.*, p.408.

[62] UTP Enquiry No. 141/1986, Order dated 23-2-1990.

In some of these cases respondents deserved to be prosecuted under the provisions of the Drugs and Magic Remedies (Obligationable Advertisement) Act 1954 and the rules framed under it. For example in *re Bengal : Dawakhana, Faridabad Delhi*,[63] the respondent advertised offering medicines and treatment with miraculous effects. Such advertisements are prohibited by the provisions of the Drugs and Magic Remedies (Obligationable Advertisements) Act 1954 for averting or reducing the risk of injury to the person using the medicine. As the respondent did not comply with the standards prescribed by the competent authority, it was held to be unfair trade practice by the Commission and on an undertaking given by the respondent, the case was disposed under section 36 D (2) of MRTP Act. When the Commission noticed during its enquiry that the respondent violated the penal provisions of the Drugs and Magic Remedies (Objectionable Advertisement) Act 1954, it ought to have reported the matter for prosecution. Leaving the respondent on the basis of an undertaking may not be justified in the circumstances.

These are few casess decided under MRTP Act available in India to explain the meaning as to what constitute unfair trade practice and misleading advertisement in this area. There are also few decisions of the U.S. Courts in this context which have set the standards. In U.S., as in India, there are separate regulations for advertisements of drugs sold without prescription and drugs to be

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[63] UTP Enquiry No. 238/1988 Order dated 26-4-1988.

sold with prescription. The drugs sold without prescription are also called "over the counter" drugs and are regulated by the Federal Trade Commission (FTC). The drugs sold with prescription are called prescription drugs and are regulated by the Food and Drug Administration (FDA)[64] In *Thompson Medical Company, Inc. v. Federal Trade Commission,*[65] a complaint was brought by F.T.C. against Thomson Medical Company alleging that the company's advertisement for 'Aspercreme', a tropical analgesic was false and misleading. The Commission ordered Thompson to refrain from making unsubstantiated claims and to disclose in the product's labelling and advertising that it does not contain aspirin. The company challenged the order on the ground that it was arbitrary and not substantiated by evidence. 'Aspercreme' is supposed to help arthritis victims and others who seek relief from minor aches and pains. As the name suggests, 'Aspercreme' is a creme meant to be rubbed on the area where analgesic effect is desired. Despite its name, however, 'Aspercreme' contains no aspirin. Rather its active ingredient is some other chemical. But company's advertisement of Aspercreme strongly suggested that Aspercreme and aspirin were some how related. The television advertisement used by the company was alleged to have the following monologue:

> "When you suffer from arthritis, imagine putting the strong relief of aspirin right where you hurt.

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[64] Federal Food, Drug, and Cosmetic Act 1938, section 502(n).

[65] 1986-1 *Trade Cases* 62, 671.

> Aspercreme is an adoreless rub which concentrates the relief of aspirin. When you take regular aspirin, it goes throughout your body like this. But, in seconds, Aspercreme starts concentrating all the temporary relief of two aspirin directly at the point of minor arthritis pain... [Voice over]. Aspercreme. The strong relief of aspirin right where you hurt."[66]

According to the complainant in this and similar advertisements, the announcer was shown holding aspirin tablets at the beginning of her monologue and when she spoke the aspirin was replaced by a tube of Aspercreme.

Court refused to interfere on the finding of the FTC that the advertisement contained misrepresentation when it claimed that something was existing which it did not contain. The court refused to accept the assertion that Commission order would destroy its business, and was tantamount to an order to cease selling Aspercreme. The Court observed,

> "FTC's order did not bar the sale of Aspercreme forever and under all circumstances. Indeed, the sale of Aspercreme was not barred at all. Only misleading advertising was prohibited. If Thompson does come up with new clinical studies,..... it would be free to continue to make such efficacy claims in its Aspercreme ads. In the interim, it is free to advertise as long as it does not make false or misleading representation..... "Allowing such advertisements because to stop

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[66] *Id.*, p. 62, 672.

would hurt the firm's economic interest is obviously not part of the calculus of interests Congress intended the FTC to consider."[67]

Hence company's petition for review of FTC's order was denied.

In another case[68], a manufacturer of a brand-name prescription drug containing the active ingredient propranolol sent a letter to a number of pharmacists throughout the U.S. warning them not to substitute generic version of the drug for the brand name item, if the pharmacist did not know the reason for the prescription. The letter also claimed that the brand-name drug was the only one approved by the FDA for the treatment of post-myocardial infraction. This claim was false because there were other drugs approved by FDA for the same treatment. The court held that it was a misleading advertisement but did not amount to anti-competitive conduct and was not deceptive as a matter of law because the letter fairly stated that the issues discussed in it were open ones and that the views expressed were its own. But court answered the question whether a commercial party has a reasonable interest to be protected against the alleged false advertising negatively. In this case the petitioners were rival manufacturers of similar drug. The Court held that "the plaintiffs do not have a reasonable

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[67] *Id.*, p. 62, 676.

[68] *The National Association of Pharmaceutical Manufacture, Inc., and Zenith Laboratories, Inc. v. Ayerst Laboratories*, 1987-1, Trade Cases, 60, 444.

interest to be protected and therefore do not have a standing to bring this action."[69]

Most common misleading claims are relating to the medicinal capacities to reduce weight without diet. One such case was brought to the notice of F.T.C., where a doctor engaged in a deceptive practice in connection with sale of "Fat Magnet" diet pills, which were falsely advertised as capable of helping the users lose weight without diet or exercise. The judgement permanently enjoined on Dr.Shell from making unsubstantiated claims regarding the performance, efficacy or safety of any weight control food or, drug or device he markets to consumers. He was also required to pay Rs. 20,000 for consumer redress[70].

Provisions dealing with labelling of packages of drugs

Labelling is an advertisement as per definition of advertisement[71]. Perhaps the dissemination of information aspect is taken care of by the provisions dealing with labelling of packages of medicines. The law provides that no drug can be sold without being properly labelled[72]. The manner of labelling is also provided in the law[73]. It is intended to ensure the publication of all the information to ensure safety and efficacy of the drug when it is used by the

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[69] *Id.* at 60, 450.

[70] Reffered in S.M. Dugar, *Law of Monopolistic Restrictive & Unfair Trade Practices*, Wadhawa & Co., Nagpur (Third Edition, 1997) at p. 413.

[71] See *supra* n.1, section 2 (a)

[72] Druga and Cosmetics Rules 1945, Rule 95

[73] *Id.*, Rule 96.

consumer. The contents to be included in labelling is clearly indicative of the purpose in this regard.

The law insists that for certain drugs only the 'proper name' of the drug should be printed on the label in a more conspicious manner than the trade name[74]. The proper name generally means a name which is in the Indian Pharmaceopocia or any other recognised pharmacoepocia or National Formulary of India or any non-properietary name published by the World Health Organisation. Proprietary name or trade name means words indicating a particular manufacturer. All new drugs and drugs provided in Shedule 'W' must bear only proper name and not trade name[75].

Apart from the name, the label must bear clear description of the pharmaceutical form of the product. It should contain the list of active and non-active ingredients and the quantities of each. The quantity of the product in a container i.e. the net weight, or measure, except in certain special cases where a dosage is permitted instead of the actual statement of quantity should be expressed on the label[76]. It should also contain proper directions for use and a statement of warnings or special directions as prescribed by the product licence and a statement about any special conditions for the safe handling or storage of the medicine.

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[74] *Id.*,Rule 96 (i) A.

[75] *Id.*, Rule 96 (i) B.

[76] *Id.*, Rule 96 (iii).

Other contents to be incorporated include the name and address of the product licence holder and his product licence number preceded by the letters 'PL', a 'batch reference' so that the particular container can be clearly identified as to source date and time of the manufacture. The manufacturer's licence number preceded by letters 'ML' must be printed on the inner most container[77]. The date of expiry of potency prescribed by the manufacturer is to be included in the label. If the drug is intended for distribution to the medical profession as a free sample, it should further bear the words, 'physicians sample - not to be sold' on the container.

Container of a prescription medicine for internal use should conspicuously display the warning that it should be sold by retail only on the prescription of a Registered Medical Practitioner[78]. In the case of any ointments it must be labelled with words in capital 'for External use only'. The container of a medicine made up for treatment of animal should be labelled conspicuously with words 'Not for human use; for animal treatment only ' and should bear a symbol depicting the head of a domestic animal[79].

Any shop keeper who sells a medicinal product which contravenes these regulations is criminally liable. But he can show that the product was in the same

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[77] *Id.*, Rule 96 (iv) (v) & (vi).

[78] *Id.*, Rule 97.

[79] *Id.*, Rule 97 (3).

state when it was sold to him and he had no reason to believe that there was any wrong with it. Then the proceedings could be launched against the manufacturer.

There was a move to make it a statutory requirement for insertion of package inserts in consumer packs of medicine which was opposed by the manufacturers of medicine[80]. A package insert gives information of the description of the product, its composition, indications, contraindication, adverse reactions, drug interaction, dosage and administration. It was opposed on the ground that it is highly labour intensive and time consuming. In addition to this, in a multi-lingual country like India, when major companies are selling medicines in different parts of the country they are bound to face the language probelm if they have to prepare package inserts by keeping every user in view. Another basic problem would be cost of package inserts. If the manufacturers are insisted to use package inserts for the purpose of every user of medicine, they may comply with the requirement if they are allowed to recover the cost by including the expenses of package inserts in the conversion costs. Therefore, ultimately it is a cost-benefit analysis from the point of view of the consumer.

The scope of misleading information in pharmaceutical advertisement is so broad that it is beyond the capability of authorities to correct without substantial new funding for enforcement. There is an answer in the Canadian experiment to

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[80] See *Financial Express*, April 13, 1989.

the drug advertising critics.[81] In Canada, its pharmaceutical Advertising Advisory Board must approve in advance all advertisements and direct mail to physicians and other health providers. The board is made up of representatives of medical journals, physicians, consumer groups and pharmaceutical and advertising industries. The Canadian FDA has an ex-officio member on the board to ensure that the members carry out their responsibilities properly. The pharmaceutical companies are charged a fee for each advertisement submitted for review and so there is no cost to the Government.[82]

There is every need to create such an authority in India and confer it with statutory status which can review and approve all prescription drug advertisement before mailing it to physicians and pharmacists. It must be an independent body so that it can take impartial and balanced decisions. By reviewing prescription drug advertisements before they get to readers, such body could keep misleading information out of the hands of doctors and consumers and prevent false claims causing irreversible harm to patients and their families.

The provisions of the Act and rules are commendable but in the absence of an enforcing body there is little protection to the consumer. Many cases can be noted in the daily newspapers and in other media in which these provisions are grossly violated but the advertisers and the media go scot free. Most deplorable is

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[81] See *Health letter*, August 1992, p. 2.

[82] *Ibid.*

the fact that these advertisements appear in reputed papers with very wide circulation and are placed by well known manufacturers. What all this means is that protection is left to the gullible consumer to protect himself against this menace.

Chapter VIII

REGULATION ON SALE, DISTRIBUTION AND COMPOUNDING OF DRUGS

The sale, purchase, and compounding of medicines are activities subject to regulations by the State to the extent necessary to protect the public health. There is nothing in the Drugs and Cosmetics Act 1940 and the rules framed under it to curtail the exercise of the power by the State to regulate the sale or compounding of medicines. Rather, law gives wide powers to the State administration to regulate these activities in the interest of the public. The power of the State to regulate the distribution of medicines is not only restricted to substances that are inherently dangerous but also extends to all drugs including those patently harmless. But the extent of regulation may vary depending upon the degree of its dangerous nature. The patent, proprietary medicines are thus subject to regulation and it is considered to be a valid exercise of power.

The Act is based on the premise that the drugs are not like ordinary commodities whose sale can take place anywhere or can be effected by any person and be left to the ordinary commercial pressures of the market. Though criminal sanctions are also envisaged, the general framework for controlling sale and distribution is a system of statutory licensing administered by a body constituted under the rules. The justification for insisting on the license with regard to sales and distribution of drugs is that special care is needed because of the revolutionary

changes that are taking place in modern drugs and because of the possibility that they could have dangerous properties or dangerous side effects. In fact such possibility was made real in the Thalidomide tragedy.[1] An additional factor of course is that the consumers are in a very vulnerable position of having no choice to exercise when it comes to prescribed drugs for they simply rely on their medical practitioners.

The licensing procedure and the conditions to be imposed before granting any licence on any application for sale and distribution of drugs is analysed in this context. Under the rules, drugs are now divided into various categories (1) those which may be sold only from registered pharmacies under the supervision of a qualified person and upon the prescription of medical practitioners and (2) those without supervision of a qualified person with reasonable safety. This categorization was considered necessary because special care and precaution is required where there is more toxicity hazard in respect of some drugs and where the hazards to health and risk of misuse are minimal and the need to take special precaution in handling is small in respect of some other drugs.

The civil liability of druggist in case of his negligence or breach of duty is also discussed here with the support of case law available from common law countries.

The law intends multiple controls on the drugs. They include prohibition on sale of any drug which is not of standard quality. Even exhibiting or offering for sale of a misbranded, adulterated or spurious drug comes under prohibited activity.[2] As

[1] For a detailed discussion of this aspect see Chapter V *supra*.

