

Review Research Paper

The Critical Appraisal of Drug Advertisement Directly to Consumers: A Mockery of Drugs and Magic Remedy (Objectionable Advertisements) Act

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Abstract

Media has a profound effect over masses to shape and mould the ideas regarding any product. Thus it is an essential tool for mass awakening and welfare of the public at a large. But regarding drugs this tool of advertisement should be used very meticulously. If pharmaceutical companies are allowed to advertise the drugs, then it leads to increase in self medication and the society has to face the menace of adverse effects for long lasting time. Despite the existing legislations banning the advertisement of drugs in certain diseased conditions, lucrative advertisements of drugs and medical remedies are freely flowing in the Indian mass media nowadays. These advertisements allure the vulnerable consumers thus increasing the threat of self medication in the society.

Through this article it is tried to critically appraise the advantages, disadvantages and remedies regarding direct to consumer drugs advertisement.

Key Words: Drug Advertisement; Drug and Magic Remedy Act; Critical Appraisal, OTC, DTCA

Introduction:

Advertisement is meant to attract or made aware the customers to purchase the products of the company. Direct to Consumer Advertising (DTCA) involves promoting products directly to consumers by the use of popular media. [1] Advertisers have used the traditional mass media as radio, television, newspapers, magazines, and billboards to send their messages and now-a-day's these are largely being added by network marketing, home to home advertisement, Internet advertising and cell phones. In our view, it is responsibility of the state to check that the advertisement should be free from obscenity and also to preserve customer rights to purchase the genuine product.

Thus the state has three fold responsibility, first is to prevent the obscenity in the adds so as to preserve the values and culture of the society. Secondly to secure the customers rights by preventing wrong or placebo medical gadgets into the hands of customer.

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Thirdly, to observe strict rules of advertisement regarding drugs to prevent people from self-medicating regard to various diseases and conditions.

Historical Perspective of Advertisement of Drugs and Magic Remedies:

In 1927, in view of the clandestine behavior of the fake medical practitioner, a resolution was adopted by then Council of State recommending to the Central and Provincial Governments to take immediate measures to control the indiscriminate use of medical drugs and for standardisation of the preparation and for the sale of such drugs. Thus the process of regularizing control over drugs initiated for first time in India in pre independence era.

In August 1930, the Government of India appointed the Drugs Enquiry Committee with Sir R. N. Chopra as its Chairman, [2] This Committee made a report pointing out the necessity of exercising control over import, manufacture and sale of patent and proprietary medicines in the interest of the safety of the public and public health. [3]

The Chopra Committee Report also dealt with the popularity of the patent and proprietary medicines in the following words: "The pride of place must be accorded to ingenious propaganda clever and attractive dissemination of their supposed virtues and wide and alluring advertisements.

Perusal of the advertisements of cures' produces a great effect on patients who have tried treatment by medical men without success. Widest publicity is given to these and the preparations become invested with miraculous virtues. The reassurances of cure, the force of argument advanced to guarantee it and the certificates of persons said to have been cured which are all set out in advertisements make a deep impression, especially on those with weak nerves. As a result the 'Drugs Act' was passed in 1940. [3] This is followed by 'Pharmacy Act' in 1948. [4]

The Bhatia Committee in 1953 reported that there were a large number of objectionable advertisements in the Press in regard to patent medicines. The Indian Medical Association had also suggested the barring of advertisements of medicines which claim to cure or alleviate any of the diseases specified by them. [3]

At present the Acts and Rules made there under that govern the manufacture, sale, import, export and clinical research of drugs and cosmetics in India are:- The Drugs and Cosmetics Act, 1940, The Pharmacy Act, 1948, The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954, The Narcotic Drugs and Psychotropic Substances Act, 1985, The Medicinal and Toilet Preparations (Excise Duties) Act, 1956, The Drugs (Prices Control) Order 1995 (under the Essential Commodities Act) [4-6, 16-18]

Concise Outlook of the Legislations to Control Advertisement of Drugs:

The Drugs and Magic Remedy (Objectionable Advertisements) Act, (DMRA) 1954 [5] has been enacted with a view to control the advertisements of drugs in certain cases and to prohibit the advertisements for certain purposes of remedies alleged to possess magic qualities.

