DEVELOPMENT OF DRUGS LEGISLATIONS IN INDIA

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ABSTRACT

The drugs play a vital role in the economic development of an individual country, so that several legislations have been enacted to regulate the manufacture, sale and distribution of drugs to protect the specialized knowledge, skill and experience of human being. And to promote the development, production, manufacture, possession, transport, consumption of all compounds investigated for use in human only a small fraction is eventually approved in most nations by the Government appointed medical institution or boards those have to approve new drugs before they can be marketed in those countries. There are chances of high pricing, objectionable advertisement, selling of adulterated and spurious drug in a country. Being the welfare and developing country India has its own obligations towards the peoples of India. For regulating all these issues government of India has passed the various Law for protecting public as well as inventors or pharmaceutical company's interest.

KEY WORDS: Drugs legislation, Intellectual property right, Pharmacy law, economic liberalization

Introduction

The new biotechnology, resulting from advances in molecular biology and genetic engineering, plays a crucial role in the dynamics of scientific and technological development in the contemporary world. In a global scenario where economic competition is increasingly driven by knowledge and innovation, the new developments in the pharmaceutical industry, resulting from biotechnology, has been extraordinary. In this scenario, recombinant vaccines and drugs have emerged as important breakthroughs, radically changing the strategies for prevention and treatment of a broad range of infectious and chronic diseases.

The introduction of these new regulatory barriers favoring unbalance in the international trade of life saving drugs has been supported by an international system for patenting life and life saving products, which has emerged after the Uruguay Round in 1984 and the creation of the World Trade Organization (WTO). The new IPR system introduced by the TRIPs (The WTO Agreement on Trade Related Intellectual Property Rights, signed in 1995) included pharmaceutical products as subject to patents, equivalent to any other product.

History of Drugs Legislation

In ancient Indian the sources of drugs were of vegetable, animal and mineral origin. They were prepared empirically by few experienced persons. Knowledge of that medical system was usually kept secret within the family. There were no scientific methods of standardization of drugs. During rule in the India, the system of medicine declined during the Muslim rule while the Arabic or Unani- Tibbi system flourished. During British rule in India, the western or so called Allopathic system came into India with British traders who later become the rulers. Under the British rule this system got state patronage. That time it was meant for the ruling race only. Later it descended to the people and become popular by the close of the 19th century.

According to one medical historian, Henry Siegerist, every culture has developed a system of medicine and medical history is but one aspect of the history culture. It must be a sound belief that the first doctor was the first man because he had to survive against so many odds like sickness and accident. Drugs and medicines developed out of necessity. In ancient society, service to the mankind was considered to be the service to the God and people were having a religious bent of mind. The drugs used those days were mostly the crude vegetable drugs and to a lesser extent those derived from mineral and animal origin; whatever was naturally available. Synthetic drugs and formulations were not known. Better drugs were evolved when

different systems of medicine developed. History of drug legislation in India can be divided into parts.

PRIOR 1940's

In India, the modern drug manufacturing has been started by the end of the 19th century with the setting up Bengal Chemical and Pharmaceutical Works in 1892, which was followed by the establishment of Alembic chemical work in 1907 and Bengal Immunity in 1919. In 1908 -09 the import and export of drugs amounted to Rs. 73 lakhs and Rs. 15.5 lakhs respectively. Drugs were mostly exported in crude form and imported in finished form. There was no control whatsoever on drugs and anything under the name of drugs could be made; sold or imported that might be completely devoid of any therapeutic agent. The pharmaceutical industry in India received a fillip during the First World War as the imports were completely cut off and the spirit of "Swadeshi" gained ground. Manufacture of Surgical dressing was established and the manufacture of sera and vaccines was also established towards the close of First World War. Imports of drugs were resumed after the World War I. In the absence of any restrictions on the quality of drugs imported, unscrupulous manufacturers abroad took advantage and flooded the Indian markets with adulterated and spurious drugs, which ultimately culminated in the 'great quinine fraud'. Sir Haroon Zaffer moved a resolution on March 9, 1927 in the Council "to take immediate steps to control the craze of medicinal drugs by legislation for standardization of the preparation and sale of such drugs".

