

5.1. INTRODUCTION :

The Act was passed on 1st April, 1955 and was amended in 1963.

5.2. OBJECTS (PURPOSE) :

- (1) To control the advertisement of drugs :

The advertisement of consumer goods is made directly to the consumer, but advertisement of drugs should be addressed to Medical / Pharmaceutical / Nursing profession and not to patient. As drugs are toxic and advertisement **provokes self-medication**.

- (2) To prohibit the advertisement for certain purposes of remedies alleged to possess magic qualities:

In India there is another problem regarding charms and magic remedies, in addition to the remedies for venereal diseases and sexual disorders. The Act was enacted to prohibit such kinds of advertisements relating drugs and magic remedies which makes false claims and mislead the public.

5.3. DEFINITIONS :
ADVERTISEMENT :

Matter which is published for payment or other valuable consideration and which draws the attention of the public to a product in a manner to promote that product. It includes any notice, circular, label, wrapper, or other document and any announcement made orally or by means of producing or transmitting light, sound or smoke. OR through electronic media inclusive of internet.

It excludes those communication addressed to medical and pharmaceutical professional personnel.

(2) **MAGIC-REMEDY :**

It includes a talisman, Mantra, Kavacha and any other form of any kind which is alleged to possess miraculous

powers for or in the diagnosis, cure, mitigation, treatment or prevention of any diseases in human beings or animals or for affecting in any way the structure or any organic function of the body of human beings or animals.

(3) **VENEREAL DISEASES :**

It includes Syphilis, Gonorrhea, Soft chancre, Venereal granuloma and Lymphogranuloma.

5.4. PROVISIONS OF THE ACT :

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| (i) Prohibited Advertisements |
| (ii) Prohibition of Import and Export of Certain Advertisements |
| (iii) Exempted Advertisements |
| (iv) Exempted Advertisements with Conditions |
| (v) Code of Ethics for Advertisement |
| (vi) Offences - Penalties |

(1) **PROHIBITED ADVERTISEMENTS :**

The following classes of advertisements are prohibited to advertise :

(1) **Advertisements relating to drug which are use in the following conditions (diseases) :**

- The procurement of miscarriage or prevention of conception in women.
- The maintenance or improvement of the capacity of human beings for sexual pleasure.
- The correction of menstrual disorder in women.
- For the diagnosis, cure, mitigation treatment or prevention of any disease, disorder or conditions specified in schedule 4 (Incurable diseases - Refer Drugs and Cosmetics Act).

(2) **Misleading Advertisement :**

Advertisements which directly or indirectly give false impression regarding the true character of the drug or make any false claims.

- (3) Advertisement relating to magic remedies claiming their efficacy for the schedule-J drugs.

An advertisement of drugs :

- (4) contain statements which are considered to be offensive to good taste or are misleading.
- (5) be designed to arouse unwarranted expectations of product effectiveness.
- (6) mislead with regard to safety, usage or immediacy of relief.
- (7) be derogatory to other competing products.
- (8) allow statements, which create fear or apprehension in the public mind such as a person may suffer from an ailment by not using a particular product.
- (9) allow offer of rewards or other inducement leading to excessive use of drug by a consumer.
- (10) give an impression that a medical consultation or surgical operation is unnecessary.
- (11) refer to or imply reference to the statutory bodies like Drug Control Authorities, Medical Council, Dental Council, Govt. Laboratories etc.
- (12) include products, which are required to be sold only against prescriptions written by a registered medical practitioner.
- (13) contain a claim which makes reference either directly or indirectly or by implication to the diseases mentioned in the Schedule J to the Drugs and Magic Remedies (Objectionable Advertisements) Act 1954, and the Rules made thereunder.
- (14) make any claim or statement that it is a universal panacea, infallible, unfailing, magical, miraculous, a certainty, guaranteed or sure cure.
- (15) imply that it is recommended by health professionals i.e., medical practitioners, psychologists, dentists, nurses, pharmacists, practitioners of Ayurvedic Siddha, Unani or Homeopathic system of medicine, unless scientifically substantiated.

- (16) Advertisement for non prescription systemic analgesics/painkillers shall carry a warning "use only as directed". This must be clearly visible or audible or legible (as appropriate, depending upon the medium of advertising).

- (17) An advertisement for Vitamins preparations and Tonics shall not infer that such products are a substitute for good nutrition or could replace a balanced diet.