Section 3: deals with the prohibition of advertisement of certain drugs for treatment of certain diseases and disorders.

Subject to the provisions of this Act, no person shall take any part in 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 improvements 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,

disorder or condition (by whatsoever name called) which may be specified in the rules made under this Act; The schedule in the Act specifies the diseases and conditions namely mentioned in Table 1

Section 4: Prohibition of misleading advertisements relating to drugs. Subject to the provisions of this Act, 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 the true character of the drug; or (b) makes a false claim for the drug; or (c) is otherwise false or misleading in any material particular.

Section 5: Prohibition of advertisement of magic remedies for treatment of certain diseases and disorders. No person carrying on or purporting to carry on the profession of administering magic remedies shall take any part in the publication of any advertisement referring to any magic remedy which directly or indirectly claims to be efficacious for any of the purposes specified in Section 3.

Section 6: Prohibition of import into, and export from India of certain advertisement. No person shall import into, or export from, the territories to which this Act extends any document containing and advertisement of the nature referred to in Section 3, or Section 4, or Section 5, and any documents containing any such advertisement shall be deemed to be goods of which the import or export has been prohibited under Section 19 of the Sea Customs Act, 1878.

Rule 106 of DCA [6] stated that (1) No drug may purport or claim to prevent or cure or may convey to the intending user thereof any idea that it may prevent or cure, one or more of the diseases or ailments specified in Schedule J. (2) No drug may purport or claim to procure or assist to procure or may convey to the intending user thereof any idea that it may procure or assist to procure, miscarriage in women.

Diseases and ailments (by whatever name described) which a drug may not purport to prevent or cure or make claims to prevent or cure as stated in schedule J in addition to schedule of DMRA are as mentioned in [Table 2]

Similarly Sections 17, 17 A, and 17 B of the Drugs and Cosmetic Act 1940 defines Misbranded drugs, Adulterated drug and Spurious drugs respectively.

Over the counter OTC Drugs and Distance selling and teleshopping of non-prescription medicines [7]: OTC Drugs means drugs legally allowed to be sold "Over the Counter" by pharmacists, i.e. without the

prescription of a Registered Medical Practitioner. OTC has no legal recognition in India, the drugs which are not included in the list of "prescription-only drugs" in Schedule G, H and X are OTC drugs.

OTC drugs registered as Ayurvedic Medicines (i.e. traditional Indian system of medicines containing natural/ herbal ingredients) do not require a drug prescription to sale.

Distance selling and teleshopping of non-prescription medicines is not permitted in India as the sale of drug products can only take place through licensed stores. [7]

Judicial View:

In *Hamdard Dawakhana (Wakf) Lal ... vs. Union of India and Others* on 18 December, 1959 [3] the constitutionality of the Drugs and Magic Remedies Act was challenged pleading that advertisement is a fundamental right of every Indian citizen.

The judiciary opined at that time that, the object of DMRA [5] was the prevention of self-medication and self-treatment by prohibiting instruments which may be used to advocate the same or which tended to spread the evil. Its object was not merely the stopping of advertisements offending against morality or decency.

The provisions of the Act which prohibited advertisements commending the efficacy, value and importance in the treatment of particular diseases of certain drugs and medicines did not fall under Art. 19(1) (a) of the Constitution (which is the right of citizen to speech and expression).

The provisions of the Act were in the interests of the general public and placed reasonable restrictions on the trade and business of the petitioners and were saved by Article 19(1) (g) (which is the right to practice any profession, or to carry on any occupation, trade or business).

Thus it is not fall within the purview of freedom of speech and freedom and to carry on trade or business and the constitutional validity of the act is upheld.

In *Tata Press Limited vs. Mahanagar Telephone-Nigam ...* on 3rd August, 1995 [8] court opined that the *Hamdard Dawakhana's* case was dealing with advertising of prohibited drugs and commodities. The Court came to the conclusion that the sale of prohibited drugs was not in the interest of the general public and as such "could not be a speech" within the meaning of freedom of speech and expression under Article 19(1) (a) of the Constitution.