[2] See *ibid*.

part of regulatory measures, dealing with the drugs is permitted under certain conditions. This may include certain general conditions like proper labelling before the sale of any medicine or drug.[3] The other means of control is by way of administrative control like licencing. Under the regulatory system of drugs control, one can sell or stock or exhibit for sale or distribute any drug only under licence[4]. It is necessary to understand the meaning of the words 'sale', stock and 'distribute' before dealing with the licensing system.

The meaning of 'sale' and 'offer for sale':-

To constitute sale for the purpose of the Drugs and Cosmetics Act 1940, it must be for human consumption or use. It may be a whole sale or retail[5]. It may include sale for cash or on credit or an agreement for sale. Though an agreement for sale is conceptually distinct from actual sale, an agreement for sale is was also made penal. In the sale, property in the goods passes to the buyer immediately where as in the 'agreement to sell', transfer of property is conditional. In an offer for sale only

[3] See Chapter VII *supra* .

[4] Drugs and Cosmetics Act 1940 Section 18(c). It reads: "18. Prohibition of manufacture and sale of certain drugs and cosmetics - From such date as may be fixed by the State government by notification in the Official Gazette in this behalf, no person shall himself or by any other person on his behalf -

....

(c) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic, except under, and in accordance with the conditions of, a licence issued for such purpose under this chapter."

[5] Sale of Goods Act 1930 Sec 4 (1),(3)& (4) clearly brings out its meaning. The sectionruns as follows :-

"(1) A contract of sale of goods is a contract by seller to transfer or agrees to transfer the property in the goods to the buyer for price.....

(3) where under the contract of sale the property in the goods is transferred from seller to buyer, the contract is called a sale, but where the transfer of the property in the goods is to take place at a future time or subject to some condition there after to be fulfilled, the contract is called an agreement to sell.

(4) An agreement to sell becomes a sale when the time lapses or the conditions are fulfilled subject to which the property in goods is to be transferred."

one of the two ingredients which go to constitute a contract or agreement is present. The other ingredient being acceptance is absent. An agreement is bilateral whereas an offer is unilateral affair. But under the Drugs and Cosmetics Act, mere exposure for sale is covered. Hence distinction between these phrases has lost its relevance.

Meaning of `Stock for Sale':-

This phrase 'stock for sale' has been extensively used in the Act and the rules framed under it[6]. These provisions do not use the word in any technical sense. The plain meaning, of the word 'stock' in these provisions is 'to keep'. The injunction of the law is that no person should keep for sale a drug in contravention of the Act. It is not necessary that the drug should be stored in a place in order that it can be said to have been stocked for sale. If any one keeps or carries a drug on his person in contravention of the terms of the Act and if it is proved that the drug is kept or carried for sale, the act must fall within the ambit of law under consideration. The Supreme Court in *S.K. Amir v. The State of Maharashtra*[7], discussed the meaning of the world 'stock for sale'. The brief facts of this case were that the appellant obtained a delivery of a parcel. The parcel was found to contains 95,000 capsules of Seco Barbital Sodium which is sedative agent and is commonly used for intoxication. He was apprehended by police and tried under the Drugs and Cosmetics Act 1940, on the charge that he had 'stocked for sale' a misbranded drug and that he had no licence for stocking the drug for sale.

6. See Drugs and Cosmetics Act, 1940 Ss. 18(a), 18(c) and 27(a) and the rules framed under these provisions.

7. A.I.R. 1974 S.C. 467

It was urged before the court on behalf of the accused that the fact that the drug was found on the person of the appellant was not enough to establish that he had stocked the drug. The court said,

> "In busy commercial cities, streets are crowded with mobile hawkers who display their wares on their person. It is neither sound common sense nor sound law to say that such wares are not 'stocked for sale'. What is intended for sale can as much be stocked on one's person or in a shop or in a godown. 'Keeping' for sale is of the essence of the matter, not the mode of and manner of keeping. To keep for sale is to stock for sale."[8]

Again in *Mohd. Shabbir v. State of Maharashtra*,[9] the Supreme Court got the opportunity to interpret these words. In this case the Drugs Inspector found the appellant in a railway station with 17 plastic containers containing 17,000 white coloured tablets. Samples of the tables were sent to public analyst and after receiving his report the complaint was filed. The issue before the court was when a person is in the possession of tablets of a very huge quantity, a presumption can be drawn that they were meant for sale or for distribution. The court interpreted the words by saying that the absence of any comma after the word 'stocks' clearly indicated that the clause "stocks or exhibits for sale" is one indivisible whole and it contemplated not merely stocking the drugs but stocking the drugs for the purpose of sale and unless all the ingredients are satisfied the Act would not be attracted. The court found that there was no evidence to show that the appellant had either got these tablets for sale or

[8] *Id.* at p. 470.
[9] A.I.R. 1979 S.C. 564

was selling them or had stocked them for sale. In the opinion of the Court before a person was to be made liable for prosecution under these provisions "it must be proved by the prosecution affirmatively that he was manufacturing the drugs for sale or was selling the same or has stocked them or exhibited the articles for sale. The possession simplicit of the articles does not appear to be punishable under any of the provisions"[10]

It may be stated that the interpretation of the Court was very narrow. What is required in such cases is the broader interpretation by keeping in view the objectives of the legislation. Hence, the interpretation, by presuming that the drugs in possession especially of such large quantity, as in this case, were meant for sale or distribution would have been a reasonable interpretation.

In *Khasim Bhai v. State*,[11] eight tubes of date expired pencillin ointment were recovered from the shop. The court held that there was nothing in the statement or evidence produced to show that those tubes kept in the shop were not for the purpose of sale but for any other purpose. Hence the court presumed that they are stocked for sale. In yet another case Supreme Court appeared to have given a wider meaning to these words by keeping the legislative intention in mind. In *Swantraj v. State of Maharashtra*,[12] the petitioners were whole sale dealers having licence to stock drugs at Bombay and were having further licence to distribute the drugs through the motor van throughout the territory of the State of Maharashtra. But one of the partners of the petitioner released the goods from the transport operator at a place called Yeotmal

[10] *Id.* at p. 566
[11] A.I.R.1956 All. 703
[12] A.I.R.1974 S.C. 517

and temporarily kept them in the godown of a local dealer. The petitioner claimed that they intend to load the van subsequently with those drugs and distribute the drugs as permitted by the licence.

The question before the Supreme Court was whether the act of the appellant in temporarily storing drugs, not for immediate sale there but intended for ultimate sale in various parts of the State, was contrary to section 18(c). Interpreting the provision Krishna Iyer, J., laid down the law as:

> "If any godown, depot or premises become the nidus of spurious, time expired or unscientifically stored drugs, can they be allowed to escape the coils of the penal law on the plea that they are not to be sold *there*, without great peril to patients? Then legal shelter for spurious drug rackets would be judicially ensured. And this colours construction. Stocked for sale there and then? or to be sold certainly but elsewhere later? are the two alternatives flowing from the language of section 18(c). The former permits abuse through loopholes, the latter tightens up but loads the dealer with expenses and need for more licences. Since risk to life and health is avoided by the latter interpretation, we hold that the storage, even through for short spell and on ad hoc basis and without intent to sell at that place but as part of the sales business, comes within the scope of the 'storage for sale' in section 18(c) and rule 62. To loosen the law in its joints is to play with life and therefore anti-humanistic"[13].

[13] *Id.* at p.520

Meaning of distribution:-

Distribution means the act of dealing out to others or dispensation. The word distribution has not been defined under the Act. According to dictionary it means delivery of something to several persons. Several meanings have been given to the word distribution in various dictionaries. Accordingly it means to divide among several or many, to deal out a portion or allot, spread out as a cover, a surface or space, or to divide or separate especially into classes, orders, kinds. According to Lexicon of Law, distribute means the act of spreading of goods anywhere by whatever means that may be employed.

In *State v. Nathumal Damumal,*[14] the word 'distribution' has been interpreted while deciding a case under this Act. A person who was trading at Nasik, purchased certain drugs from Calcutta and transported them to Nasik. Those drugs were not found to be of standard quality by the Drugs Inspector, and prosecution was launched at Nasik. A point was taken in course of trial at Nasik that the purchase was made at Calcutta and therefore, the court at Nasik had no jurisdiction. It was held that "the word distribute was wide enough to include the repose of goods at Nasik even though the sale was completed at Calcutta"[15]. It was further held that the process of distribution started at Calcutta and ended at Nasik[16].

The ordinary and general meaning of the word 'distribute' conveys spreading of the goods any where by whatever means that may be employed.

[14] A.I.R. 1962 Bom. 21
[15] *Id.* at p23
[16] *Ibid.*

Conditions to be satisfied before a licence is granted:-

1. Application for licences in prescribed forms:-

An application in the prescribed form[17] accompanied by a prescribed fee should be made to the licensing authority appointed by the state government. for the grant or renewal of a licence to sell, stock or exhibit for sale or distribute drugs[18]. The form prescribed varies depending upon the various categories of drugs for which licence is sought[19]. The licencing authority may delegate the power to sign licence to any person under his control with prior approval of the state government[20]. If the drugs are sold or stocked for sale at more than one place, seperate application form should be made and a seperate licence must be obtained in respect of each place[21]. But for the itinerant vendors who have no specified place of business and who will be licensed to conduct business in a particular area within the jurisdiction of the licensing authority the above provision is not applicable.

Restricted Licences:-

In respect of drugs whose sale does not require supervision of a qualified person, the licensing authority can issue the restricted license to dealers or firms in a separately prescribed form.[22]

[17] See Forms 19 to 21CC in Schedule A for prescribed form through which an application can be made. Form and fees vary depending upon the category of drugs for sale of which the applicant in seeking licence.

[18] See Drugs and Cosmetics Rules, 1945 Rule 59.

[19] See *id.*, Rule 61 to 63B

[20] See *id.*, Rule 60

[21] See *id.*, Rule 62

[22] Drugs and Cosmetics Rules 1945, Form 20A and Form 21A under Rule 62A, (a) in Schedule - A. Also see section 51 and orders under the Medicines Act 1968 (England) for similar provisions. In England these drugs are specified in the general sale list which can be sold through the automatic machine without the supervision of a qualified person.

In exceptional circumstances licences may be issued for bonafide travelling agents or firms dealing in drugs or for vendor who purchases drugs from a licensed dealer for distribution in sparsely populated rural areas where other channels of distribution of drugs are not available. The restricted licence may also be issued to a travelling agent of a firm for the specific purpose of distribution of samples of biological and other special products specified in schedule C to medical practitioners or dealers[23]. But the travelling agents of licensed manufactures, agents of such manufactures and importers of drugs are exempted from taking licence if they are distributing samples of medicines among members of the medical profession, hospitals, dispensaries and the medical institutions or research institutions[24].

Such of these restricted licences will be granted by the authority only if it is satisfied that the premises in respect of which the licence is to be granted are adequate and equipped with proper storage accommodation for preserving the properties of drugs to which the licence apply[25]. The authority granting such licence is also empowered to take into account the number of licences already granted in that locality within one year immediately preceding and the occupation, trade or business carried on by such applicant before granting licence. The licencing authority may refuse to grant or renew the licence in respect of persons who are convicted for any offence under the Act or rules or the authority is of the opinion that the applicant is not a fit person to whom such licence should be granted[26].

[23] See *id.*, Rule 62A (c)
[24] See *id.*, proviso to Rule 62A (c)
[25] See *id.*, Rule 62B(1)
[26] See *id.*, proviso to Rule 62B(2)

3. Licence other than restricted licence.

A licence other than a restricted licence to sell, stock are exhibit for sale or distribute drugs can not be granted to a person unless the licensing authority is satisfied that the premises are in-charge of a person competent, in the opinion of the licencing authority, to supervise and control the sale, distribution and preservation of drugs. The premises in respect of which the licence is to be granted must be adequate and equipped with proper storage accommodation for preserving the properties of the drugs to which licence applies.[27]. But in the case of pharmacy license, the same can not be granted unless the authority is satisfied that the requirements prescribed for a pharmacy[28] have been complied with. Same requirements are made applicable to a chemist and druggist.

4. Pharmacy licence:-

Pharmacy here means and includes every store or shop or other place where drugs are dispensed, where prescriptions are compounded or where drugs are prepared. It also includes the place which has displayed upon it a sign bearing the word or words "pharmacy", "pharmacist", "Dispensing chemist" or "pharmaceutical chemist".[29]

In granting licence under rule 64 of the rules the licensing authority must have regard to the average number of licences granted during the period of three years

[27] See *id.*, rule 64
[28] See *id.*, Schedule N
[29] See *id.*, Explanation to Rule 64 (1)

immediately preceding. He must also take note of the occupation, trade or business ordinarily carried on by such applicant during the period of three years immediately preceding.

5. General condition

These conditions[30] are generally imposed by the licensing authority for all licences except licences to dealers in respect of drugs whose sale does not require supervision of a qualified person.