(II) PROHIBITION OF IMPORT AND EXPORT OF ADVERTISEMENT :

The above classes of advertisements mentioned above are prohibited to be either exported from or imported into India.

(III) EXEMPTED ADVERTISEMENTS :

The following classes of advertisements are exempted from the provision of the prohibitions.

- (1) Any signboard or notice displayed by a Registered Medical Practitioner on his premises indicating that treatment is undertaken for any disease, disorder or conditions.
- (2) Books or Treatises dealing with the diseases published from bonafide scientific or social standpoint.
- (3) Advertisement relating to drugs which are sent confidentially to R.M.P. it should bear the following words on top "For the use of R.M.P. only".
- (4) Any advertisement relating to a drug printed or published by the government.
- (5) Any advertisement relating to a drug printed or published by any person with previous permission of government.
- (6) Labels or sets of instruction send with package of product which are permitted under Drugs and Cosmetics Act.

(IV) EXEMPTED ADVERTISEMENTS WITH CONDITIONS (Notification issued in 1967)

The following classes of advertisements have also been exempted from the provisions of the Act, provided the conditions are complied with :

ADVERTISEMENTS	CONDITIONS
(1) Leaflet OR literature send with Packaging OR Advertisement of drugs in Medical, Pharmaceutical Scientific Technical Journal.	(1) (a) Advertisement should contain only such information which are required for guidance of R.M.P. Such as : * Therapeutic Indications * Route of Administration * Dose * Side effects * Precautions. (b) It shall be the responsibility of the advertiser to prove that any claim made in the advertisement in respect of the drug is not false, exaggerated or misleading.
(2) Price List OR Therapeutic Index published by manufacturer, importer OR medical literature distributed by medical representatives.	(2) (a) Advertisement should contain only such informations which are required for guidance of R.M.P. Such as : * Therapeutic Indications. * Route of Administration. * Dose * Side effects * Precautions

	(b) The distribution of such literature is limited only to R.M.P. Hospital, Dispensary, Medical and Research Institute. (c) It shall be responsibility of the advertiser to prove that any claim made in the advertisement in respect of the drug is not false, exaggerated or misleading.
(3) Advertisement of chemical contraceptives for oral use.	3. (a) The composition per tablet should be : → <u>DL-Norgestrel</u> - 0.30 mg → <u>Ethinylestradiol</u> - 0.30 mg OR → <u>Levo-norgestrel</u> - 0.15 mg → <u>Ethinylestradiol</u> - 0.03 mg → <u>Centehroman</u> - 0.30 mg (b) It shall be the responsibility of the advertiser to prove that any claim made in the advertisement in respect of the drug is not false, exaggerated or misleading.

(V) CODE OF ETHICS FOR ADVERTISEMENT OF DRUGS : MODEL GUIDELINES :

The text of document finalised by the Subcommittee on Code of Ethics for Advertisement of Drugs under the Directorate General of Health Service (D.C. Section) as received from Dr. Ashwini Kumar, Jt. Drugs Controller (India)

[under letter no. X-110 24/1/98-DC dated 17-2-98]] is reproduced here. (The draft code was published in IDMA Bulletin issue no. 48 dated 31-13-98)

CODE FOR ADVERTISING OF DRUGS IN INDIA :

Preamble :

1. The object of this Code is to ensure responsible advertising in promoting the sale of medicines which may be purchased by the public without prescription and for which therapeutic claims are made.
2. While evolving the Code, the following have been taken into account : *Recommendation of the Committee on Drugs and Magic Remedies, 1954; Code of Medical Standards of Indian Newspaper Society as appearing in its publication: "Rules Governing Accreditation of Advertising laid down by Prasar Bharti."*
 - (a) World Health Organisation "ethical Criteria for Medicinal Drug Promotion 1988." In particular "advertisements in all forms to the general public."
 - (b) Advertisement ethics and code of Medical Standards of Indian Newspaper Society as appearing in its publication: "Rules Governing Accreditation of Advertising laid down by Prasar Bharti."
 - (c) Code for commercial advertising laid down by Prasar Bharti.
 - (d) Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 and Rules made thereunder.
 - (e) Guidelines for Voluntary Codes of Advertising Practices - laid by World Federation of Proprietary Medicines Manufacturers.
 - (f) Organisation of Pharmaceuticals Producers of India (OPP) guidelines on "IFPMA Code on Pharmaceutical Marketing Practices."
 - (g) Indian Drug Manufacturer's Association (IDMA) Guidelines on "Pharmaceutical Marketing Practices."