Areas of Drugs Advertisement Advantages as Propagated by Pharmaceutical Companies:

Switch over to OTC drugs: There are many products with minimal side effects in the prescription drugs (Rx) category like drugs for aches, cough, colds, hyperacidity, indigestion, for minor cuts, wounds and burns, muscle pains and sprains, constipation etc. [7] These drugs to be switch over to OTC drugs category.

It would act as a tool for reducing health care cost. Many countries worldwide have rules and regulations of such transferring but India does not have any such process or legislation.

But still no such need is arises because, practically all prescription drugs can be purchased without a prescription from many pharmacies. And in many instance Doctor's influence is strong in patients purchase behavior. [7] In our view, such permission for OTC should be given only under the reasonable restriction that advertisement directly to consumers is not allowed. If at all permission for OTC is given then it should be allowed only in remote areas where availability of the physician is scarce.

Promotion of responsible self-medication: Traditionally medical journals and medical representatives marketing their drugs to physicians are the only sources of advertisement. However, in 1997 the Food and Drug Administration (FDA) issued new guidelines making it easier for pharmaceutical companies to advertise few prescription drugs on television, print media as well as on the Internet. [1] It is thought to be source of quality patient information.

Direct to Consumer Advertising (DTCA) [1, 9]: If DTCA of prescription drugs are properly used, then it would be a good source of health information to a public at a large.

It would be helpful to early diagnosis, better therapy and improved patient compliance in the acute phase as well as in the continuation phase of the treatment.

But in our view advertisement of any medical information beneficial for public welfare should be in the strict control and supervision of the government agencies and the state should disseminate information of any drug regarding its generic contents in mass media sparing its brand name.

Foods Standard and Safety Act (FSSA): This law was passed in 2006 by Indian Parliament, but guidelines were not in place. Food Standards & Safety Act will finally include guidelines that clearly state which supplements

can be classed as foods instead of drugs, allowing mass market sale.

These guidelines will remove ambiguities and could encourage more pharmaceutical companies to move into OTC, food companies to move into functional foods and cosmetic companies to shift to cosmaceuticals, all under the wellness umbrella. [7] This is really a good step and such guidelines to be implemented immediately.

Areas of Drugs Advertisement Disadvantages:

The advertisements flowing in the market are not accurate, fair, balanced or truthful and are focusing only on the advantages of the drugs curbing their disadvantages. [1, 10] It promotes inappropriate use of prescription drugs, or diverts consumers from better alternatives. [1] Many a time a newly introducing drug with remote ill effect or side effects after a long period or the drug whose side effects are not fully known, might come into the hands of innocent consumers. [1]

Also the consumer will unnecessarily lure towards the costly medicine only due to impact of brand drug advertisement, although the better and cheaper alternatives are available in the market. [1] Further, higher medicine costs leads to higher overall health care costs through substitution of new, expensive drugs without treatment advantages. [1]

If the sale increases mainly due to advertisement then the main expenditure incurred by the pharmaceutical companies will be on advertisement, sidelining the expenditure over drug research and development.

However, many minor ailments do not require medical treatment at all and ones own immunity take care of such conditions. But, the innocent consumer starts consuming drugs for such ailments and falling prey to self medication and unnecessary economic burden.

Direct to Counter (DTC): DTC is prohibited for Schedule H and Schedule X drugs. DTC product promotion is permitted for Ayurvedic proprietary medicines and for homeopathy drugs but sparing the diseases mentioned in schedule of DMRA and schedule J of DCA.

However due to lack of strict implementation of laws the Indian consumers are constantly exposing to the advertisement of prescription as well as non prescription drugs and the drugs of diseases as banned by DMRA and DCA thus increasing the menace of unnecessary self medication. [1]

But there should be strict implementation of laws in regard to DTC; and in

spite of shouldering the whole responsibility to FDA a separate cell to be established immediately to keep vigilance over such illegalities.

As per the code of conduct as laid down by Medical Council of India, the self advertisement by a registered medical practitioner is considered to be an act of Infamous conduct beyond the limits set by MCI. [12] On the other hand the companies which were considered to be a legal personality are freely involved in promoting their drugs by advertisement without any check or control by the government agencies.