In 1927 the Council of States adopted a resolution recommending to the Governor General in Council to urge all Provincial Governments to take medicinal drugs and to legislate for the standardization of the preparations and for the sale of such drugs. On May 3, 1928 the Secretary of the Indian Merchants' Chamber of Bombay wrote a letter to the Government of India stating "the attention of the committee of this chamber has been drawn to druggists in India of stocking drugs of inferior quality for sale. This has affected the pharmaceutical industry to a great extent.

The Government of India responded to a strong public opinion on the subject of drugs and in pursuance thereof, and that of the Resolution of 1927; appointed the Drugs Enquiry Committee Under the chairmanship of Col. R. N. Chopra and Dr. B. Mukherjee as its Assistant Secretary. The Committee finally recommended:-

1. Central legislation to control drugs and pharmacy. The legislation may consist of either a combined Drugs and Pharmacy Act or separate Drugs Act and the separate Pharmacy Act.
2. Setting up of test laboratories in all states to control the quality of drugs and pharmaceuticals and a control laboratory to control the quality of imported drugs and also to act as expert referee in case of disputed samples sent by local Governments.
3. Appointment of an Advisory Board to advise the Government in making rules to carry out the objects of the Act.

Unfortunately, this valuable document failed to move the Government to take immediate action, but in fact it succeeded in creating better public awareness about drugs trade and profession of pharmacy. It took almost a decade before the Drugs Act. 1940 was passed and practically another decade to pass the Pharmacy Act, 1948.

AFTER 1940's

Drugs Act, 1940: In 1940 a Bill was introduced by the Government of India to regulate the import, manufacture, distribution and sale of drugs. It was submitted to a select Committee and finally passed by the legislature on the 5th April, 1940, received the consent of the Governor General on 10th of April, 1940 and became the Drugs Act, 1940 (Act No. XXIII of 1940).

Health Survey and Development Committee: This Committee was appointed by the Government of India in October 1940 under the chairmanship of Sir Joseph Bhore to make a survey of the existing position in respect of health organization in the then British India and to make recommendations for future developments.

Pharmacy Act: The Pharmacy Bill was introduced by the Government of India in 1945 to regulate the profession and practice of pharmacy. The said Act was passed in the shape of Pharmacy Act, 1948 (Act No. VIII of 1948).

Current Scenario

Legislation in any field is based on the past experiences, present conditions and the future needs. Several amendments to Drugs and cosmetics Act, 1940 and the Rules, 1945 thereunder are sufficient to prove this fact.

The Narcotic Drugs and Psychotropic Substances Act, 1985 was long awaited and has repealed The Opium Act, 1857, the Opium Act, 1878 and the Dangerous Drugs Act, 1930. This Act is a timely piece of legislation. Now we will discuss all these legislations separately. The important milestone in drug legislation in India as follows:

1. 1857-1878- Opium Act,
2. 1919- Poison Act,
3. 1940- Drugs Bill introduced in Parliament and later amended to Drugs & Cosmetic Act,
4. 1946- Indian Pharmaceutical Codex.
5. 1947- The Indian Nursing Council Act.
6. 1948- The Pharmacy Act and The Dentists Act,
7. 1956- Essential Commodities Act,
8. 1970- Drugs Price control Order,
9. 1985- The Narcotic Drugs & Psychotropic Substance Act, and
10. 1986- Consumer Protection Act.