Every drug must be compounded only under the direct or personal supervision of a qualified person. The supply of any drug on the prescription of a registered medical practitioner can be made only by or under the supervision of a qualified person. The supply of any drug on a prescription of a registered medical practitioner must be recorded in a register specially maintained for this purpose. Such register has to contain the particulars like serial number of the entry, the date of supply, the name and address of the prescriber, the name and address of the patient, or the name and address of the owner of the animal if the drug is supplied for veterinary use and the name of the drug or preparation and the quantity and in the case of medicine made up by the licensee, the ingredients and the quantities of it.[31]

In the case of drugs specified in Schedules C or H, the name of the manufacturer of the drug, its batch number and the date of expiry of potency must be recorded before any sale of such drug is made and the signature of the qualified

[30] See *id.*, Rule 65 generally
[31] Rule 65 (3) (1)

person under whose supervision the medicine was supplied is a must. But maintenance of the above register is not required in the case of drugs which are not compounded in the premises and which are supplied from the original containers and when these particulars are already entered in cash or credit memo book. If the medicine is supplied on a prescription on which the medicine has been supplied on previous occasion and entries are made in the prescription register, it is sufficient if the new entry in the register includes a serial number and date of supply, the quantity supplied with a sufficient reference to an earlier entry. Maintenance of such register is also not required for any drugs supplied against prescription under Employees State Insurance Scheme if all the above particulars are given in that prescription and any drug other than that specified in Schedule C or H if it is supplied in the original unopened container of the manufacturer and if the prescription is duly stamped at the time of supply with the name of the supplier and the date on which the supply was made.[32]

The supply by retail of a drug other than one on prescription specified in Schedule C must be recorded in a register maintained for this purpose and it should contain the entries like serial number of the entry, date of supply, the name and address of the purchaser, the name of the drug and quantity of it, the name of the manufacturer, the batch number and the date of expiry of potency and the signature of the person under whose supervision the sale was effected.[33]

[32] *Ibid.*
[33] *Id.*, Rule 65 (4)(1)

6. Records to be maintained by retailer of drugs:-

The retailer is required to maintain the records of purchase of drugs which are intended for sale. Such record must contain the details regarding date of purchase, name and address of the person from whom the drugs are purchased and the number of the relevant licence held by him, the name of the drug, the quantity and the batch number and the name of the manufacturer of drug.[34]

7. Conditions on the supply of drugs by whole sale:-

The supply of a drug by whole sale should be made only against a cash or credit memo bearing the name and address of the licences and his licencee number. The cash memo should cover the particulars relating to date of sale, the name, address of the licencee to whom drugs are sold and his sale licence number. In case of sale to an authority purchasing on behalf of goverment or to a hospital, medical, educational or research institution or a registered medical practitioner for the purpose of supply to his patients, it has to contain the name and address of the authority, institution or the medical practitioner as the case may be. In addition to these particulars, the name of the drug, the quantity and the batch number, and the name of the manufacturer must be mentioned in the cash or credit memo as the case may be.[35]

The copies of cash or credit memo should be preserved as records for a period of three years from the date of the sale of the drug. The licensee should produce for inspection by an inspector all registers and records maintained by him and he

[34] *Id.*, Rule 65(4)
[35] *Id.*, Rule 65(5)(1)to(3)

has to supply all information to the inspector to satisfy him that the provisions of the Act and rules have not been violated. These rules appear to have been intended to ensure that no sale of any drug can be made to a person who is not holding the requisite licence to sell, stock or exhibit or to distribute the drug.

8. Sale on prescription and conditions there to:-

Substances specified in Schedule 'H' or Schedule 'X' should not be sold by retail except in accordance with the prescription of a registered medical practitioner and in the case of substances specified in the Schedule X, the prescription shall be in duplicate. One copy of such prescription must be retained by the licensee for a period of two years[36]. But if such substances are supplied to registered medical practitioners, hospitals, dispensaries and nursing homes, the same can be made against the signed order in writing which has also to be preserved by licensee for a period of two years[37]. For this purpose the prescription must be in writing and be signed by the person giving it with his usual signature and be dated by him. It should also specify the name and address of the person for whose treatment it is given or the name and address of the owner of the animal if the drug is meant for veterinary use. The prescription must also indicate the total amount of medicine to be supplied and dosages to be taken[38].

The person dispensing a prescription containing a drug specified in Schedule H and Schedule X has to comply with further requirement in addition to the above requirements[39]. The prescription must not be dispensed more than once unless the

[36] See *id.*, Rule 65(9)a
[37] See *id.*, Rule 65(9)b
[38] *Id.*, Rule 65(10)
[39] See *Id.*, Rule 65(11)

prescriber has stated on it that it may be dispensed for more than once. If the prescription contains direction that it may be dispensed in a stated number of times or at stated intervals, it must not be dispensed otherwise than in accordance with such directions. Another requirement is that at the time of dispensing prescription it must be noted on the prescription above the signature of the prescriber, the name and address of the seller, and date on which the prescription is dispensed.

It is mandatory that a person should not supply any other preparation whether it contained the same substance or not while dispensing a prescription containing substances specified in Schedule H and X[40]. Substances specified in Schedule X kept in a retail shop or premises must be stored under lock and key in cupboard or drawer reserved solely for the storage of these substances or in a part of the premises separated from the remainder of the premises and to which only responsible persons have access.

9. Description of the premises:-

The licensee who do not require the services of a qualified person should display a description as "drugstore" on the premises. The description "Chemist and Druggist" should be displayed by such licensee who employ the services of a qualified person but who do not maintain a pharmacy for compounding against prescription. The description `pharmacy', `pharmacist' `dispensing chemist' or `pharmaceutical chemist' should be displayed by such licensee who employ the services of qualified

[40] *Id.*, Rule 65(11A)

person and also maintain a pharmacy for compounding against prescription.[41].

For the purpose of this rule qualified person means a person who holds a diploma or degree in pharmacy or pharmaceutical chemistry of an institute approved by the licensing authority[42]. Under these provisions the qualified person also includes a person possessing qualifications to have his name entered in the register but whose name has not been entered because the first register of pharmacist was not prepared at that time and it includes a person who has not less than four years practical experience of dispensing which is in the opinion of the licensing authority adequate and has been approved by that authority as a 'qualified person'[43].

10. Dealing with expired drugs:-

No drug should be sold or stocked by the licensee after the date of expiration of potency recorded on its container, label or wraper, or in violation of any statement or directions recorded in such container, label or wrappers. Date of expiry means the date that is recorded on the container , label or wrapper as the date up to which the substance may be expected to retain potency or not to acquire toxicity greater than that required or permitted by the prescribed test[44].

Where the licensee has taken steps in respect of such drugs with the manufacturer or his representative for the withdrawal, reimbursement or disposal of the same, such drugs may be stocked after the date of expiration of potency pending

[41] *Id.*, Rule 65 (15)

[42] See Pharmacy Act, 1948, Ss.31,32, 32 A & 32 B

[43] See Drugs and Cosmetics Rules., Rule 65(15)(c). It may be noted that these provisions are applicable to those who acquired such qualifications before 31-12-1969.

[44] See *Id.*, Schedule P for life period of various drugs

such withdrawal, reimbursement or disposal. But the same should be stored separately from the trade stocks. All such drugs are to be kept in packages or cartons, the top of which must display prominently, the words 'not for sale'[45].

Hence there is nothing in the rules to make it obligatory upon a licensee to destroy or throw away the stock as soon as it crosses the date of expiry. It was held in *Aftab Ahmad v. State,*[46] that if for claiming rebate from income tax and sales tax departments, the licensee keeps expired date medicines in his stock, due precaution is to be taken so that everybody should know that the same were not intended for sale. Then he can not be said to have committed any offence.

11. Sale of free samples:-

Drugs intended for distribution to the medical profession as free samples which bears a label on the containers or carton or wrappers and drugs meant for consumption under Employees State Insurance Scheme, the Central Government, Health Scheme, the Govt Medical Stores depots, the Armed Forces Medical Stores or other government institutions which bear a distinguishing mark or any inscription on the drug or on the label affixed to the container indicating such purpose should not be sold or stocked by the licensee on his premises. Of course, this rule provided exemption to licensees who have been appointed as approved chemists by the State govt in writing under the ESI scheme for drugs meant for consumption under the scheme[47].

[45] *Id.*, Rule 65(17) proviso
[46] 1978 Cr. L.J. 1333
[47] See Drugs and Cosmetics Rules 1945., Rule 15(18) and proviso

12. Supply of drug in containers:-

The retailer is required to supply the drug only in container through which the manufacturer has marketed the drug. The supply by retail of any drug in a container other than the one in which the manufacturer has marketed the drug is allowed only by dealers who employ the services of a qualified person. Such supply is to be made only under the direct supervision of the qualified person and in an envelope or other suitable wrappers or container showing the name and quantity of the drug supplied and the name and address of the dealer.[48]

13. Sale of Veterinary drug:-

The medicines for treatment of animals kept in a retail shop or premises must be labelled with words clearly stating that these are not for human use but are only meant for treatment of animals. These drugs are to be stored in a cupboard or drawer reserved solely for the storage of veterinary drugs. Otherwise, these medicines are to be kept in a part of the premises separated from the remainder of the premises. Customers should not be permitted to have any access to such premises[49].

14. Seperate Register for supply of Schedule X drugs:-

The supply of drugs specified in Schedule 'X' should be recorded in a register bound and serially numbered and specially maintained for this purpose and seperate pages are be allotted for each drug. It may be noted that all the entries must be made

[48] *Id.*, Rule 65(19).
[49] See *id.*, Rule 65(20)

only at the time of supply of the drug. The particulars to be entered in the register are date of transaction, quantity received, the name and address of the supplier and the number of the relevant licence held by the supplier. Name of the drug, quantity supplied, manufacturer's name, batch number or lot number, name and address of the patient or purchaser, reference number of the prescription against which supplier were made, bill number and date in respect of purchases and supplies made by him, are to be entered in the register in addition to signature of the person under whose supervision the drugs have been supplied[50]. Obviously these stringent conditions are intended to ensure the safety of the consumers because of their toxic content and fatal consequences that may flow out of the misuse of these drugs.

It may be stated that these rules relating to prescription drugs appeared to have been observed more by violation though the authorities claim that their inspectors regularly conduct surprise checks on the retail outlets to monitor these regulations. Consumer associations pointed out that most of the retail outlets do not have the qualified pharmacist to supervise the sales though it is mandatory under law that every chemists shop should have such qualified person. The result, according to them is that drugs which do not fall under 'over the counter' category are being sold freely in the market without prescription. According to them any drug can be purchased over the counter in India without any prescription.[51]

[50] See *id.*, Rule 65 (21) (a) & (b)

[51] See *Indian Express* (Kochi Edn) May 26, 1998 p. 12.

Power to demand information:-

The licensing authority at any time may call for any information from the applicant for licence. It may demand for documentary evidence in respect of the ownership or occupation on rental or other basis of the premises specified in the application for licence. Other details required may include the constitution of the firm or any other relevant matter necessary for the purpose of verifying the correctness of the statements made by the applicant while applying for the license. Similar information may be called even from those who have already been licenced.[52]

Cancellation and suspension of licences:-

The licensing authority may cancel a licence by an order stating the reasons in writing for such cancellation. But before passing such an order the licensee should be given an opportunity to show cause why such an order should not be passed. It may suspend the licence instead of cancellation for such period as it thinks fit. This suspension may be in respect of some of the substances to which the licence relates if in its opinion, the licensee has failed to comply with any of the condition of licence or with any of the provisions of the Act or rules. But where such failure or contravention is in consequence of an act or omission on the part of an agent or employee, the licence can not be cancelled or suspended if the licensee proves to the satisfaction of the licensing authority that the act or omission was not instigated or connived at by him[53]. And it cannot also be cancelled if he or his agent or employee had not been

[52] See Drugs and Cosmetics Rules 1945. Rule 65(A).
[53] See *id.*, Rule 66

guilty of any similar act or omission within twelve months before the date on which the act or omission in question took place. Where his agent or employee had been guilty of any such act of omission, the licensee had no knowledge or could not reasonably have had knowledge of that previous act or omission, action can not be taken against him. Also licence can not be cancelled if the licensee proves to the satisfaction of the authority that he had used due diligence to ensure that the conditions of licence or the provision of the Act or the rules were observed.[54]

Procedure for disposal of drugs in the event of cancellation of licence.

In case a licensee, whose licence has been cancelled, desires to dispose of the drugs in his possession at the premises in respect of which the licence has been cancelled, he can apply in writing to the licensing authority for this purpose. In that case he has to give the particulars as to the name and address of the person to whom the drugs are proposed to be sold or supplied. It must also contain the particulars relating the number of the license which the buyer possess for sale or manufacture and the names of the drugs together with their quantities and batch numbers. It must also contain the particulars relating to the dates of expiry of the drugs proposed to be sold[55]. The licensing authority after examination of the particulars and if necessary, after inspection by an inspector of the premises where the drugs are stocked may grant the necessary permission for their disposal.