They have been permitted only to create awareness about their drug in to medical professionals through the medical representatives and medical educational literature but are now crossing their boundaries freely. Uncontrolled dispensing of such drugs by pharmacist on the demand of the customer by passing the RMPs or technical persons in the health care field paralyzed the main essence of the existing legislations. Thus they should be checked immediately.

Now days the advertisements related to power building drugs and fairness increasing drugs are so common that society is completely insensitive towards illegality of such ads. Even the well reputed news papers and a news channel doesn't consider such ads to be illegal, unsocial and unethical. Many superstars are involved in the ads of fairness increasing creams and lotions as they were ignorant regarding the legislations banning such ads.

Advertisement of sex stimulating drugs crossed all the limits. In one of the advertisement snake has been represented as male genital and has shown that it is been erected after using that product (Japani oil aid).

Similarly, advertisement of Ayurvedic oil which claims 100% cures for quick discharge, nightfall, impotency, gonorrhoea, syphilis, infertility, etc. [13] thus not only the violation of these legislations but violation by obscene means has entered into the scenario. FDA, public broadcasting, health and judicial authorities are the mute spectator of the whole scenario although it is clearly mentioned that these are cognizable offences.

All the agencies and general public seems to be immune towards such advertisements. According to us, state should conduct widespread publicity of illegalities of such advertisements. Moreover, the state should sensitize the related authorities/ personnel for not only to ban such ads but also to take strict action against the perpetrator.

Recently, The Food and Drug Administration (FDA) plans to pull the plug on television channels that offer air time to promote medicines which guarantee to cure joint pain, impotence and weight reduction. After sending show cause notices to the firms, the FDA now plans to send letters to the television channels and actors, who are involved in the promotion of such medicines. [14]

The Directorate of Food and Drugs Administration (FDA) has also warned citizens against self-medication loaded by medicine advertisements (including Ayurveda, Siddha, Unani and Herbal) that not only make false claims but are also illegal. [13] Such actions and punishments should also be given wide publicity to deter the other established or upcoming culprits. Recently new issue is striking to the affluent class that one-fourth of students are overweight or obese.

Though junk food and fast food ads aren't completely to blame for childhood obesity but they do contribute to the overall problem. Thus the Australian Medical Association has requested a ban on junk food. [15] In India we fail to even check the drugs add.

The Drug and Magic Remedies Act also does not cover advertisements that appear in various media pertaining to health gadgets of unproven efficacy, like tummy trimmers, bands for blood pressure control, and gadgets to increase height. Hence an immediate amendment in the DMRA is needed.

Advertisement through internet and email, IT and Mobile Telecommunication technologies is another threat to consumers who are not informed of side effects or misinformed with no remedy for complaint or redressal.

There is urgent need for Amendments in IT Act, 2000 and enactment of Cyber Law for prevention of such crimes in India. At present in India, there is no central statutory agency or uniform legislation regulating the advertising industry. The Indian advertising market as a whole is regulated and controlled by a non-statutory body, the **Advertising Standards Council of India (ASCI)**.

False advertisements are restricted under the various legislations including the Consumer Protection Act, 1986; Cable Television Network Rules, 1994; Norms for Journalist Conduct issued by the Press Council of India Act and ASCI Code [19].

Under information and technology act 2000 [20] publishing of Information which is obscene in electronic form:

“Whoever publishes or transmits or causes to be published in the electronic form,

any material which is lascivious or appeals to the prurient interest or if its effect is such as to tend to deprave and corrupt persons who are likely, having regard to all relevant circumstances to read, see or hear the matter contained or embodied in it shall be punished on first conviction with imprisonment of either description for a term which may extend to five years and with fine which may extend to one lakh rupees(Rs.1,00,000/-) and in the event of a second or subsequent conviction with imprisonment of either description for a term which may extend to ten years and also with fine which may extend to two lakh rupees(Rs.2,00,000/-)”

Conclusion:

Advertisement of any drug should be strictly under control and supervision of government agencies; as the main objective of government agencies is to prevent certain diseases and thus policies are directed towards public welfare in contrast to the money making by the pharmaceutical companies.