Indian Drugs Legislations

The Drugs and Cosmetic Act, 1940

The Drugs and Cosmetic Bill was passed by the Central Legislative Assembly and it received the assent of the Governor General on 10th April, 1940 and thus become the Drugs and Cosmetic Act, 1940. In relation to the state of Jammu and Kashmir, the chapter relating to imports of Drugs and Cosmetics shall take effect only from such date after the commencement of the Drugs and Cosmetic (Amendment) Act, 1972 as the central Government may, by notification in the official Gazette, appoint in this behalf. Various chapters of the Act come into force at various dates in various states. Presently the Drugs and Cosmetic Act extend to the whole of India. The Act has amended several times, mainly in 1960, 1962, 1972, 1982, 1986, 1995and 2008.

The Drugs and Cosmetics Act, 1940 have been passed with the objective of regulating the import, manufacture, distribution and sale of drugs and cosmetics. Cosmetics are although a luxury item, they may contain some Ingredients the constant use of which might prove to be harmful and hence need control. The Act regulates the manufacture and sale of drugs and cosmetic through licensing so that these are manufactured, distributed and sold only by qualified persons. To have a check on such operations the central and state drugs control authorities are established. Prior to the enactment of this Act, any drug or cosmetic could be imported into India and hence a drug banned in the country of origin could be easily imported and sold in India. Now no such Misbranded, adulterated or spurious drugs or drugs not of standard quality can be imported in India.

The Act is mainly concerned with standard and quality of drug manufactured in this country and controls the manufacture, sale and distribution of drugs. It has nothing to do with duties of excise and their imposition on narcotic drugs.[1]

The main object of the Act is to prevent standard in drugs, presumably for maintaining high standards of medical treatment. That's good certainly be defeated if the necessary concomitant of medical or surgical treatment were allowed to be diluted, the very same evil which the Act intents to eradicate would continue to subsist.

The provisions of this act are in addition to, and not in derogation of the Dangerous Drugs Act, 1930 (now NDPS Act) and any other Law for the time being in force.

The Act comprises five chapters and two schedules, including 38 sections. Chapter 1 deals with the introductory part of the Act. Chapter 2 of the Act establishes a Board of Technical Expert to advise the Central and State Government on the technical matters. Chapter 3 provides for the control of the import of the drugs in India. The executive Power under this chapter will be exercised by the Central Government. Chapter 4 relates to control of the manufacture, sale and distribution of drugs and contains the provisions relates to it.

The first schedule prescribes the standers to be complied with by importing drugs and the second schedule identical. The Central Government has the power to amend the first schedule,

[1] The Indian chemical and pharmaceutical works, Hyderabad V. the State of Andhra Pradesh, AIR 1996 SC 713 (717).

but power to amend the second schedule has rested with state government.

The Narcotics Drugs and Psychotropic Substance Act, 1985

India is a party to the three United Nations drug conventions – the 1961 Single Convention on Narcotic Drugs (1961 Convention), the 1971 Convention on Psychotropic Substances (1971 Convention) and the 1988 Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988 Convention). Domestic legislation to give effect to these treaties was introduced only in the 1980s, when the 'grace period' for abolishing non-medical use of cannabis and opium under the 1961 Convention expired.[2]

The Narcotic Drugs and Psychotropic Substances Act, commonly referred to as the NDPS Act, is an Act of the Parliament of India that was assented by President Giani Zail Singh on 16 September 1985, and came into force on 14 November 1985. The Narcotic Drugs and Psychotropic Substances Bill, 1985 was introduced in the Lok Sabha on 23 August 1985. Under the NDPS Act, it is illegal for a person to produce, manufacture, cultivate, possess, sell, purchase, transport, store, and, or consume any narcotic drug or psychotropic substance. The Act has been amended thrice - in 1988 and 2001 and most recently in 2014. The Act extends to the whole of India and it applies also to all Indian citizens outside India and to all persons on ships and aircraft registered in India.