[54] *Ibid.*
[55] *Id.*, Rule 66A

Minimum space and facilities required for premises or pharmacy in respect of which license is to be granted :-

Space that is required at the premises where the business is to be carried out depends upon the nature of the business to be carried out by the applicant for licence. If the applicant desires to have both whole sale and retail business in drugs at the same place, obviously the required space for dispensing the drugs must be more. This appears to be evident from the rules.

In respect of application for grant of licence for sale of drugs by whole sale, the licensing authority is to be satisfied that the premises in respect of which a whole sale licence is to be granted are of an area of not less than ten square meters.[56] The same space is required for the grant of licence in sales by retail. But in respect of an application for grant of a licence for both wholesale and retail sales in drugs the licensing authority shall satisfy itself that the premises are of an area for which the licence is sought is not less than fifteen square meters.[57] Perhaps the amended provisions are intended to ensure sufficient space for dispensing the drugs when the applicant is seeking licences for both whole sale and retail sales and also for more variety of drugs at the same premises.

Minimum equipment for the pharmacy:-

The front of a pharmacy should bear an inscription pharmacy. The premises

[56] *Id.*, Second proviso to Rule 64 (2)
[57] Id., Rule 64 (2), see 1997 CCL 95 part III for amendments made to the Rules.

of pharmacy should be separated from rooms for private use. The premises should be well built, dry, well lit and ventilated and of sufficient dimensions to allow the goods in stock, especially the medicaments and poisons to be kept in a clearly visible and appropriate manner . The area of the section to be used as dispensing department should not be less than 6 square meters for one pharmacist with additional two square meters for each additional pharmacist. The hight of the premises is to be at least 2.5 meters[58].

The floor of the pharmacy should be smooth and washable. The walls should be plastered and tiled or oil painted so as to maintain smooth, durable and washable surface devoid of holes, cracks and crevices. The pharmacy must be provided with ample supply of good quality water. The dispensing department should be separated by a barrier to prevent the admission of the public[59]. The furniture and apparatus of a pharmacy is to be adequate for the uses for which they are intended and correspond to the size and requirements of the establishment.

Drugs, chemicals and medicaments should be kept in a room appropriate to their properties and in such special containers to prevent any deterioration of the contents. Drawers and glasses and other containers used for keeping medicaments must be suitable in size and are to be capable of being closed tightly to prevent the entry of dust. Every container should bear a label of appropriate size, easily readable with names of medicaments as given in the pharmacopoeia.[60]

[58] See *id.*, Schedule N and rule 64(1)
[59] *Ibid.*
[60] *Ibid.*

A pharmacy is required to be provided with a dispensing bench the top of which is to be covered with washable and impervious material like stainless steel, laminated or plastic. The pharmacy is also required to be provided with a cupboard with lock and key for the storage of poisons and should be clearly marked with the word "Poisons" in red letters on a white background. Containers of all concentrated solutions should bear special label or marketed with words "to be diluted".

The pharmacy has to be provided with the minimum apparatus and books necessary for making of official preparation and prescriptions. The books on current edition of Indian Pharmacopeia and National Formulary of India along with Drugs and Cosmetics Act and rules and Indian Pharmacy Act should also be provided at the pharmacy. The requirement of this literature at the pharmacy is required obviously to enable the pharmacist to consult these books in case of any doubt relating to compounding of any drugs and to follow the rules scrupulously.

A pharmacy is to be conducted under the continuous personal supervision of a registered pharmacist whose name has to be displayed conspicuously in the premises. The pharmacist should always put on clean white overalls. The premises and fittings of the pharmacy should be properly kept and everything must be in good order and clean. All records and registers are to be maintained in accordance with the laws in force.

Any container taken from the poison cupboard must be replaced there immediately after use and the cupboard is to be locked. The keys of the poison

cupboard are to be kept in personal custody of the responsible person. The medicaments when supplied should have labels conforming to the provisions of laws in force.

It must be noted that the above requirements are subject to modification at the discretion of the licencing authority. If he is of the opinion that it is necessary to relax the above requirements or to impose additional requirements in the circumstances of a particular case and depending upon the drugs dispensed, compounded or prepared by the licensee he can take an appropriate decision. For instance the items like Pill Machine, Pill boxes, and suppository mould are to be provided in the pharmacy only by those who intend to dispense pills or suppositories as the case may be. Anyhow, the decision of the licensing authority in that regard is final.

A critique of the format of licence:-

From the reading of Rule 61 and 62 it is clear that six prescribed forms of licences are available to make applications to sell drugs by retail or whole sale. Of these, three forms are for licences to sell drugs in schedule C and C(1) and other three for licences to sell other drugs by retail or whole sale. Obviously there is no seperate form prescribed to obtain licence to stock or store the drugs for a brief period under circumstances that may necessitate during the course of transit where the drugs are to be taken delivery from railway or other public transport and loading into some other mobile van. If the time gap between taking of delivery from one

vehicle to the other vehicle is more and the goods are to be stored in a godown, the licence obtained for distributing the drugs through vehicle may not be sufficient to the requirements of law. No seperate forms are provided for licences for itinerant vendors for an area who are required to take licences under law. The Supreme Court in *Swantraj v State of Maharashtra*[61] has pointed out that it was a glaring deficiency that when the rules visualized whole sale distribution licences, the forms do not spell out licences for mobile vans or distribution depots which are essential for whole sale distribution system. The Court said,

> "there is no doubt that if a scientific system of overseeing whole sale distribution and viable scheme of protected distribution is to be devised, licences for large and well equipped conveyances and storage depots is desirable, nay necessary[62].

The court also pointed out that storage in transit must also be licenced so that medicines do not suffer in the process. At present no rules take care of transit by road or rail. Actually, cold storage or air conditioned facilities for sensitive medicines are scarce in nationalized and private transport services and the drugs rules do not appear to have taken cognizance of this fact. Therefore, the forms do not provide for storage depots or medical vans for whole sale supplies. The court urged for the legislative intervention by saying,

> "social guilt attaches to legal lacuna, the community being the victim. Arguments in this case have exposed these short falls in

the law and we state them for legislative attention."[63]

In fact the statutory scheme does provide for retail and wholesale sales and storages for sale. It does prescribe forms for itinerant retailers for specified areas. But storage for sale in mobile vans resorted to by wholesalers is not expressly covered by statutory forms. There is also no express power to modify the forms prescribed by the rules or innovate according to need though it is desirable. If the licences are not insisted on for every place or makeshift storage in a far flung area served by wholesaler, it would be unsafe for the people who are susceptible to ailments and who are largely ignorant of health hazards. Then purpose of regulation through licensing will not be a vigilant medical watch over drugs and medicines. The Supreme Court pointed out that "if godowns, temporary stores and depots can remain unlicensed, they escape official attention and can deteriorate into foci of dubious or deceptive drugs harmful to society".[64]

Hence there is a need that every place where storage for sale is made must be licensed. That is to be the plain meaning of section 18(c) in fulfillment of the clear purpose in reasonable defence of the sick and ailing.

Regulations for collection, storage and supply of blood:-

Blood is treated as a 'drug' under the Act[65]. Blood is an essential component

[63] *Ibid.*

[64] *Id.* at 3520

[65] See Drugs and Cosmetic Rules 1945, Part XII B. It may be noted that blood was not defined under rules as drug. As it was brought under the controlling provisions, it may be treated on par with drugs for all purpuses of its collection, manufacture, storage and supply

of the body which provides sustenance to life. There can be no greater service to humanity than to offer one's blood to save the life of other fellow human being. At the same time instead of saving life can also lead to the death of the person to whom the blood is given if it is contaminated. As a result of the developments in medical science, it is possible to preserve and store blood after it has been collected so that it can be made available in case of need. There are blood banks which undertake the task of collecting, testing and storing the whole blood and its compounds and make the same available when needed.

In view of the dangers inherent in supply of contaminated blood it is necessary to ensure that the blood that is made available for use is healthy and free from infection. Hence, in the Drugs and Cosmetics Rules, provision regarding equipment and supplies required for a blood bank were made[66]. In these rules, requirement regarding equipment, blood collection, supplies, canter equipment and emergency equipment for the blood donor room were prescribed . Similarly provisions were made for the laboratory, general supplies, technical staff, accommodation for blood bank, label for whole blood and colour scheme for label. These rules have been revised to govern the licensing operation of the blood banks also.[67] These rules prescribe the requirements for collection, storage, processing and distribution of human blood and human blood components by blood banks. The manufacture of blood products are also regulated. The procedure for granting and of renewal of licence for the operation of the blood bank is also prescribed. Under the provisions,

[66] *Ibid.*
[67] Id., Rules 122F to 122P inserted by notification in 1993

licence can be granted or renewed only with the approval of the Central Licence Approving Authority that is the Drug Controller of India[68].

A Critique of the functioning of the blood banks

A report submitted to the government[69] high lighted the deficiencies with regard to the facilities of testing blood, licencing of blood banks, storage of blood and the problem of professional donors. It was stated in the report that out of the total number of 1018 blood banks as many as 611 are reported to be unlicensed. There are only 201 licensed commercial blood banks. The supply of blood by licenced commercial blood banks is only about 1/4th of the blood used in the hospitals of the country. The report also said that no medical check up is done on the blood donors, and their health status is not examined.[70]

It is a mandatory requirement to conduct tests on blood which is to be administered to a patient or to be issued to hospitals for transfusion. The blood so issued has to be free from AIDS, Viral Hepatitis, Malaria, Venereal diseases etc. It was reported that mandatory tests which are required to be done are rarely conducted and the blood banks have been thriving on bleeding the professional blood donors. These professional donors, according to the report, are the victims of ill health, low haemoglobin level and many infections.[71]

The blood banks have to necessarily possess facilities like refrigerators exclusively for storage of blood with a specified range of temperature for ensuing

[68] *Ibid.*
[69] A.S. Fergusan Committee Report (1990). Quated in *Common Cause v Union of Inida*, A.I.R. 1996 S.C. 929 at p. 930
[70] *Ibid.*
[71] *Ibid.*

safety of blood. The storage facilities in the blood banks are reported to be far from satisfactory. In the existing blood banks many items of equipment remain unattended for years, electricity failure are frequent, generators are rarity. This applies not only to private commercial blood banks but also to government hospitals. It was also reported that these blood banks are located in unhygienic environment and they collect and store blood in a very dirty conditions. In some places, it was reported that strong middle men operate for the blood banks by arranging donors. The middle men dictate the charges to be paid and take a heavy commission. The report says that a large part of the professional donors are alcoholics or drug abusers. Thet do have indiscriminate sexual habits and are high risk group for Hepatitis and AIDS[72].

Trained personnel are generally not available in blood banks. It was reported that drug control department, which is expected to ensure the appropriate functioning of blood banks do not themselves have specified trained personnel.[73]

The Supreme Court in *Common Cause v. Union of India*,[74] made several recommendations for the improvement in the functioning of the blood banks in the country on the basis of the recommendation made by the committee constituted for this purpose by the Court. The Supreme Court among other things, has recommended for launching of effective motivation campaign through utilization of all media for stimulating voluntary blood donations in educational institutions.[75] It directed the government to undertake the comprehensive programme for training the personnel

[72] *Ibid.*
[73] *Ibid.*
[74] A.I.R. 1996 S.C. 929
[75] *Id.*, p.934

operating in various aspects of functioning of blood banks. The court also directed that the system of licensing of blood banks should be strengthened to ensure that all quality banks operating in the country are equipped with licences within a period of one year and said that the system of professional donors of blood should be discouraged through all appropriate media. [76]

The Court agreeing with the recommendation of the committee held the view that the entire range of schemes relating to operation and requirements of blood banks including the launching of effective motivation campaign for stimulating voluntary blood donations, and training of personnel should be entrusted to an autonomous representative body at national level which may be called at the National Council on Blood Transfusion.[77]

Administrative machinery:-

Effective administrative measures are required to supervise, monitor and to ensure that the conditions of licences are fulfilled by the licensee. This require the establishment of enforcement machinery with all adequate facilities to efficiently discharge their duties under the laws and rules. For this purpose, law provides for the establishment of inspectorate at the grass root level and sufficient number of drugs laboratories. The system of inspections is to ensure effective enforcement of all laws relating to quality in manufacture, sale and distribution. Drugs control laboratories are intended to analyse the drug samples sent to them by the inspectors

[76] *Ibid.*
[77] *Id.* at p.935

or by the affected person or consumer groups. The person in charge of these laboratories who are responsible for analyzing drugs are known as government analysts. The law prescribes qualifications and duties for the inspectors and govt analysts.

A person to be appointed as a government analyst should be a graduate in either medicine, science pharmacy or pharmaceutical chemistry of a recognized university. He must also possess post graduate experience of not less than five years in the testing of drugs in laboratories approved by the government for this purpose. But an experience of not less than three years would be sufficient for a post graduate in any of the above fields of science. The person to be chosen for this post should not have connections either directly or indirectly with the manufacturers of drugs. Similar qualifications in veterinary science are required for persons to be appointed to examine veterinary medicines.[78]

A person to be appointed as an inspector should be a graduate in pharmacy or pharmaceutical chemistry or post graduate in chemistry with pharmaceutics of a recognized university. An experience of not less than one year in post graduate training in an approved laboratory is required for the other graduates in science and medicine. To inspect the veterinary products, the inspector must be a graduate in veterinary science or other sciences with an experience of 18 months in the manufacture of biological products.[79]

[78] Drugs and Cosmetics Rules 1945, Rule 44
[79] *Id.*, Rule 49

There is no bar on the government in prescribing different qualifications for inspectors for different purposes. It has full freedom to prescribe any qualification and can prescribe one set of qualifications for an inspector for one purpose and another set of qualifications for an inspector for another purpose. It can therefore prescribe lower qualifications for an inspector for inspection of shops and higher qualification for inspection of manufacturing units.[80] Post graduate experience or training was held[81] to mean the experience or training that has to be gained after obtaining graduation. The object of the provision is to ensure that to be eligible for the post, the person concerned must have received training under any of the authorities after graduation in medicine or science.

