

ADVERTISEMENT ON MEDICINES / TREATMENT IN NEWSPAPERS VIOLATING INDIAN LAWS?

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ABSTRACT

Background: In recent times, the occurrence of false and misleading advertisements with exaggerated claims on efficacy has multiplied by several times. The two Indian legislations ‘Schedule J of Drugs and Cosmetics Rules’ and ‘Drugs and Magic Remedies Act’ govern the advertisement related to drugs and treatment.

Objective: The present study attempted to analyze the advertisements on medicines and treatments appearing in some Indian newspapers for their rationality, truthfulness and violation of Indian Legislations.

Methodology: In this cross-sectional study, the advertisements appearing from September 2012 to November 2012 in 10 newspapers comprising English and Hindi dailies, and covering Southern and Northern India, were collected and analyzed based on the provision of the two legislations.

Results: The analysis of 82 advertisements showed that they were about sexual pleasure medications, menstrual problems, arthritis, hair problems, slimming, weight loss, infertility in males, height gain, enlargement of breasts and for leucoderma. 77 of the 82 advertisements violated the Drugs and Magic Remedies Act and provisions of Schedule J of Drugs and Cosmetics Act.

Conclusion: The treatments or drugs advertised are false claims without any evidence. These diseases are listed in Schedule J of the Drugs and Cosmetics Act for which no one should claim to cure or advertise a cure. The misleading advertisements continue to appear in press, sometimes with celebrities endorsing these products and it is necessary that the Government should take action against these advertisements to protect the interest of the general public; failing upon which might lead to innocent public falling into this trap.

Keywords: advertisements, DMRA 1954, Schedule J, ASU medications.

INTRODUCTION

The pharmaceutical industry's primary aim is to maximize the profit to sell more of their products either by attempts to generate more prescriptions from physicians or direct to consumer advertising of its products through media.¹ Drug advertising has become a platform in India in recent years to promote false drug claims and exaggerate drug efficacy using movie stars as spokesperson. False advertising affects consumer health.² The influence of advertisements on consumer choice is indisputable. This makes it imperative that advertisements be fair and truthful. Inappropriate and incorrect advertising mislead consumers and violates their right to correct information that protects them against unsafe products and unfair services. The unwanted competition in the form of false advertisements can hamper consumer decision.³

Advertisements are meant for product promotion to an extent of even exaggerating the usefulness of the product. However, when the claims made by the manufacturer are false and detrimental to the consumers, the product advertisement becomes illegal.³ There are two categories of false and misleading advertisements. The first type of advertisements have the potential to cause consumers financial loss and mental harm since these advertisements infringe upon consumer's right to procure the right information and make an informed choice. The second type of advertisements are meant for marketing cures and promoting efficacy of questionable medications. These type of advertisements have a high potential to cause harm to consumer health.³

Though the causes of unlawful drug advertisement are difficult to chalk out, the lack of integrity in the drug advertising is a fact beyond any doubt. The pharmaceutical manufacturers, mass media, advertising agencies and drug distributors have become an important factor that severely restrict the healthy development of drug advertising in India.^{4,5} Policies for ethical promotion of drugs are established at both national and international level. At the international level, prescription and OTC drug advertisement policies coined as "Ethical criteria for medicinal drug promotion", are proposed by World Health Organization (WHO).⁶ In India, principles of prescription drug advertising are regulated by the "Organization of Pharmaceutical Producers of India (OPPI)".⁷

"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" and advertise medications that are for conditions which are regulated under the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954.⁸

The direct to consumer (DTC) was introduced mainly for marketing medications among primarily healthcare professionals and includes advertising via TV, radio and mass media. DTC is banned in the western world except in New Zealand (1981) and United States (1997).⁹ Even though DTC is banned in India since 1956, some pharmaceutical companies advertise emergency contraceptive pills using punchlines such as "Abortion say acchahai pregnancy korokna" (stopping pregnancy is better than abortion) and "ab ham hain tension free" (now I am tension free).^{10,11} Such advertisements have generated

controversy since the emergency contraceptive pill, also known as the morning after pill reduces progesterone secretion and further delays menses, prevents ovulation and pregnancy. Other side effects include clinical depression, respiratory disorders, bulimia, high blood pressure, an increased risk of ectopic pregnancy, gallbladder disease, anorexia, ovarian cyst enlargement, an average weight gain of 15 pounds, and death.¹² Such side effects are often not highlighted by the Indian pharmaceutical companies in the media due to lack of regulations and couples use the morning after pill as a regular contraceptive, mainly out of lack of awareness and to evade the fear of getting pregnant while being still able to have unprotected sex. Hence, to prevent the misuse or overuse of drugs that have side effects, a proposal is being considered by the Drug Controller General of India (DCGI) that stops DTC advertising and sale of such drugs over the counter and instead ensures that they are sold as prescription drugs instead.^{10,11,13}