Self-medication is an important element in health care. Advertising of medicinal products to the general public ought therefore to satisfy certain essential ethical criteria. Advertisement, besides being an important promotional tool in modern day trade and commerce, serves people's legitimate

desire for information concerning their health and help people make rational decisions on the use of medicines which are legally available without prescriptions or what is commonly known as "over the counter (OTC) drugs." This code does not imply that advertisers are restricted in any way in using the advertising media as a means of education and dissemination of information to public in general.

Pharmaceutical industry being the primary source of information about its products has the responsibility to ensure that medicinal products belonging to any system of medicine are advertised in a responsible manner conforming to the principles set out in this Code. The industry associations as well as individual pharmaceutical manufacturing/marketing firms are advised to adopt the guidelines set out in this Code, for the commercial advertising of their products.

This code may form the core component of the ethical guidelines, which may be formulated by individual industry associations and the media etc.

(VI) OFFENCES - PENALTIES :

OFFENCES	PENALTIES
(1) Any one who contravenes any provisions by taking part in prohibited advertisements.	(1) (a) Six months imprisonment or fine or both on first conviction (b) One year imprisonment or fine or both on any subsequent conviction.

SCHEDULE TO THE ACT :

There is Schedule-'3' which comprises list of diseases, conditions which are incurable.

Refer - Drugs and Cosmetics Act and Rules-Chapter 4.

THE NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES ACT-1985

6.1. INTRODUCTION :

In the ancient time, the systems of medicine were based on natural drugs. **coca, opium and hemp**, though excellent drugs, but they are **habit forming**. People were used these drugs freely to satisfy their addiction and luxury as they caused hallucination. Though they are powerful drugs, they are injurious to health. Excessive use of them causes physical and mental injury, producing moral weakness and lack of sense of self respect.

The addicts are not useful to the society, but they are burdensome to the society.

In view of the degenerative effects of these drugs, governments of different countries restrict their use to bonafide medical purposes only.

The cultivation of poppy (opium) was brought under control in India in 1857, and this was supplemented by Opium Act 1878. With the confirmation of Geneva Convention the Dangerous Drugs Act, 1930 was passed by the Indian Legislature.

In spite of these laws, there is ever increasing number of addicts in all corners of the world. Secondly, number of other materials derived from nature as well as synthetic substances having addictive qualities began to be used. With reference to Opium Act and Dangerous Drugs Act, the penalties charged in India were very low as compared to other countries. So to make stringent and uniform provisions exemplary (increased) punishment was provided for most of the offences. To curb the same effectively the **Narcotic Drugs and Psychotropic Substances Act 1985** was passed. This Act repealed the two Opium Acts (1857, 1878) and the Dangerous Drugs Act-1930.

6.2. OBJECTS :

- (1) To consolidate (strengthen) and amend the law relating to narcotic drugs.

- (2) To make stringent and uniform provisions for the control and regulation of operation relating to narcotic drugs and psychotropic substances.
- (3) To implement the provisions of the International Conventions on Narcotic drugs and Psychotropic Substances.
- (4) The Act provide for the most of the offences, a minimum term of imprisonment and minimum amount of fine. So once an offence is proved, the court has no option but to award at least the minimum penalty.
- (5) The present Act provide for investing (Authorised) the officers - Narcotics, customs, central excise etc. power of investigation of offences.
- (6) The prevention of illicit Traffic in Narcotic Drugs and Psychotropic substances. (ordinance-1988).

6.3. DEFINITIONS :

- (1) **ADDICT** : Means a person who has dependence on any narcotic drug or psychotropic substance.

(2) **CANNABIS (HEMP) : Means**

- (a) **CHARAS** : That is the separated resin in the crude or purified state obtained from cannabis plant and also includes concentrated preparation and resin known as Hashish oil.
- (b) **GANJA** : It is flowering or fruiting tops of the cannabis plant and (Excluding the Seeds and Leaves)
- (c) Any mixture with or without any neutral material of any of above forms of cannabis or any drink prepared therefrom.

CANNABIS PLANTS :

Any plant of the genus "Cannabis".

(3) **HEMP :**

Leaves, small stalks and flowering and fruiting tops of Cannabis Sativa and all its forms known as 'Bhang', 'Ganja' or 'Sidhi' or the resin obtained from the plant known as 'Charas' and all their mixtures with or without any neutral materials including drinks made from them.