Duties of government analyst and inspectors:-

It is the duty of the government analyst to analyse or test the samples of drugs that are sent to him by inspectors or other persons and furnish reports of the results of tests or analysis in accordance with the rules and procedure framed under the law.[82] According to the procedure laid down under rules, he has to compare the seals on the packet with the specimen impressions and also make note of the condition of the seals on receipt of the package of sample drugs for test. The report of the analyst should contain the particulars of full protocols of the test or analysis carried out by him.[83] It may be stated that the protocols of test and analysis may vary depending upon the pharmacopoeia to which the drug relates. Where there are no prescribed

[80] *See Rajkrishna* v. *State*, A.I.R 1960 All. 460
[81] *See Maheswar Prasad Sreevastava* v. *Suresh Singh*, (1977) 1 S.C.C 627
[82] Drugs and Cosmetics Rules 1945, Rule 45
[83] *Id.*, Rule 46

methods of tests available in any pharmicopoeia for a drug, the analyst may furnish the description of the test evolved by him basing on the relevant books and journals.

All inspectors are under the control of an officer appointed by the state government for this purpose. It is the duty of the inspector to inspect all the premises licensed for the sale of drug in an area assigned to him for not less than twice a year. He has to satisfy himself that the conditions of licences are being compiled with by the sales units. Either on a complaint received by him or on his own if he has a reason to suspect that certain drugs are sold in contravention of the law, he can procure and send such drugs for test or analysis. In respect of any breach of the law he can initiate legal action including prosecution of the person responsible for breach. He has to maintain a record of all inspections made and action taken by him in performance of his duties, including the taking of samples and seizure of the stocks and has to submit the copies to the controlling authority in the State. He can detain the imported packages of drugs if has reason to suspect that they are imported in contravention of law. He can make all such enquiries and inspections which are considered by him as necessary to detect sale of drugs in contravention of the law.[84]

Critical analysis:-

A study of the staff and facilities available to them would reveal that the government has to bestow much thought of expansion of the department for more stringent enforcement of drugs laws. The control of sale and distribution of qualitative drugs is a gigantic problem which requires much bigger and closer net work of

[84] See *id.*, Rule 50 and 51

organization. Given the task assigned to them, it is necessary to provide adequate staff and facilities to the department. As per the yard stick prescribed by the Task Force, there must be one drug inspector for every 25 manufacturing concerns and one drug inspector for every hundred sales concerns.[85] A drug control laboratory at every State headquarters is required to achieve the target of analyzing a minimum of 3000 drugs per annum.[86]

According to the Drug Controller of India the drug control organization remains as it was several years ago though there has been a constant growth in the number of manufacturing and sales units. [87] It seems the staff available is only one fourth of the number required by them. According to him there are no Special Cells to unearth spurious drug rackets and an intelligence wing is required for each State.[88] It appears that there is not even a single vehicle available at the disposal of drugs inspectors in each district.[89] This facility is required to check the movement of spurious drugs from one place to the other and take timely action against offenders and also to conduct surprise check and raids as and when necessary.

Most of the states do not have the laboratories to test the genuineness of drugs and those that do have laboratories, do not have the staff to conduct these tests. Only very few states have laboratories with adequate staff and facilities.[90] Therefore, there is no guarantee for the protection of the consumer of pharmaceutical

[85] See the brochure broughtout by the Directorate of Drugs Administration, November 1st, 1987, Hyderabad.
[86] *Ibid.*
[87] See *Indian Express,* Oct. 18, 1989
[88] *Ibid*
[89] *Supra* n. 85
[90] *Ibid.* See also *Indian Express,* May 26, 1998 at p. 12

products if this situation continues . What has been said by the expert committee on the functioning and facilities of blood banks may be equally applicable to the drugs sale units in the country.

Liability of the seller for injuries arising from sale and distribution of drugs.

A seller of a drug is not liable for any injury resulting from the use of a drug which he dispenses unless failure to exercise proper care is imputed to him. But he is subjected to a positive duty, independent of the contract of sale, to use such care as is ordinarily possessed and exercised by the members of his profession in selling and dispensing drugs. He may be held liable in damages for any injuries which proximately result from his failure to exercise such care.

The mere refusal of a druggist to fill a prescription does not render him liable. As a chemist, he may have cause to suspect that the physician has erred. Sometimes he may not have at hand the ingredients prescribed or he may distrust his own ability to prepare the prescription or he may perceive other causes that disincline him to undertake filling the prescription presented to him. A druggist is entitled to retain a prescription as a record of his business after filling it and delivering the medicine and in some cases he is required by law to retain the prescription.[91] But a druggist has no right to retain a prescription presented to him when he refuses to deliver the medicines called for.

[91] See Drugs and Cosmetics Rules 1945, Rule 65(9)(b)

Liability for breach of warranty:-

A druggist is held to impliedly warrant that he will deliver the drug required by the customer and he would be liable on breach of warranty for injuries resulting from a mistake in giving the wrong article. The implied warranty of fitness would be conditioned upon buyer's reliance upon the skill and judgement of the druggist.[92] In selling a harmless drug a pharmacist is to be held to warrant the safety of the preparation by implication.

When a retail druggist fills a prescription or buys in bulk and bottles the drug and places his own label on it, he impliedly warrants the preparation to be what he represents it to be. But a druggist can not be held liable on the theory of breach of implied warranty for injuries resulting from the taking of a drug furnished on a doctor's prescription directing that the drug be supplied and which was available only to those who could present such a prescription which was filled precisely in accordance with the direction of the prescription from the manufacturer's original packet. And a druggist who merely recommends in good faith a prescription of another person is not liable for injuries to a customer who orders and uses the prescription, when there is no want of skill and no departure from the recipe in compounding the prescription.

Liability for Negligence:-

A registered pharmacist or other person who undertakes to act in the capacity of a qualified person in preparing medicines and filling physicians prescriptions must

[92] See Sale of Goods Act 1930, Section 16(1)

be competent to perform the duties of his profession and is expected to possess and exercise the degree of knowledge and skill ordinarily exercised by other members of his profession. It is therefore incumbent upon a druggist to understand his business, to know the properties of the drugs and to be able to distinguish them from each other. It is his duty to attend to the business of compounding and vending medicines to see that one drug may not be sold for another and that proper medicines are used in mixing and compounding prescription. Moreover a druggist who employs others to compound prescriptions in his place of business has a duty to hire only qualified persons who are capable of differentiating between drugs offered for sale.

In keeping, handling and disposing of dangerous drugs and medicines, the public safety and security against the serious or even fatal consequences of negligence is a consideration which no druggist can safely ignore.[93] An imperative duty requires him to take such precautions as are likely to prevent death or injury to those who may be exposed to the dangers incidental to the business in which he is engaged. A druggist must give his customers the benefit of his best judgement. He must be certain that he does not deliver to a purchaser or send a patient with a poison in place of a harmless drug. He must take care not to furnish a drug which, though not pernicious, is calculated to produce a different effect from the one requested.

Standard of care:-

The standard of care which is imposed on a pharmacist or other qualified

[93] See Ratanlal & Dhirajlal, *The Law of Torts* Wadhwa & Co., Nagpur (1992), at p.474 for detailed discusion on tort of negligence.

dispenser of drugs and medicines is generally described as ordinary care in the conduct of his business.[94] The ordinary care required of him in compounding and selling drugs and medicines is that degree of diligences and prudence which is commensurate with the dangers involved and the consequences which may attend because of inattention on his part. The poisonous character of many of the drugs with which he deals and the grave and fatal consequences which may flow for want of due care must be considered. Accordingly the standard required of them must be that degree of caution and care called for by the peculiar and dangerous character of the business i.e., the highest degree of care and prudence for the safety of consumers known to practical men.[95] The reason for holding druggist to such a high standard of care in self evident. People trust not merely their health but their lives to the knowledge, care is and prudence of druggist and a slight want of care may prove fatal.

It may be stated that the rights of the consumers can be preserved and responsibilities of the retail druggist are established by the concept that druggist who sells a prescription warrants that he compounded the drugs prescribed and used proper care in filling the prescription and that the drug has not been infected with some adulterous foreign substance. But the concept of strict liability without fault may not be applied to a druggist who furnishes a drug to a customer presenting a doctor's prescription precisely in accordance with the directions of the prescription from the manufacture's original packet. A druggist selling patent or proprietary remedies generally is not liable for injurious consequences to the purchaser from

[94] *Id.* at p. 444

[95] See *Northen Western Utilities Ltd.* v *London Guarantee and Accident Co. Ltd.* [1936] A.C. 108. *Paris* v. *Stepney Borough Council*, [1951] 1 All E.R. 42(H.L.) and *The Wagon Mound (No.2)* [1966] 2 All E.R. 709, also see Margaret Brazier, *Street on Torts*, (eighth edition) Butterworths, at p. 196.

use of such remedies and the latter must look to the manufacturer for redressal.[96]

In compounding drugs and medicines druggists are required not only to be skillful, but to be exceedingly cautious and prudent. The care employed should correspond with superior knowledge which the law requires of the profession. Moreover the care required of a pharmacist is generally commensurate with the dangers involved. The greater the danger, the greater the care that must be exercised. Thus, a druggist is bound to exercise the highest degree of care in dispensing drugs.

All persons engaged in the business of handling drugs, whether as distributer, seller or otherwise, are bound to exercise the same degree of care and may be held liable for their failure to do so.

Proximate Cause

Failure of a druggist to exercise the standard of care required of him constitutes negligence which renders him liable in damages for any injury sustained as a result of proximate cause. The rule of liability is the same as that which governs the liability of all other professional persons whose work requires special knowledge or skill.[97] Thus, a druggist is not responsible for an unintentional injury resulting from a lawful act if the failure to exercise due care cannot fairly be imputed to him. Although a druggist is not necessarily responsible for the results of an error of judgement which is reconcilable and consistent with the exercise of ordinary skill and care, a presumption or an inference sufficient to require the druggist to disprove negligence

[96] See Sale of Goods Act 1930, proviso to subsection (1) of s. 16

[97] See Margarat Brazier, *Street on Torts*, (8th Edn) Butterworths p. 210 - 211.

arises upon proof of mistake or inadvertence on his part.

Where a druggist negligently sells a dangerous product to a person who uses it to commit suicide or acquires through its use a state of mind which leads to suicide the druggist is not generally liable for the customer's death, since the sale is not deemed the proximate cause of the suicide.[98] In a case reported from the US, the drugist sold barbiturate capsules to cure nervous condition without prescription. He committed suicide by hanging after taking the medicine. The American Supreme Court held that the druggist was not liable since the person whom the drug was sold was capable of consenting and was not under the influence of any drug when it was sold to him.[99]

If some ingredient not called for by the prescription is included without notice to the purchaser, the liability for injury may be fixed on a druggist who sells a drug to one who is allergic to it. In an action against a druggist to recover damages for injuries allegedly sustained as a result of his failure to exercise due care, the negligence of the defendant and its operation as a proximate cause of the plaintiff's injuries are to be proved and are questions of fact for the determination of court in each case.

Mistake in filling prescription

In filling prescription a druggist must exercise the highest possible degree of prudence, thoughtfullness and diligence. He must employ the most exact and reliable safeguards consistent with the reasonable conduct of the business. Druggists

[98] *Riesbeck Drug Co.v Wray*, 111 Ind. App. 467, 39 NE 2nd 776 quoted from 25 Am. Jur 332 (2nd).
[99] *Scott v. Greenville Pharmacy*, 212 S.C. 485 (U.S.).

are liable for injurious effects as a consequence of negligence in compounding a prescription when the ingredients are improperly mixed. The legibility of the prescription is a circumstance to be considered in determining the negligence of the druggist who fills it. But the illegibility of a writing may not lessen or otherwise affect the obligation of the druggist. He has to take extra precaution especially when his first perusal indicates that the prescription calls for the inclusion of a drug which in the quantity specified is likely to be harmful. Accordingly if the dosage of a poisoning drug prescribed by the physician appears to be unusual it is prudent for druggist filling the prescription to make enquiry of the physician to ensure that there has been no error.