The Act repeals the Opium Act, 1857, the Opium Act, 1878 and the Dangerous Drugs Act, 1930 while the Rules repeal the Central Opium Rules, 1934, the Dangerous Drugs Rules, 1957 and the Central Manufactured Drugs in addition to and not in derogation of the Drugs and Cosmetic Act 1940 or the Rules made there under. The Narcotic Drugs and Psychotropic Substances Act can be truly called a timely and progressive piece of legislation.

India had no legislation regarding narcotics until 1985. Cannabis smoking in India has been known since at least 2000 BC and is first mentioned in the Atharvaveda, which dates back a few hundred years BC. The recreational use of cannabis was common place in India until 1985. All cannabis derivatives (marijuana, hashish/charas and bhang) were legally sold. Most state governments had their own retail shops to sell these drugs. Their consumption was not regarded as socially deviant behavior, and was seen as similar to consuming alcohol. Ganja and charas,

[2] Charles, M., Bewley-Taylor, D. & Neidpath, A. (October 2005),Drug policy in India: Compounding harm?, The Beckley Foundation Drug Policy Programme, Briefing Paper Ten, http://reformdrugpolicy.com/wp-content/uploads/2011/10/Drug-Policy-in-India-CompoundingHarm.pdf

however, were often viewed as the poor man's intoxicant by the upper classes, although the people consumed bhang during Holi festival. Following the adoption of the Single Convention on Narcotic Drugs in 1961, the United States began campaigning for a global law against all drugs. However, India opposed the move, and withstood American pressure to make cannabis illegal for nearly 25 years. American pressure increased in the 1980s, and in 1985, the Rajiv Gandhi government buckled and enacted the NDPS Act, banning all narcotic drugs in India.

The Act was passed to 'consolidate and amend the law relating to narcotic drugs, to make stringent provisions for the control and regulation of operations relating to narcotic drugs and psychotropic sub-stances, to provide for the forfeiture of property derived from, or used in illicit traffic in narcotic Drugs and psychotropic substances, to implement the provision of the International Convention on Narcotic Drugs and Psychotropic Substances, concern matters.

The Act covers three broad classes of substances:

1. Narcotic drugs, that is, those covered under the 1961 Convention;

2. Psychotropic substances or those covered under the 1971 Convention as well as other psychoactive substances such as ketamine which are not yet classified under 3 international conventions; and

3. "Controlled substances"20 that are used to manufacture narcotic drugs or psychotropic substances, for example precursor chemicals such as acetic anhydride, ephedrine and pseudoephedrine.

Under this Act it is illegal for a person to produce, manufacture, cultivate, process, sell, purchase, trance port , store and or consume any narcotic drugs or psychotropic substance.

The Supreme Court commenting on the social object of the Act observed, "with deep concern, it may be pointed out that the organized activities of the underworld and the clandestine smuggling of narcotic drugs and psychotropic substances into this country and illegal trafficking in such drugs and substances have led to drugs addition among a sizeable section of the public, particularly the adolescents and students of both sexes and the menace has assumed serious and alarming propositions in the recent year. Therefore the parliament in its wisdom

has made effective provisions by introducing this Act[3].

NDPS Act consists of 6 chapters, including 83 sections**.** Chapter 1 deals with the preliminary area of Act and definitions, etc. Chapter 2 deals with authorities and officers. It empowers the Central Government to take all such measures as a deems necessary or expedient for the purpose of preventing and controlling abuse of narcotic drugs and psychotropic substances and the illicit traffic it also provides for the establishment of narcotic drugs and psychotropic substances consultative committee . The state government, such officers as it is thought fit for the purpose of the Act.

Chapter 2A provide for the establishment of national fund for control of drug abuse. Chapter 3 deals with prohibition, control and regulation it prohibits to cultivate or gathering any portion or COCA plant or cultivate the opium or any cannabis plant or produced, manufactured possess, sell, purchase, transport, store, consume, import and export any narcotic drugs and psychotropic substance including ganja.