Advertising of prescription drugs is currently allowed only in the USA [9] and up to year 2005 in New Zealand. [10] The European Parliament has emphatically opposed advertising to patients in line with the “precautionary principle”. Internet transcends country boundaries and it is more difficult to control and regulate. So there is an urgent need to increase vigilance with respect to any inappropriate use of DTCA on internet. [1]

Accountable drug information services and health campaigns should be identified and promoted by governmental agencies. [16] There is need of clear guidelines and specifications regarding the diseases to be included or excluded from the schedules of the said Acts.

There is a strong need to closely monitor the range, availability, clarity and particularly the quality of independent and unbiased information regarding prescription drugs on mass media and Internet. Only a vigilant today could lead to a safe tomorrow.

Thus an urgent review and amendment of the legislations and their strict implementation is a need of an hour.

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Table 1
Prohibition of Advertisement of Certain Drugs for Treatment of Certain Diseases and Disorders under DMRA

S.N.	Diseases & Disorders	S.N.	Diseases & Disorders
1	Appendicitis	28	Hydrocele
2	Arteriosclerosis	29	Hysteria
3	Blindness	30	Infantile paralysis
4	Blood poisoning	31	Insanity
5	Bright's disease	32	Leprosy
6	Cancer	33	Leucoderma
7	Cataract	34	Lockjaw
8	Deafness	35	Locomotor ataxia
9	Diabetes	36	Lupus
10	Diseases and disorders of the brain	37	Nervous debility
11	Diseases and disorders of the optical system	38	Obesity
12	Diseases and disorders of the uterus	39	Paralysis
13	Disorders or menstrual flow	40	Plague
14	Disorders of the nervous system	41	Pleurisy
15	Disorders of the prostatic gland	42	Pneumonia
16	Dropsy	43	Rheumatism
17	Epilepsy	44	Ruptures
18	Female diseases (in general)	45	Sexual impotence
19	Fevers (in general)	46	Smallpox
20	Fits	47	Stature of persons
21	Forms and structure of the female bust	48	Sterility in women
22	Gall stones, kidney stones and bladder stones	49	Trachoma
23	Gangrene	50	Tuberculosis
24	Glaucoma	51	Tumors
25	Goitre	52	Typhoid fever
26	Heart diseases	53	Ulcers of the gastro-intestinal tract
27	High or low blood pressure	54	Venereal diseases, including syphilis, Gonorrhoea, soft chancre, venereal granulomas and lymphogranuloma

Table 2
Diseases and Ailments to Prevent or Cure or Make Claims to Prevent or Cure under DMRA

S.N.	Diseases and Ailments	S.N.	Diseases and Ailments
1	AIDS	36	Maintenance or improvement of the capacity of the human being for sexual pleasure
5	Baldness	37	.Mental retardation, sub-normalities and growth
10	Change in colour of the hair and growth of new hair	41	Parkinsonism
11	Change of Foetal sex by drugs	42.	Piles and Fistulae
17.	Encephalitis	43.	Power to rejuvenate
18	Fairness of the skin	44.	Premature ageing
21	Genetic disorders	45	Premature graying of hair
28	Increase in brain capacity and improvement of memory	47.	Sexual Impotence, Premature ejaculation and spermatorrhoea
30	Improvement in size and shape of the sexual organ and in duration of sexual performance	48	Spondylitis
31	Improvement in the strength of the natural teeth	49	Stammering
32	Improvement in vision	51	Varicose Vein
33	Jaundice/Hepatitis/Liver disorders		

Table 3
Diseases for which advertisement of treatment is banned

S. N.	Disease /Illness	S. N.	Disease /Illness
1	Asthma	12	Stature
2	Blindness	13	Gallstones
3	Cancer	14	Kidney Stones
4	Cataract	15	Bladder Stones
5	Deafness	16	Paralysis
6	Diabetes	17	Insanity
7	Menstrual and Uterus Disorders	18	Leucoderma
8	Nervous disorders	19	Obesity
9	Dropsy	20	Rheumatism
10	Epilepsy	21	Sexual Impotence
11	Structure of female Bust	22	Sterility in women and HIV/AIDS, etc.

Source: The Times of India October 7, 2006: 13, Advertisement by Secretary, Government of India, Ministry of Health and Family Welfare, Department of Ayurveda, Yoga, & Naturopathy, Unani, Siddha & Homeopathy (AYUSH) IRCS Building, Red Cross Road, New Delhi