It a druggist is negligent in filling a prescription, he can not escape liability merely because the doctor who wrote the prescription is also liable. But it does not follow that because the physician is liable the druggist who filled the prescription is also liable. The druggist may be liable for filling a prescription as written if it calls for dosages that are obviously fatal.[100]

Sale of substance other than that requested:-

A druggist may be held liable for negligence in selling a harmful drug or medicine in place of the harmless one asked for by the purchaser or prescribed by his physician. Moreover, since the druggist is held to warrant that he will deliver the drug asked for by the customers, he may be liable on grounds of breach of warranty for injuries resulting from a mistake in giving the wrong product. A dealer in drugs is

[100] See *Peoples Service Drug Stores v. Somerville*, 161 Md, 662 quoted from 25 Am. Jur. 333 (2nd).

liable for injury sustained by a consumer who was deliberately given a drug other than the one he was requested when the preparation asked for being out of stock.[101]

Failure to warn about dangerous properties of substances sold:-

The duty of care imposed upon a druggist comprehends a duty to warn of known dangers connected with drugs and medicines which he compounds and sells. In the absence of a contributory negligence on the part of the plaintiff, a druggist is generally liable for injury resulting from his negligence in selling a poisonous drug or a dangerous substance unaccompanied by a proper warning. A different question may arise if a druggist sells an inadequately labelled substance whose dangerous properties are generally known and recognized. In this situation, though no instructions as to the use of the product were given, the dealers should know or should have known, from the circumstance of the transaction, that the purchaser could not safely be entrusted with the preparation requested. And this is true regardless of how little knowledge the buyer had of the dangerous properties of the substance.[102] The reason advanced to this rule of non-liability is that a person who has reached the age of discretion and is in apparent possession of his mental faculties, in asking a druggist for a particular preparation, represents by implication that he knows the properties of the substance requested and that he is fit person to whom it may be sold.

The fact that a letter ordering 'phosphorous' is incorrectly worded and spelled and that the writing is poor, is not of itself sufficient to charge the sellers with notice

[101] *Wilcox v. Butt's Drug Stores*, 38 NM 502, 94 ALR 726 quoted from 25 Am Jur 333 (2nd)
[102] *Id.* at p. 334

that the purchaser can not be entrusted with the article without instructions as to how to handle it safely.[103] A druggist is obliged to warn a customer of the effects of a drug which is harmless but injurious when combined with another and the druggist has reason to know that the substance will be so used. And a druggist is liable for resulting injuries where unable to supply the kind of medicine called for by a customer, he fills the order with other medicine and represents that it is as good as that requested, without explaining that it contains poison in quantities harmless only when administered in proper doses.

Liability of druggist for negligence of employee or agent:-

A druggist who employs others to compound prescription in his place of business is obliged to hire only qualified persons who are capable of discriminating between drugs offered for sale.[104] Where a druggist undertakes as part of his regular business to fill prescriptions, it is immaterial to a customer, so far as the druggist's liability is concerned, whether the prescription is filled by the druggist personally or by one of his employees. Accordingly, where one is injured as a result of negligence of a druggist's employee, acting in the course of his employment, the druggist is liable in damages.[105] Similarly, a corporation, as owner of a drugstore is liable for the negligence of its manager.[106]

Where a clerk negligently sells an injurious drug to a customer instead of the harmless one asked for, the latter has a cause of action against the employer of the

[103] *Gibson* v. *Torbert*, 115 Iowa 163, 88 NW 443 quated in *Id.* at P. 334
[104] See Drugs and Cosmetics Rules 1945, Rule 65(1)
[105] See *Sarjoo Prasad* v. *State of U.P.*, A.I.R. 1961 S.C. 631
[106] Drugs and Cosmetics Act 1940. Section 34(1)

clerk for the pain and suffering caused by the mistake. And if a druggist's employee departs from a prescription or ignorantly, carelessly or negligently introduces other drugs, his employer is responsible for the consequences to the person injured. Moreover, the fact that the employee who compounds the prescription is a competent registered druggist of wide experience does not relieve the employer from liability for the employee's negligence. A druggist is also answerable for the act of his employee who in response to a request for a solution of a particular chemical, sells a solution of such abnormal strengths as to cause serious injury to the user.

A dealer in drugs and medicines whose agent or employee carelessly labels a deadly poison as a harmless medicine and sends it into the market, is liable to all persons who are injured by using the substance in consequence of the false label.[107]

Liability of druggist for injuries resulting from sale of patent or proprietary medicine:-

Where a druggist sells a patent or proprietary remedy in the original package, accompanied by the directions of its use prepared by manufactures, the druggist is not generally liable for any injurious consequences of the use of the remedy. The injured person must look to the manufacturer of the product for redressal. With respect to such medicines, a druggist is not required to analyse the contents of each bottle or package he receives and if he delivers to the customer the article called for with the label of the proprietor or patentee upon it, he can't be justly charged with negligence. But a druggist purchasing a proprietary preparation in bulk and selling it from the broken package may become liable to one injured as a result of the negligence of

[107] *Thomas v. Winchester*, 6 NY 397 quoted from 25 Am Jun 337 (2nd)

the manufacturer. This distinction is supported on the ground that in a sale from the broken package the vendor has an opportunity of seeking or knowing and determining the character of the drug.

Effect of contributory negligence:-

Contributory negligence on the part of one who sustains injury from the use of drugs or medicines will defeat a recovery against a negligent druggist. In this regard a druggist is not liable to one purchasing drugs on a physicians prescription for injuries caused by violating the instruction of prescription by taking the drugs in amounts exceeding the directions of the prescription. There is a reason to support that one who has been adequately warned that the use of a drug may produce certain consequences, but who, not withstanding such warning, elects to use the drug, assumes the risk of injury.

Contributory negligence was attributed to a minor who was injured but shown to be old enough to possess a knowledge and understanding of the dangers attending the course he has pursued. In *Cullinan v. Tetrault*[108] it was held that one who attempted to purchase a harmless extract from a plainly incompetent boy in charge of a drugstore, and who relied upon his own sense of smell to determine whether or not the article offered was what he wanted, was negligent and that he could not hold the proprietor of the store liable when he was injured by the article received. In yet another case, *Scheres v. Schlaberg*,[109] a father permitted the administration of medicine which he knew differred in character, in dose and in frequency of dose, from that

[108] 123 Me 302, 31 A.L.R. 1330 quoted from 25 Am. Jur. 338 2nd
[109] 18 ND 421, 122 NW 1000, quoted from 25 Am Jur 338 (2nd)

which the attending physician had prescribed to a child of 3 months old who was dangerously ill. The father was held guilty of negligence, and barred from recovering for the death of the child resulting from the negligent act of a druggist in furnishing medicine other than that called for by the prescription. It may be stated that the general principle in law of torts with respect to contributory negligence where the negligence of both the parties caused the death or injury, the common law rule was that the plaintiff was to fail.[110]

In actions to recover damages for injuries allegedly caused by negligence of a druggist, the question of plaintiff's contributory negligence is ordinarily one of fact for the court to determine in each case.

Effect of lack of privity between druggist and injured person:-

A druggist is liable to one injured by a drug sold by him even though the injured person did not purchase the substance from the druggist, provided that the injury complained of is the direct, natural and probable consequence of the druggist's negligence in selling, labelling or preparing the drug. The liability in such a case arises not out of any contract or privity between the druggist and the person injured but out of the duty which the law imposed on the druggist to avoid acts in their nature dangerous to the lives of others. Accordingly a dealer in drugs is responsible in damages to persons other than the immediate purchaser for injury or death resulting from the negligent sale of a poison as harmless drug. Moreover, a pharmacist who carelessly labels a poison as a harmless medicines, and sends it so labelled into the

[110] See for general principles on contributory negligence, Ratanlal & Dhirajlal, *The Law of Torts*(1992) Wadhwa & Co. Nagpur at p. 477

market is liable to any person who, without fault on his part, is injured by using it as a medicine in reliance on the label, even though the preparation may have passed through many intermediate sales before reaching the person injured.[111]

The sale by a druggist of a substance innocent in itself but dangerous when combined with certain other drugs does not render him liable to a third person who subsequently makes such use of it, unless the druggist at the time of the sale had knowledge of how the preparation was to be used.

The law on sale and distribution of drugs: a critical overview:-

The foregoing discussion discloses that the legislation regulating sale and distribution of drugs in India are comprehensive and self explanatory. Except in the case of collection and distribution of blood and blood products, the existing law can protect consumers effectively if it is implemented in true spirit. What is distrubing is that machinery for enforcement is inadequate and devoid of modern devices. Training of personnel and providing infrastructural facilities may improve the situation. In the case of blood and blood products the law is not clearly laid down. It may be possible to extend rules regulating the manufacturing, storage and supply of drugs to the collection, storage and distribution of blood also till a comprehensive legislation in ture with the Supreme Court direction is enacted.

[111] *National Sav. Bank v. Ward.*, 100 U.S. 195.

CHAPTER IX

CONCLUSIONS AND SUGGESTIONS

The present study revealed that the theory of freedom of contract is only an ideal relevant when the parties are assumed to be on equal footing. In a more complicated social and economic society, it ceased to have any relevance. Many countries in the world enacted legislations to protect the consumers of pharmaceutical products. Stringent enforcement measures have been undertaken by the governments all over the World to prevent the abuse by the manufactures and sellers of pharmaceutical products. India also enacted legislation and created administrative machinery to protect the consumers of pharmaceutical products. Basing on the study of these provisions and functioning of the enforcement machinery created for this purpose, the following conclusions are drawn.

The meaning of 'consumers of drugs' provided in the law is inclusive and not exhaustive one. The definition of 'drug' as interpreted by the courts is comprehensive enough to take in it not only medicines but also substances. The meaning of the word substances has been widened by the interpretation of the courts so as to include all the things used in treatment. The definition of the word 'consumer' has been liberally interpreted by the courts so as to provide protective net to a large section of the public. Hence it covers not only the buyer, hirer of the goods but also every conceivable user of the goods. In the case of pharmaceutical consumer, one can expect

that the courts will make the beneficial interpretation to cover persons who receive medicines from government hospitals free of cost and persons who could not get adequate quantity of medicines though they are eligible for such medicines from the government hospitals. Inability of the government to provide safe, efficacious and adequate quantity of medicines in such hospitals due to financial constraints should not be allowed as a defence to escape from the obligation in the light of the Supreme Court rulings. Still the pharmaceutical business in India revealed several short comings. The important among them are summerised below.

Need for emphasis on production of essential drugs

Majority of the Indian population suffer from diseases like malaria, tuberculosis and other non sexually communicable diseases. The production pattern of the pharmaceutical industry should provide adequate quantity of drugs to meet these needs. Hathi Committee which inquired into the drugs and pharmaceutical industry concluded that the drug companies have been concentrating on production of money spinning non essential and often irrational combinations of drugs. The studies subsequent to this report also revealed that there is a shortage of essential drugs necessary to cure local diseases like tuberculosis and malaria where as drugs containing vitamins and other combinations which are more profitable for the manufacturers are produced and marketed in abundance.

Doctors prescribing habits are found to be partially in response to the intense sales promotional pressures used by the manufacturers of drugs. Studies conducted in England showed that the industry incurs substantial expenditure as a cost of promotion for every doctor. Even if one considers that the benefits that a doctor receives from the manufacturer are of a trivial value, the kind of relationship that these promotional devices create between the doctors and manufacturer is not conducive to the best interest of patients.

Hence, there is need to confine the production and prescription of drugs to a large extent to the essential drugs list which is to be prepared keeping in view of the national needs and recommendations of the World Health Organisation. Use of brand names is to be avoided as far as possible both in production and prescription. Drugs are to be produced and prescribed in generic names. This would not only reduce the cost of the medical bill to the consumer but also prevents colossal national wastage of drugs arising out of the production of irrational combination drugs. New drug policy of 1994 do not envisage these measures. Rather it tends to abolish all the requirements for the licence to manufacture new formulations except in cases of specific cell or tissue targeted formulations. It also seeks to abandon the conditions stipulating mandatory production and supply of certain percentage of bulk drugs.

These measures may lead to large scale import of bulk drugs. the multinational manufacturing units have a tendency to introduce new

products of similar activities with slight differences. When they patent these products under the proposed patent regime, the prices of these drugs will be very high. Hence the new policy guidelines are clearly against the reasoned recommendations of the Hathi Committee and the directives of the Constitution. It is, therefore, necessary to revise these policy guidelines keeping in view of the national needs. The policy should state the ratio-parameters linking bulk drug production to the formulations and limit the use of imported bulk drugs as far as possible. The main consideration for granting licence for the manufacture of new drugs must have distinct advantages in India over the existing range of drugs. The production of drugs must be oriented to meet the needs of large sections of the people living in poverty. While framing such policy all the agencies who are concerned in this area are to be consulted. Then only comprehensive and meaningful guidelines can be brought out and can be implemented with their cooperation.

Need for law regulating clinical trial procedure

Another disturbing area is the conduct of clinical trial of new drugs and formulations. Research in medicine is a continuous process. When new diseases are noticed, new medicines to combat with these are to be found. Accelerating research in the field of medicine is a necessity. In the process of research and before marketing a new drug, sufficient safeguards are necessary to ensure that human beings are not unduely exploited by the

researchers and unsafe drugs are not marketed by the overambitious manufacturers.