Chapter 4 describes offences under the Act, and the punishments to be applied for contravening provisions of the Act. The various sections under this chapter prescribe a minimum term of rigorous imprisonment of 10 years, which may extend to 20 years for offenders, and also a fine which shall not be less than one lakh rupees but which may extend to two lakh rupees. In all cases, the court may impose a higher fine, for reasons to be recorded in the judgment. Chapter 5 deals with the procedure to be followed in case of any contribution of the provisions of this Act. Chapter 6 deals with miscellaneous provision of this Act.

Under one the provision of the Act the Narcotic Control Bureau (NCB) was set up. The NCB is the Chief Law enforcement and intelligent agency of India responsible for fighting drug trifling and abuse of illegal substances. It was created on 17 March, 1986 to enable the full implementations of NDPS Act, 1985 and fight its violation through the prevention of illicit trafficking in narcotic drug and the psychotropic substance Act, 1988.

The Prevention of Food Adulteration Act, 1954

[3] Durand Didier v. Chief Secretary, Union Territory of Goa, AIR 1989 SC 1966 at p. no.1971.

Food is the most fundamental requirement of all living organisms, including human being. It is the obligation of any Government that this essential commodity is made available to the public in a pure form, free from adulteration. The anti-social elements find it easy to adulterate the food materials for making quick money at the cost of user life. Although some of the adulterants may be harmless, most of them would inflict harm, either temporarily or permanently, or even cause the death of the user.

Foods and drugs are generally controlled through common administrative machinery i.e. Food and Drug Control Administration (FDA) in various States.

The Act passed in 1954 and came into force on the first June 1955. It extends to the whole of India. The Act has now been extended to the State of Jammu Kashmir by virtue of the Prevention of Food Adulteration (Amendment) Act, 1971, section 2. Further, it has come into force in that State with effect from 26 January 1972.

The Prevention of Food Adulteration Act 1954 is an Act to make provisions for the prevention of adulteration of food. The name of the Act clearly indicates of objects of the enactment of this Prevention of Food Adulteration Act 1954 and therefore it is clear that the government has decided to root out the evil of adulteration in food articles.

The Act consists of five Chapters and 25 sections. Chapter 1 deals with preliminary. Chapter 2 provides the establishment of the Central Committee for Food Standards and central food Laboratory. It empowers the central Government to constitute a Central Committee for Food Standard to advise the central and state Government on matters arising out of the administration of the Act. Further, the central government may establish one or more central food laboratory to carry out the functions under this Act.

Chapter 3 deals with General Provision as to food. It prohibits the importation of food items and also prohibits manufacture, sale, etc. of adulterated food items.

Chapter 4 describes analysis of food. The Central and State Government may appoint two types of analysts namely, public analyst and food inspector for local area assigned to them. This chapter further describes the power, procedure and duties of these analysts.

Chapter 5 deals with miscellaneous provisions regarding as coloring matter of the food, preservatives classification, other food additives and standards of quality for various categories of food articles.

The Patent Act, 1970

A patent is a monopoly right granted to a passim who has invented a new and useful article as to improve of an existing article or a new process of making on articles. Patents provide rewards and protection for inventor, but they also benefit society. In return for patent protection, inventors agree to reveal all the technical information about their inventions.

The Patents Act, 1970 came into force on 20 April 1972. It extends to the whole of India. The Patents Act, 1970 highlights the inventions that satisfy the universally accepted requirements of patentability, such as novelty, inventive step and industrial application. There are no sue generis system for the grant of Patent in the field of pharmaceutical, medicines and drugs. These are also regulated by the same procedure as other field's innovations. But prior to the passing of the Patent (Amendment) Act of 2005, section 5 the patents Act, 1970 provides only process patents in the field of pharmaceutical for a very short period 5 to seven years. But to comply with the TRIPs agreement of which India is signatory, the Patents Act, 1970 had undergone several amendments in 1999, 2002 and finally 2005 with introduction of product Patent in substances capable of use as medicine and drugs. This area is already mentioned in chapter 2 in details.