Very few studies are based on the issue of ethical concerns regarding advertisements of OTC medications published in newspapers. Gautam et al 2009 conducted a study on direct to consumer advertisement of drugs and observed that the manufacturer gave fake claims in their advertisements to attract maximum number of customers to boost sales.⁹ There are many laws existent for consumer protection against unfair trade practices. Yet, false and misleading advertisements target the needs of vulnerable consumers, because of the poor enforcement of laws. Drug advertising can be seen not only in newspapers but also on TV and with the increase in the number of audience exposed to these advertisements; it is now possible for even illiterate people to get influenced by these advertisements. In fact, advertising products such as health cures, get slim and beauty products of unproven worth through TV can bring in a bigger audience compared to newspaper advertising.

The present study is an attempt to document drug or treatment related misleading and illegal advertisement that appear in daily newspapers violating the Indian laws.

METHODOLOGY

In this cross sectional study, we screened a total of 82 drug advertisements from pharmaceutical companies which had appeared in different news papers which were published from September 2012 to December 2012.

Only new drug advertisements were included, particularly those being a part of schedule J and drug magic remedies act (DMRA). Repeat advertisements were excluded from the present study. The advertisements were categorized according to their claimed indication. The selected news papers for the study were from two places in North India (Sahaswan, Uttar Pradesh and New Delhi) and a town in South India (Chidambaram, Tamil Nadu). The North Indian news papers were famous Hindi news papers and the South Indian news papers chosen, were in English, one Hindi and one Tamil news paper. The Hindi and Tamil newspaper advertisements were translated in English using the standard proposed guidelines by researchers in sociology and psychology.¹⁴ The newspaper advertisements were translated by six individuals separately for Hindi and Tamil advertisements. Five of the six selected individuals in one group were native Hindi speakers. In another group, five of the six selected individuals were native Tamil speakers. The group of translators included healthcare care personnel who were fluent in either English and Hindi or in English and Tamil health related terminologies. Translators not related to healthcare, had Tamil or Hindi educational background with a familiarity of colloquial terms. The translators were asked to translate the Tamil and Hindi advertisements into semantically equivalent English version rather than the literally equivalent English version. The researchers then reviewed the translations. The English version was sent for back translation to four bilingual individuals each for Hindi and Tamil advertisements, who produced back translation of the advertisements. The study objective was not disclosed to the back

translators. Out of the four back translators, three were native Hindi language speakers and the remaining one was native English language speaker. The same selection process was followed for back translation of Tamil advertisements. The researchers again reviewed the semantic equivalence of the back translation of the Hindi and Tamil advertisements. If the translations was not semantically equivalent, the entire process was repeated again.¹⁵

A total of ten news papers were included in the present study. WHO criteria for drug advertisements published in news papers included evaluation of information illustrated , taking into account the media employed, the name(s) of the active ingredients(s) used, either international nonproprietary names (INN) or the approved generic name of the drug, the brand name, major indication(s) for use, major precautions, contra-indications and warnings, name and address of manufacturer or distributor.⁶ The advertisements were categorized based on the product indications, under schedule J and Drug and magic remedies act 1954.

The competent advertisements were analyzed for the sources of information provided in support of their claims. The relevant extracted data were presented in the predesigned data forms in a personal computer. Descriptive statistical analyses were performed using Microsoft Excel 2007 on Windows 7 Ultimate.

RESULTS

Because of duplication of same advertisements in different news papers, a total 82 drug advertisements out of which 77 (94%) come under DMRA 1954, were included for evaluation as per the WHO guidelines.