The study of the provisions in this regard revealed that the duty of the drug controlling authorities is confined to scrutinize the data of the clinical test already conducted by the sponsor of the drug. In practice, clinical tests conducted by the foreign companies and if the data has been accepted elsewhere is considered sufficient to support approval of the drug in India. It was found that the approaches of most of the countries for new drug regulations are similar. But it was noticed that the procedures envisaged under the U.S. law is more acceptable and close to the guidelines issued by the World Health Organisation, the European convention on human rights and other international conventions.

Study of the clinical trial procedure under the U.S. law revealed that there is a continuous supervision over clinical trials and controls are provided on the treatment use of an investigational product. The treatment protocols are to be examined by the regulating authorities. During the treatment use of the investigational new drug, treating physicians are required under law to obtain informal consent from the investigational subject or from his lawful guardian. At the same time procedures are also envisaged to expedite the approval process of new drug which is intended to meet the needs of patients for whom there is no standard therapy existing. This flexibility in the procedures is clearly restricted to such drugs which

make promising signs of providing some relief for people with AIDS and terminal diseases like cancer and who do not have satisfactory treatment options.

There is a need for similar provisions in India. The object of such law is to monitor the ongoing clinical trials and also to provide for the procedure to be followed in such trial to ensure safety and rights of the subjects participating in the trials. The law should allow the trial only when it can lead to conclusive data for approval. The system must allow for on-site inspection of the quality of the data. It must also ensure that protocols of clinical trials be submitted to the regulatory authorities in advance for its review. The regulatory authorities should be able to check the reliability and quality of the reported results. This would prevent the ambitious sponsors from manipulating the data.

In this context, the guidelines issued by the World Health Organisation, the Helsinki Declaration, European convention on Human Rights in bio medical research involving human beings are to be incorporated in the national legislation. The idea behind these guidelines is that in research on man, the interest of science and society should not take precedence over the considerations of the well being of the human subject.

Need for re-consideration of the proposed Patent Bill 1995

The idea in conferring exclusive right in the form of patent is that it stimulates research by rewarding the inventor. It induces investor to embark

on new lines of production which otherwise may not be profitable for him. At the same time, it must be ensured that the exclusive right do not lead to monopoly to the detriment of the public. Therefore, the law requires to ensure that patented inventions are properly worked in the country to protect the public interest.

An analysis of the provisions of the Patents Act 1970 revealed that it took all the safeguards to reconcile the conflicting interests. It brought some revolutionary provisions in the patent system to ensure effective protection to the consumers of pharmaceutical products. The life period of the patent for pharmaceuticals has been considerably reduced. Patentability has been confined only to the process of manufacture of the drug and not to the product. The Act allows only one process, the best known to the applicant, to be patented. In addition to this, an elaborate compulsory licensing system is provided to ensure that patent rights do not lead to monopolistic tendencies to the prejudice of public. The Act provided 'licences of right' after three years of date of sealing. Even before the expiry of three years the controller is empowered to grant compulsory licence if it is necessary in the interest of public. There are special powers to use the patent by the government or public undertakings for official purposes.

An analysis of the data provided by the studies in this area revealed that Indian pharmaceutical industry prospered by leaps and bounds after the enactment of the Patents Act 1970. It also revealed that the prices of the

drugs in India are reduced to below the international levels because of the competition among the foreign multinationals as well as Indian firms.

But the developments in the international trade and business brought pressure on India to sign the international trade agreement called Trade Related aspects of Intellectual Property Rights Agreements. As a consequence to this agreement, an attempt was made to amend the existing patent law. A brief survey of the provisions of the TRIPS agreement and the Patent Amendment Bill 1995 revealed that these provisions, if enacted, would take away the benefits that are presently enjoyed by the consumers of pharmaceutical products. The Bill provided for patenting a medicine or drug and thereby recognised product patent. It enabled the granting of exclusive marketing rights to the applicant to sell or distribute such patentable product. It also provided that the patent rights can be made available even if the product is not manufactured in India since the 'working of the invention' under the Bill, would mean selling and distribution of the patented article. By these provisions, a legislative attempt has been made to do away with the working of the patented product by way of manufacturing in India. It will also make the price control on these products most ineffective as they can be manufactured outside.

Hence, there is need to reconsider the proposed amendments to the Bill. It must ensure that the patented product is manufactured in India. The provisions should ensure that exclusive marketing rights are not abused by

the multinational manufacturers. Compulsory licensing system that is envisaged in 1970 Act should be retained to subserve the public interest. The proposed legislation may even provide protection to the consumers without violating the TRIPs agreement. It can invoke the objectives and principles laid down in the TRIPs which contain provisions for measures to protect public health and social and economic welfare in sectors of vital importance. Comprehensive compulsory licensing system and price control regime can be devised in Indian law as a part of the measures to achieve the objectives envisaged in TRIPs.

Need for a public liability insurance scheme for injuries caused by pharmaceutical products

Many instances exposed the loopholes in the system of regulating drug manufacture and enforcing safety standards. Given the complex nature of the pharmaceutical product, it is difficult to control the quality and ensure safety. Frequent design changes in formulations make it much more difficult task for enforcement agencies to implement the standards of safety. These changes make the product susceptible to incorrect use resulting in fatal consequences.

However, the study of the provisions of the Drugs and Cosmetics Act and the rules framed under it revealed that the law in this regard is comprehensive to protect the consumer provided it is sufficiently supported by adequately equipped enforcement machinery. It stipulated conditions for

licence to manufacture. More rigorous conditions are provided in case of certain drugs which contain properties that can cause fatal consequences if any mishap takes place in the course of manufacture. Provisions are also made for compulsory inspection of the manufacturing premises before any licence or renewal of licence is granted. Severe penalties are also imposed for manufacturing and selling of adulterated and spurious drugs. Procedures are envisaged for taking samples of drugs from the site of manufacture and send it to the laboratories for testing.

The study of these provisions revealed that the Act mainly relies on administrative supervision and penal provisions to enforce the standards. Liability of the manufacturers for the drug related injuries to the victim is not considered by the Act. Though the amended provisions enable the aggrieved person or the consumers association to take samples, send it for testing and also initiate prosecution, the aspect of civil liability of the manufacturers or the state which permits the manufacture is still governed by tort law. In addition, the Act claims immunity to the state against any claim from the consequences of its action under the law. The problem gets compounded due to the limitations of law of contract and torts. To prove negligence or causative factors is very difficult in the adversorial system of litigation. To identify the defendant itself would be difficult in case of injury caused by a generic drug and if the injury manifests after lapse of a long period as demonstrated through the facts of *Sindel*'s case, it is all the

more difficult. In addition to this it was found from the studies conducted in this area that cost of litigation would in many cases be equivalent or more in some cases than the compensation awarded to the victim.

Therefore, the traditional systems of redressal may not be of much help to the claimants of drug injuries. Special plans devised in developed countries like Germany, Japan, Sweeden and other Scandinavean countries appears to be more beneficial to the victim. Such plans are desired in India. The provisions of the Public Liability Insurance Act 1991 envisages compensation for injuries arising out of handling of hazardous substances. But the Act do not clearly cover the drug injuries. Rather the definition of hazardous substance would have the meaning given to it under the Environmental Protection Act 1986. It appears that the Public Liability Insurance Act 1991 was mainly intended to meet the consequences arising out of industrial hazards like Bhopal gas tragedy. These provisions can be made applicable to the injuries of hazardous pharmaceutical products by a strained extention only. But separate legislative provisions to compensate the victims of drug injuries is desirable in the light of drug disasters such as thalidomide in England and Europe and J.J.Hospital incidents in India.

Any such plan should envisage compulsory insurance on the part of the pharmaceutical industry and its importer. The scheme should cover all cases of personal injury and death resulting from defective drugs. It should also reach to non-negligent manufacturing defects and failures to warn. The

scheme should also envisage compensation to cover the developmental risks which are not foreseeable or known by the manufacturer at the time of marketing the drug in the light of existing scientific knowledge. It may provide for the establishment of drug injury committee which can decide the quantum of compensation in accordance with prescribed tariffs. Preparing such tariff may not be difficult since such criteria is already adopted in the case of motor accident injuries. The entitlement should depend upon no-fault basis and the victims should remain free to pursue their tort remedy. The premium payable by each manufacturer may depend upon factors like risk rate of the pharmaceutical product, and the market share of the drugs sold by the manufacturer or importer.

Duty to prevent evasion of price regulation of pharmaceutical products

Because of the imperfections in the market structure, price fixing can not be left entirely to the free market forces. The drug manufacturing firms have been effecting the prices of their product without regard to the general economic principle of demand and supply and thereby reaping huge profits. Drugs price control orders are framed from time to time under the Essential Commodities Act 1955 to fetter and curb the profiteering in drugs. An evaluation of the provisions of the drugs price control orders disclosed that effective control is not possible under the existing rules because of the devices adopted by drugs manufacturers to evade the controls. The present system of price control operate through a single list of price controlled drugs

with a maximum allowable post manufacturing expenses of 100 percent on all the drugs. The criteria of including drugs under price control is based on the minimum annual turnover of a drug. High turnover of a drug is considered as an index of its extent of usage and is considered as justifiable ground to clamp control. It is made mandatory to furnish the details of cost of each scheduled bulk drug to enable the government to fix the price. The Government while fixing the price of a bulk drug has to consider factors like post tax returns on net worth or returns on capital employed. There is a different procedure for fixing prices of non-scheduled drugs. The provisions also empower the government to fix the retail price of any formulation in accordance with a formula laid down in the Order.

A bare reading of the formula envisaged under the Order and the annexure provided in the Order through which the government intends to obtain the information from the manufacturer reveals that the decision to fix or revise the price of a drug depends mainly on factors like, cost of the raw materials, conversion costs, cost of packaging material, packaging charges, capital employed, persons employed, their grades and emoluments and transport and selling expenses. The main difficulty for the authorities is to obtain accurate information of the costs of materials used and other expenditures shown to have been incurred by the manufacturers. This will be doubly difficult given the ability of the manufacturers who engage in devices like overinvoicing of imported materials and transfer of pricing

methods. The experience showed that the manufacturers invoke the power of the government to review the prices of drugs frequently on the pretext of hike in the cost of imports and devaluation of rupee. In addition to this, the power of exempting a manufacturer from the operation of the provisions are also vulnerable for abuse. While exempting a manufacturer the authorities have to take into account factors like number of workers employed, the capital invested, range of products manufactured and its sales turnover. Many big multinational companies get certain products manufactured by small scale units through loan licensing arrangement and market them through their brand name. By all these devices the manufacturing firms evade price control provisions.

Hence, effective steps are to be undertaken to prevent the evasion of the price control provisions. This requires effective means of information channels to ascertain the prices of the material in the national and international market. Then only the authorities would be able to ascertain the cost of the materials and compare the cost shown in the records submitted by the manufacturing firms . The loan licensing system should be dispensed with to prevent abuses of accounting and transfer of turnover devices. Otherwise, the system should enable the authorities to include the turnovers of the small scale manufacturing unit with that of the multinational or other company with whom such arrangement was made. Unless these measures are undertaken, the price controls on drugs may not be effective.

Need to have a body to screen advertising of drugs

The study of the legal provisions regulating pharmaceutical advertisement disclosed that they fail to prevent misleading information from reaching the public as well as medical professionals. The provisions of Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 and rules framed under it prohibit certain advertisements and regulate certain other advertisements. These provisions are intended to prevent self medication by the public and prevent the advertising by unscrupulous advertisers. The law also lays down the procedure to send certain advertisements to the medical professionals. Though the Act ideally reposes trust on the doctors when it insisted that certain advertisements should only be directed to doctors and other professionals, it cannot prevent the misleading information from reaching the medical professionals. Studies show that most pharmaceutical advertisements directed at physicians are false or misleading and can cause doctors to prescribe drug improperly. It was noticed that virtually every medical journal contains advertising that is one way or the other either false or misleading and most of them have little or no educational value. It was also found that majority of them would not lead physicians to proper prescribing practice. Substantial percentage of advertisements that addressed issues of side effects and contra-indications did not appropriately highlight the side-effects. Most of the doctors mainly

rely on these advertisements supplied to them by the pharmaceutical companies either by post or by their salesmen.

Thus the scope of misleading information in pharmaceutical advertisement is so broad that it is beyond the capability of authorities to correct without substantial new funding for enforcement. In this context the experiment made in developed countries like Canada may be appropriate. The Act of 1954 can be amended to provide for a pharmaceutical advisory board which may be empowered to approve in advance all the advertisements before they are addressed to physicians and other professionals in the medical field. The board may consist of physicians, consumer groups, representatives of medical journals, pharmaceutical companies and advertising industries. The drug control authorities also can have an ex-officio member in the board. The pharmaceutical comapnies can be charged a fee for each advertisement submitted for review so that there will not be any additional financial burden to the government.

Such regulation may invite the wrath of the pharmaceutical companies. The provisions are to be framed in such a way that they survive the test of constitutionality. This danger is imminent in the light of interpretation given to the right of advertisement in *TATA yellow pages* case and elevating it to the status of freedom of speech by overruling *Hamdard* case. Now the restrictive power of the state of this right is made limited by the Court. This interpretation, it may be submitted, is unwarranted in the

light of the rempant commercial advertising which has admittedly lost any educational value.