The main object of the Patent Law is to promote economic growth by harnessing the inventiveness and science and technology for economic development. As we have discussed above in chapter 1 and 2, section 83 of the Patents Act, 1970 provides for the general principles applicable to working of patented inventions. In the area of pharmaceutical once a drug has been discovered, developed and marketed by a firm, other firm can produce and sell the drug at a price that is considerably lower than that of the innovation since their price need not include the cost of R&D or the cost of creating the market. Thus, if there are no restrictions on market entry later entrants may have a significant competitive advantage. In view of these facts, research intensive pharmaceutical firms consider patent protection as a prerequisite to innovation. Thus patent secures individual interest (innovator) with a view to ensure societal interest also.

The Patents Act, 1970 consist of 23 chapters and 1 schedule, including 163 sections. Many sections have been repealed by the various amendments Act. Chapter 1 deals with introductory the part of the Act. Section 2 of the Act runs with various definitions a interpretations included inventions, inventive step, Patent, new invention, pharmaceutical substances etc.

Chapter 2 deals with inventions which are not patentable namely inventions against public policy or a known invention or methods of treatment or tradition knowledge or the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or inventions relating to atomic energy are not Patentable.

Chapter 3 to 8 deals with the procedure of granting of Patents as we have discussed in chapter 1 of this work.

Chapter 12 deals with the surrender and revocation of the patents, a patentee may at any time by giving notice to the controller, offer to surrender his patent. Section 64 describes the condition when a patent can be revoked.

Chapter 16 provides about working of Patents, compulsory licenses and its revocation. Father the chapter gives direction about the general principles applicable to working of patented inventions. Section 84 deals with CL.

Chapter 17 deals with the Governmental use and acquisition of invention by Central Government. A Patent has a same effect against the Government as against any other person, but the Government can use the invention in specified circumstances.

Chapter 18 provides for suit concerning infringement of the patents. Infringement of the patent is the violation of monopoly rights conferred by the grant. Chapter 19 deals with appeal to the Appellate Board and chapter 22 with International Arrangement. Section 133 tells about Conventional Countries. Chapter 23 runs miscellaneous provisions of the Act.

The Poisons Act, 1919

Special provisions are needed to deal with the substances that are poisonous. Earlier the schedule E to the Drugs and Cosmetics Rules, 1945 enlisted the poisons, but the same has been dropped in the 1982 amendment to the said Rules. The poisons Act, 1919 was passed on 3rd September, 1919. The Act of 1919 replaced the position Act of 1904 which was intentionally limited in this scope to restrict interference with legitimate industries as much as possible, but

it was proved by experience that the control afforded by the Act of 1904 over the traffic in poisons was inadequate. The Act of 1919 was passed with the object of tightening the control over traffic in poisons. The Act extends to the whole of India but is not applicable to the State of Jammu and Kashmir except to the extent to which the provisions of this Act relate to the importation of any specified poison into India.

The poison Act 1919 is an Act to consolidate and amend the Law regulating the importation, possession and sale of poison.

The poison Act, 1919 consist of 10 Sections. According to the provision of this Act Central Government has been empowered to regulate the importation of poison into India and may prohibit the importation of any specified poison across and defined costumes frontier into India. The various State Governments have been empowered to make rules regarding the possession and sale of poison within their respective territories. The term poison has not been defined under the Act, but any substance specified as a poison in a rule made or notification issued under the Act is deemed to be a poison for the purposes of this Act.