We found that the 10 categories drugs that were mostly advertised in our study period were sexual pleasure medications, drugs acting on uterus and menstrual flow for women, medicines for arthritis, hair problems, alopecia, sliming, weight loss, infertility in males, height gain, breast development, and leucoderma. (Table 1)

Table 1: List of Advertisements appear in different news papers in north to south India

Systems	Drugs comes under DMRA & Schedule J	Total no. of Advertisements, n (%)	At the site of North India, n (%)	At the site of South India, n (%)
Sexual problems	Yes	32 (39.24)	25 (30.48)	7 (8.53)
Menstrual problems	Yes	4 (4.87)	3 (3.65)	1 (1.21)
Hair problems (Baldness)	Yes	10 (12.19)	8 (9.75)	2 (2.43)
Height gain	Yes	4 (4.87)	3 (3.65)	1(1.21)
Breast development	Yes	4 (4.87)	3 (3.65)	1 (1.21)
Arthritis	Yes	4 (4.87)	4 (4.87)	-
Antilipidemics (weight loss)	Yes	4 (4.87)	3 (3.65)	1 (1.21)

Infertility in males	Yes	3 (3.65)	3 (3.65)	-
Leucoderma	Yes	3 (3.65)	3 (3.65)	-
Skin preparations	Yes	3 (3.65)	3 (3.65)	-
Anal diseases	Yes	3 (3.65)	3 (3.65)	-
Weight gainer	No	2 (2.43)	2 (2.43)	-
Diabetes	Yes	3 (3.65)	3 (3.65)	-
Strength	No	3 (3.65)	3 (3.65)	-
Total n (%)	12 (85.71)	82 (100)	69 (84.14)	13 (15.8)

Most of the claims were based on safety and efficacy of drugs. Superlative claims were commonly used without any further scientific evidence. Commonly used adjectives were 100% guaranteed, no side effects, money back guarantee, high-quality, unsurpassed, unmatched, fastest, best, superior, safest, trusted, first line, powerful, outstanding and so on. Advertisements were usually placed strategically in the appropriate therapeutic sections. (Table 2)

Table 2: Examples of drug advertisements not supported by claims

Type	Claim	Reason for not support
False statement	Pleasure, time and size increases of male sex organ	Incurable disease by medicine
Exaggeration of efficacy	Baldness, hair re-growth within 3 months	Baldness is untreatable by hair oil or shampoo
Unjustified Generalization	100% Ayurvedic, no side effect	Every medicine has side effects
Absence of relation	Upto 34 year, 3-5 inch height gain	It is not possible by medication or magnetic therapy

We found that out of 82 advertisements, 78 (95.12%) belonged to the Ayurvedic system of medicines, 2 (2.43%) belonged to the Unani system of medicines and 2 (2.43%) belonged to homoeopathic system. Advertisements on allopathic medicines appeared as well but they are not part of DMRA so we excluded them from the study.

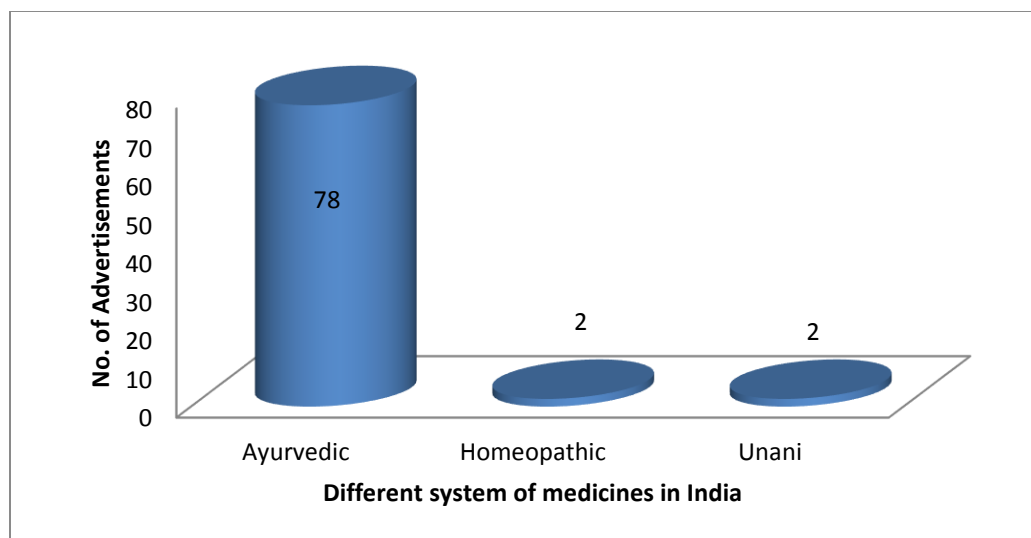


Fig. No. 1: Total No. of Advertisements appear in News Papers with their reported of medicines