Need for a comprehensive law for storage and distribution of blood and blood products

It was found in this study that the Drugs and Cosmetics Act 1940 and rules framed under it provides for a comprehensive system of control on sale, storage and distribution of drugs. The law considers that the drugs are not like any other commodities which can be sold by any person and stored at any place. The Act mainly relies on licensing and inspection system in this regard. The drug licensing authority must ensure that the applicant complied with the conditions for granting licence. Conditions have been imposed depending upon the degree of hazardous properties that the drugs for the sale or distribution of which the licence is sought. The facilities that a pharmacy should provide before obtaining licence are also provided in the Act.

There are also provisions in the Drugs and Cosmetics Rules 1945 to regulate the storage, supply of blood and blood products that was made available through blood banks. The rules provide for equipment that is required for a blood bank., It also provide for the requirements such as equipment for the laboratory, technical staff and accommodation for blood bank. These rules also prescribe requirements for collection, processing and distribution of human blood and its components. Under the provisions,

licence for blood banks can be granted or renewed only by the approval of the Central Licence Approving Authority.

However, a report submitted to the government highlighted the deficiencies with regard to facilities of testing blood, licensing of blood banks and the problems of professional donors. It was found that most of the blood used is being supplied by the unlicenced commercial blood banks. It was found that the blood is procured from high risk professional donors and their health status is not examined. Most of these blood banks including government hospitals where blood is stored were found to have no facilities like refrigerators and other storage facilities. The blood was found to have been collected and stored under very dirty conditions. The middle men seems to have been dictating the charges to be paid for the blood. It was found that trained personnel were not available in blood banks.

Therefore, it is necessary to make a comprehensive law on the basis of the recommendations made by the Supreme Court in the *Common Cause*. The Court recommended for launching effective motivation compaign for stimulating voluntary blood donations. A comprehensive training programme for the personnel operating blood banks and the supervising officials is recommended. The licensing system should be further strengthened. The professional blood donors should be discouraged. The law should envisage creation of an autonomous representative body at national level to monitor every aspect of blood banks.

Need for strengthening the administrative set-up

A study of the provisions dealing with quality control and safety measures in manufacture, import, sale and distribution reveals that the drug control agencies are entrusted with enormous powers and responsibilities. It was made compulsory for the inspectors to visit the manufacturing premises and evaluate the facilities, equipment and other requirement existing at the site of manufacture and submit a report to the licensing authority before any licence or renewal of licence is granted to any manufacturer. It is the duty of inspectors in case of establishments licensed to manufacture Schedule C and C(1) drugs to inspect the plant, the process of manufacture, the means employed for standardisation and testing the drug, the methods and place of storage, the technical qualifications of the staff employed and cumulative effect of all these on the purity and potency of the product and submit a detailed report. Similar responsibilities are also entrusted to the inspectors inspecting sale and distribution units . They are also empowered to take samples and get them tested and if necessary initiate the prosecution against the wrong doer under the law.

All these provisions indicate the need for elaborate administrative set up. This agency must be fully equipped with personnel qualified and trained in the field. It must be furnished with adequate facilities like laboratories, technical staff and other facilities. But the study revealed that drug control organisation at the Centre as well as states have been facing the problem of

inadequate number of qualified and trained personnel. As per the yardstic prescribed by the Task Force, there must be one drug inspector for evey 25 manufacturing concerns and one drug inspector for every hundred sales concerns. A drug control laboratory at every state headquarters is required to achieve a target of analysing a minimum of 3000 drugs per annum.

The drug control organisation remained as it was several years ago though there have been a constant growth in the number of manufacturing and sales units. The Drug Controller of India admitted that the staff available is only one fourth of the number required by them. There is no intelligence wing to unearth spurious drugs. It appears that there is not even a single vehicle available at the disposal of drug inspectors in each district without which it would be difficult to check the movement of spurious drugs from one place to other and take timely action and to conduct surprise checks.

It was found that most of the states do not have laboratories to test the genuineness of drugs and those that do have laboratories, do not have the staff to conduct these tests. The Ferguson Committee reported that the regulating authority which is expected to ensure appropriate functioning of the blood banks do not themselves have trained personnel. It is equally true of drug regulatory agencies through out the country.

Therefore, unless the enforcement agencies are strengthend with sufficient trained personnel and with all the facilities, one cannot expect any

improvement in its functioning. Any sound system of legal control should be able to integrate all the agencies in the system and co-ordinate them in an effective manner so as to achieve the desired objective. There appears to be no such integration and support in the matter of enforcement inspite of the availability of comprehensive legal provisions of control.

It may be submitted that situation in the area of control will be improved to a great extent if the above recommendations are implemented. As the things stand now, there is an inadequate protection to the consumers of pharmaceutical products in the country.

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ANNEXURE-I

Table -1

Time Lag Between Introduction of a New Drug in the World Market and its Introduction in India

Drug	INTRODUCED (Year) In		Time lag:Intrdn in India (Yrs.)
	World Market by the inventor	Indian Market by domestic cos.	
Salbutamol	1973	1977	4
Mebendazole	1974	1978	4
Rifampicin	1974	1980	6
Naproxen	1978	1982	4
Bromhexin	1976	1982	6
Ranitidine	1981	1985	4
Captopril	1981	1985	4
Norfloxacin	1984	1988	4

Table -2

Drug	Number of Manufacturers
Ampicillin	32
Amoxycillin	22
Cephalexin	23
Chloramphenicol	68
Diazepam	20
Diclofenac sodium	20
Erythromycine	22
Ibuprofen	52
Mebendazole	35
Paracetamol	63
Rifampicin	27
Tinidazole	40
Trimethoprim	88

Quated in B.K. Keayla,"TRIPS Agreement on Patent Laws: Impact on Pharmaceuticals and Health for All" a paper presented in International Conference on *Global Health Laws* organised by Indian Law Institute in collaboration with the World Health Organisation, New Delhi, December 5-7,1997.,at p.15-16

ANNEXURE-II

Table -1

COMPARATIVE PRICES OF IMPORTANT DRUGS IN INDIA AND OTHER ASIAN COUNTRIES

(in Rs)

Name of the Drug	Unit	India			Pakistan			Sri Lanka			Indonesia		
		1986	1992	Percentage Change	1986	1992	Percentage Change	1986	1992	Percentage Change	1986	1992	Percentage Change
1 Chloramphenicol	250mg/10 tabs	5.72	9.95	73 9	6.93	16 78	145.0	15.74	31 86	102.4	15.36	44.76	191.4
2 Metronidazole	200mg/10 tabs	2.76	3.65	32 2	5.74	15 64	172.4	6.74	19.30	186.3	43.52	99.15	127.8
3 Ibuprofen	200mg/10 tabs	6.13	3.71	- 39.4	4 68	6.78	44.8	10 34	8.87	-14.2	12 80	9.52	- 25.6
4 Ferrous Sulphate	150mg/15 caps	8.46	8.64	2.12	9 36	20 84	122.6	13.15	45.04	242.5	—	48.31	—
5 Propranolol HCL	10mg/10 tabs	1.96	3.70	88 7	4 66	10 06	115.8	4.49	5.71	27.1	—	—	—
6 Salbutamol	2mg/10 caps	1.11	1.93	73.8	3 40	—	—	2.97	6.82	129.6	10.24	—	—
7 Nifedipine	10mg/10 caps	6 00	5.7	- 3 6	31 65	37 18	17 5	5.49	10 64	93.8	20.48	61 28	199 2
8 Cimetidine	200mg/10 tabs	7.96	8.75	9.9	36 41	45 92	26.1	17.54	94.52	438.8	49 92	106.72	113.7

Table -2

CHANGE IN INTERNATIONAL PRICES *VIS-A-VIS* INDIAN PRICES OF IMPORTANT DRUGS

Name of the Drug	Unit	Times Costlier in Pakistan		Times Costlier in Sri Lanka		Times Costlier in Indonesia	
		1986	1992	1986	1992	1986	1992
1 Chloramphenicol	250 mg/10 caps	0.21	0.68	1.75	2.20	1.68	3.49
2 Metronidazole	200 mg/10 tabs	1.08	3.28	1.44	4.29	14.76	26.16
3 Ferrous Sulphate	150 mg/15 caps	0.10	1.41	0.55	4.21	—	4.61
4 Ibuprofen	200 mg/10 tabs	-0.23	0.82	0.68	.9	1.08	1.56
5 Propranolol HCL	10 mg/10 tabs	1.37	1.72	1.29	0.34	—	—
6 Salbutamol	2 mg/10 tabs	2.06	—	1.67	2.53	—	—
7 Nifedipine	10 mg/10 caps	4.28	5.43	-0.08		0.70	9.60
8 Cimetidine	200 mg/10 tabs	3.57	4.25	1.20	9.60	1.57	11.19

Source: OPPI.

Quated in Prasad and Butt, " Strengthening India's Patent system : Implications for Pharmaceutical Sector", *Economic and Political Weekly* , May22, 1993, p1037 at1046.

ANNEXURE-III

Illustrative List of Combinations under Patent in USA

Generic Name and Patent Expiry Year	Brand and Company Names	Dosage/ Formulations	Patent Expiry Date
Aspirin (1973)	SOMACOMPOUND.W. CODEINE Wallace Labs.	a) Aspirin 325 mg + Carisoprodol 200 mg + Codeine Phosphate 16 mg b) Aspirin 325 mg + Carisoprodol 200 mg	13/8/2002 13/8/2002
Diazepam (1980)	VALIUM Hoffman La Roche – – VALRELEASE	a) 10 mg tab b) 2mg tab c) 5mg tab d) 2 mg/ml inj. e) 15 mh Cap	23/2/1999 23/2/1999 23/2/1999 23/2/1999 23/2/1999
Diltiazem Hcl (1988)	CARDIZEM SR Marion Labs	a) 120 mg Caps b) 180 mg Caps c) 60 mg Caps d) 90 mg Caps	26/10/2005 26/10/2005 26/10/2005 26/10/2005
Hydrochlorothiazide (1979)	PRINZIDE - 12.5 Merck Sharpe & Dhome	a) 12.5 mg + Linosporil 20 mg tabs	30/12/2001
Methyldopa (1976)	ALDOMET Merck Sharpe & Dhome	250 mg/ml suspensio	13/09/2000
Norfloxacin (1996)	NOROXIN Merck Sharpe & Dhome	400 mg tabs	27.01.2004
Oxazepam (1984)	SERAX Wyeth Labs	a) 10 mg Caps b) 15 mg Caps c) 30 mg Caps	04/11/2003 04/11/2003 04/11/2003
Ranitidine Hcl (1995)	ZANTAC 150 ZANTAC 300 Glaxo	a) Eq. 150 mg base tab b) Eq. 15 mg base/ml syrup c) Eq. 25 mg base/ml inj. d) Eq. 300 mg base tab e) Eq. 50 mg base/ 100ml inj	5/12/1995 29/04/2003 29/04/2003 04/06/2002 29/04/2003

Source : FOI Services Inc., USA

Quated in B.K. Keayla,"TRIPS Agreement on Patent Laws: Impact on Pharmaceuticals and Health for All" a paper presented in International Conference on *Global Health Laws* organised by Indian Law Institute in collaboration with the World Health Organisation, New Delhi, December 5-7,1997.,at p.23.

ANNEXURE-IV

*[THE SCHEDULE

(See Sections 3 (d) and 11)

S. No.	Name of the disease, disorder or condition
1.	Appendicitis
2.	Arteriosclerosis
3.	Blindness
4.	Blood poisoning
5.	Bright's disease
6.	Cancer
7.	Cataract
8.	Deafness
9.	Diabetes
10.	Diseases and disorders of the brain
11.	Diseases and disorders of the optical system
12.	Diseases and disorders of the uterus
13.	Disorders of menstrual flow
14.	Disorders of the nervous system
15.	Disorders of the prostatic gland
16.	Dropsy
17.	Epilepsy
18.	Female diseases (in general)
19.	Fevers (in general)
20.	Fits
21.	Form and structure of the female bust
22.	Gall stones, kidney stones and bladder stone
23.	Gangrene
24.	Glaucoma
25.	Goitre
26.	Heart diseases
27.	High or low blood pressure
28.	Hydrocele
29.	Hysteria
30.	Infantile paralysis
31.	Insanity
32.	Leprosy
33.	Leucoderma
34.	Lockjaw
35.	Locomotor ataxia
36.	Lupus
37.	Nervous debility
38.	Obesity
39.	Paralysis
40.	Plague
41.	Pleurisy
42.	Pneumonia
43.	Rheumatism
44.	Ruptures
45.	Sexual impotence
46.	Smallpox
47.	Stature of persons
48.	Sterility in women
49.	Trachoma
50.	Tuberculosis
51.	Tumors
52.	Typhoid fever
53.	Ulcers of the gastro-intestinal tract
54.	Venereal diseases, including syphilis, gonorrhea, soft chancre, venereal granuloma and lympho granuloma.]

[a] Inserted by the Drugs and Magic Remedies (Objectionable Advertisements) (Amendment) Act, 1963 (42 of 1963), S. 11 (7-12-1963).

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