The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954

During these days of competition, advertising has become a part of our life and hence the modern age may be called the advertisement era'. Advertisements have occupied such a position in our life that it has become impossible to imagine living without them. The media for advertisement has made enormous progress and newer methods are being evolved continuously. Advertising one's own merits, about fifty years ago was never appreciated, but now the position is quite different. Modern methods of advertising like TV and internet have proved to be very effective. Drugs and cosmetics manufacture are often blamed for spending exorbitantly on advertising their products. This however has become necessary for their existence and further growth, although drugs are essential commodities which one has to take without option. Ethical advertising is never objectionable, but when the advertising is misused it may cause harm to the user of the advertised goods or materials. This is the point for which the Drugs and Magic Remedies (Objectionable Advertisement) Act was passed.

The Act as well as rules came into force on first April 1955 and were amended in 1963. It extends to the whole of India except the state of Jammu and Kashmir and applied also to persons domiciled in the territories to which this Act extends who are out sides these Act territories.

In India it is a common practice that in the streets in the streets in any city some persons might be selling some magic remedies like kavachas mantras, talismans etc. which are claimed to be a universal cure for any disease, etc. Similarly, one may find advertisements in the magazines, newspapers and on the premises of certain doctors, hakims or voids (so called) claiming cure of diseases for which no drug or no treatment is yet available. Innocent people always fall in the trap of such unsocial elements and waste their time; money and worse of all, spoil their health and sometimes forced to leave this world prematurely.

These advertisements tents to cause the ignorant and the unwary to resort to self-medication with harmful drugs and appliances, or to resort to quacks who indulge in such advertisements for treatments which cause great harm. It is necessary in the public interest to put a stop to such undesirable advertisements.

The Drugs and Magic Remedies Act, 1954 was passed with the objective of controlling the advertisements of drugs in certain cases, to prohibit the advertisements for certain purposes for remedies alleged to possess magic qualities and to provide for related matters.

The Act consists of 16 sections and 1 schedule. According to the provision of the Act, no person can take part in the publication of any advertisement referring to any drug in terms which suggest for the procurement of miscarriage in women, or prevention of conception in women, or improvement of the capacity of human beings for sexual pleasure, or correction of menstrual disorder in women or diagnosis, cure, treatment of any dieses disorder specified in the schedule of Drugs and Cosmetics Act, 1914. Further import and export of all the above mentioned advertisement is also prohibited. Further, it provides for offences and penalties of the Act and Rules made there under shall be punishable with imprisonment up to six months or with fine or both on first conviction and imprisonment up to one year or fine or both of any subsequent conviction.

Since the scene has changed to a considerable extent over the period of time, so also the legislation affecting the drugs trade and pharmaceutical profession. It is a common principle of law that ignorance of law is no defense. Thus the responsibility of doing anything contrary to the provision of law, even ignorantly, is no excuse, although the law always takes cognizance of the intention or moto behind every act or omission. In general, it is also desirable that every citizen be familiar with the law of the land so that he may appreciate his duties and assert his right as a good citizen.

Development of Law in general hand, those related to drugs and pharmaceutical in particular cannot be looked into in isolation. Development of a forensic pharmacy runs parallel to the development of mediation.

CONCLUSION

The need for economic liberalisation in India was recognized after facing severe balance of payment crisis in 1991. It was observed that many countries of East Asia have achieved high growth and poverty reduction through policies focusing on encouraging private sector and export orientation. This led to shift in economic policy of India. The neo liberal policies included opening for international trade and investment, deregulation, initiation of privatization, tax reforms, and inflation-controlling measures. The objective of the government was to transform the economic system from socialist to capitalist.

There are so many legislation have been passed by the Government India and various amendments have been made. However, it must be remembered that whatever amendments are made, will not serve the purpose unless they are strictly enforced and this is where the problem lies. Even today the misbranded, spurious and adulterated drugs are sold and objectionable advertisements are made. Drugs control departments in the States are ill-equipped and sometimes lead by persons who may have no qualification and experience in pharmacy. Legal proceedings are very slow. If necessary, special courts should be set up to deal with the cases under the Drugs and Cosmetics Act and Rules so that the cases are decided within a reasonable time. On the whole the Drug legislation in India has been progressive.