DISCUSSION

The central argument is the ethical nature of direct to consumer advertisement in newspapers, particularly for advertisements pertaining to diseases under the Drug and magic remedies act. In India, drug advertising is intended for the sole purpose of persuading consumers to buy rather than educating the healthcare personnel or the consumers about the usage of drugs.¹

Most of the advertisements appearing in news papers are about sexual problems, menstrual problems for women, hair problems (baldness), height gain, breast development, arthritis and antilipedemics (weight loss). Many medication/drug advertisements claim to be a 'magic remedy' and include "a talisman, mantra, kavacha, and any charm of any kind which is alleged to possess miraculous powers helping in the diagnosis, cure, mitigation, treatment or prevention of any disease in human beings or animals or affecting or influencing in any way the structure or any organic function of the body of human beings or animals".⁸ The DTC advertisements we studied claim 100% money back guarantee. Since most of them are ayurvedic (Herbal) product advertisements, the manufacturers claim no adverse effect on the human body. Hence, the consumers also think that these herbal medicines are free from adverse drug reactions (ADRs) and if such drug sare not beneficial, they might have no harmful effect as well so there is no harm in trying at least once. Many advertisements were about mechanical devices to increase the size of penis or increasing the sexual contact time. The penis enlargement advertisements use crowd pleasing names such as "Japanilingvardhakyanttra" (penis increaser instrument) and include a 30 days course with provision of free uttejak capsules, joshila spray, kamasutra book and 8Gb memory card with money back guarantee. We found 3-5 small advertisements in a news paper with similar claims with different phone numbers but no manufacturer address.

Arthritis is an incurable disease, and recently many treatment options are available in news papers and on television. Many herbal hair oils for arthritis are marketed in newspapers and on TV at a very high price (70\$-110\$ per bottle). The high retail price is an attempt to recover the marketing costs of such products by involving Bollywood celebrities who act as spokesperson. For example many formulations like oil, capsules, gel and are endorsed by famous Bollywood film stars news papers and TV. The arthritis oils are available at a discount money back guarrantee price if purchased in bulk. A single bottle worth \$110 can

be bought for 70\$ if additional 2 more bottles are purchased. Innocent on lookers might be easily fooled into buying products due to the trust they place in the celebrities.

Now a day's companies have adopted new strategies for marketing a product by advertising with "testimonials" from people who, the advertisements claim, have been cured of diseases. Many herbal hair oils, shampoos and capsules the market claim to cure baldness. A pictorial description before and after 3 months of treatment by consumers often accompanies the advertisement.

Such advertisements are banned under schedule J and DMRA 1954. Same is the case with cream for fairness, capsules for height gain, capsules and gel for breast development, capsules and tablets for infertility in males, slimming capsules and capsules for piles etc. Even the hawkers are selling medicines without any fear in public places like government buildings, bus stands and small markets in villages (market based on weekly bases). The medicines include churnas, tooth powders, balm and some skin preparations without any manufacturing date or name and address of the manufacturer.

These types of advertisements are only observed in Hindi news papers in North India. Many states like Karala, Maharashtra, Tamilnadu and Gujarat have already seized some of the involved companies. AbhidnyaMatwankar 2012, reported through Pharmabiz.com¹⁶, that the Maharashtra Food and Drugs Administration (FDA) seized medical products worth around \$22,600,000 across the state during the last year for violating the provisions of DMRA, 1954. The Act is being enforced to curb the misleading ads about exaggerating claims of drugs in print and electronic media via hoardings and in trains, etc.¹⁶ In May 2012, the Kerala drug controller raided 3 big ayurveda companies in Chennai because they were violating DMRA. A team of enforcement officials from various districts conducted investigations of the depots of wholesalers and manufacturing premises in different places and seized products valued at \$104,235.¹⁷ The manufacturing some companies that were found violating.¹⁷ However, the manufacturers continued advertising in Uttar Pradesh in news papers, on metro railway station in Delhi and on television too.

The Delhi Institute of Pharmaceutical sciences and Research (DIPSAR),¹⁸ investigated 15 herbal products in the market in September, 2010. 5 of the 15 products contained either of the two ingredients: sildenafil or tadalafil. These ingredients are used for erectile dysfunction. DIPSAR reported these products to the official authorities such as the the CDSCO, Central government health ministry and the Delhi government health ministry upon which the DCGI delegated state drug controllers to handle the issue. The manufacturing institution was requested to perform pharmacovigilance studies of the herbal products and was also banned from marketing the herbal products to the consumers.¹⁸ Herbal medications fail to act quickly and frequently have a mild impact on the patient's ailment. Though the manufacturers are aware that the drug response is procured only upon prolonged dosing, they claim to cure the problem of erectile dysfunction with a single dose.¹⁸ Since many years, the manufacturers continue illegal advertising in news papers in northern states of India even though on paper, such activities should be prohibited. The frequency of such advertisements is particularly higher in the state of Uttar Pradesh and the state authorities fail to take action against these manufacturers who are making huge profits and in turn patients are losing their money and becoming more vulnerable to chronic conditions eventually.^{16-17,20-22}

The drug advertisements in different Indian news papers provides less content which is related to the vital aspects of the drugs like major interactions, major precautions, contraindication, side effects and drug storage, etc. The advertisements are not designed according to national or international guidelines. We also found that a majority of the drug advertisements were coloured, as well as models or celebrities were used for advertising the drugs. In our study 95% medicines were Ayurvedic and showed on label or in advertisement as 100% safe, but the question is if ayurvedic really means safe and effective. In USA, the Center for Diseases Control and Prevention recently reported 6 cases from New York city about lead poisoning caused by taking ayurvedic preparations during pregnancy. These preparations were manufactured by big Indian Ayurvedic companies. A similar incident was reported by DIPSAR New Delhi,^{14, 16}. So in India there is no quality control for these medicines and they are sold on a large scale. There is a need to establish regulations about alternative medicines.

India's market economy is underdeveloped. In developed countries, if pharmaceutical manufacturers and drug dealers issued illegal drug advertisements then they would lose the public's trust on their product. If the mass media published or broad casted illegal advertisements without any authorization, they would lose their integrity. Public image of celebrities or pseudo experts will get tarnished if they became spokesperson for a drug product that makes fake claims.¹

There is a need for modifications in the five decade old Drugs and Magic Remedies Act 1954 (DMRA) that should be enforced. The DMRA was enacted in 1950s to prevent unfair practices by Ayurvedic, Siddha and Unani (ASU) practitioners such as false and free advertisements that could harm and mislead patients. With the advancement of pharmaceutical industry and technology, it is now possible to perform evidence based treatment with both allopathic and ASU medications for a number of diseases. The Indian government should adapt the regulations of the DMRA with regards to the Drugs and Cosmetics Act and Food Safety Standards Act to ensure provision of safe and quality healthcare to patients. TV or news paper advertisement for drugs that are part of Schedule J and DMRA should be pre-approved by the FDA prior to its release and the drug manufacturer should be made to pay fees for the process. Advertising for newly approved drugs by the FDA should be delayed till their full safety profile becomes known and they should also have a symbol on their packaging. Rather than allowing drug advertisements about a particular brand, government should create awareness through educational campaigns about drug classes and their advantages and encourage patients to consult with their primary care physicians in order to know more about the safety of those drug classes. Drug companies could mention in their advertisements if a generic version is available. This might benefit the people who cannot afford expensive branded drugs. In case of newspaper or online advertisements, the pharmaceutical company should be made responsible for making clinically incorrect or unverified claims. The drug advertisements should be made such that people with low literacy can understand them. Drug advertisements could include quantitative information about benefits and risks of products rather than qualitative emotional information for patients to make an appropriate appraisal of the drug.²³

CONCLUSION

We conclude that most of advertisements fake claims for sexual pleasure, leucoderma, arthritis, piles, height gain, breast development, baldness, menstrual problems, fairness creams, diabetes and weight loss. These disorders are part of Schedule J and Drug & Magic remedies act 1954, so these are incurable by medications and pharmaceutical companies can't give advertisement for general public. The government has to enforce rules strongly to protect innocent people from the claims proposed by these pharmaceutical companies giving advertisement for OTC drugs with fake claims or statements in news

papers as well as in electronic media. Patients need to be aware that even though drug advertisements back their claims with scientific evidence purported by either specialty physicians or pharmacists, they are not trust worthy.

We strongly suggest the need for uniform regulations and codes to be followed and effectively supervised by central agencies as well as state government, located especially in North Indian states. Government has to make clear guidelines about quality and safety of ASU products. In our opinion, legal actions such as administrative fines, suspension of license and imprisonment of the manufacturer of faulty products may be required to ensure systematic monitoring of the accuracy of pharmaceutical marketing claims as well as to sustain accuracy of the same in the future.

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