

Direct To Consumer Advertising: A Mixed Blessing

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Abstracts: Direct-to-consumer advertising (DTCA) is a tool used by pharmaceutical companies to market and promote medicines directly to potential consumers by means of different media but the debate for and against this is ongoing and fairly balanced. Direct to consumer promotion of pharmaceutical product is considered illegal in many parts of the world. United States and New Zealand are the only two countries which have legalized DTCA, but the advent of internet has broken all barriers. Advertisement of prescription medicines through internet and social media has made it difficult for government and regulatory authorities to effectively implement the laws which govern DTCA. In India 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. A multi prong strategy involving government, pharmaceutical industry, doctors, medical associations and consumers is urgently required to curb the inappropriate use of DTCA. Through this article it is tried to critically appraise the advantages, disadvantages and remedies regarding direct to consumer drugs advertisement in India. [Goyal M NJIRM et al 2015; 6(3):113-117]

Key Words: Direct to consumer advertisement (DTCA), Types of DTCA, Impact of DTCA.

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Introduction: Direct to consumer advertisement (DTCA) is an effort by pharmaceutical companies to promote & market their products (prescription drugs, non-prescription drugs, medical devices) to the general population / consumers by means such as ; print media (newspaper, magazines, booklets, etc.), electronic media (television, radio , internet, etc.) & other forms such as , billboards, hospital display boards etc. This effort has successfully paid by increasing the movement of these products from the manufacture's laboratory to the patient's homes.¹ DTCA has proved to be an effective tool for the pharmaceutical companies by transforming the consumers into their sales representatives thus increasing their revenue & ultimately the profits.

History of DTCA: Prior to 1983, the sole target for the pharmaceutical companies to promote & market their products was the prescriber, i.e. the physician or other health care professional. However, after the FDA relaxed its rules regarding DTCA in 1997 the pharmaceutical companies have been able to advertise their prescription drugs directly to the consumers (potential patients) through electronic & broadcast media with only a brief mention of a few "important" risks of these products.^{2,3,4}

This change in the rules was completely opposite to that of the food, drugs & cosmetic act,1938 which had prohibited pharmaceutical companies from advertising their drug's brand name & its intended use in the same advertisement.⁴

In India the process of regularizing control over drugs was initiated in pre-independence era. In 1930, government of India appointed Sir R. N. Chopra as a chairman of drug enquiry committee as a result of this "Drug Act" was passed in 1930 followed by "Pharmacy Act" in 1948. Later in response to the report of Bhatia committee (1953) that found a large number objectionable advertisement in the press, "The Drug & Magic Remedy Act" was passed in 1954.⁵

The only two countries that allow DTCA are USA & New Zealand, most other countries do not allow DTCA at all. However, Canada allows ads that mention either the product or the indications for its use but not both.⁴

Types of DTCA⁶:

Product claim advertisements: It is the most common type of DTCA, It includes the brand name & intended use of the drug, briefly describes risks

& benefits, & it must comply with the fair-balance rule.

Reminder advertisements: It is less common type of DTCA, it includes the drug name, dosage form & costs but not its uses, as no product claims are made fair-balance rule doesn't apply, & it reinforces brand name & brand loyalty.

Help seeking advertisements: It describes the disease or condition but doesn't mention a specific drug that treats it, as no product claims are made the rule of fair-balance doesn't apply. It aims to create awareness of health conditions among consumers, & encourages patients (consumers) to get physician consultation.

Pros and cons of DTCA: The debate for & against the DTCA is ongoing & the arguments are fairly balanced.

Proponents of DTCA claim that it offers a patient a large number of benefits such as;

- It helps in educating, informing the patients regarding the disease or a condition & also empowers them by providing information regarding the drugs & other treatment options available.^{4,7}
- It enhances patient compliance.⁴
- Encourages patient to seek medical treatment /help for their previously untreated condition which in turn will improve public health.^{4,7}
- It facilitates patient-clinician communication & relationship by bridging the information gap between the patient & his attending doctor, the argument regarding this goes that the participation of an informed patient in a decision regarding his healthcare is beneficial for the patient as he/she are able to ask more thoughtful questions, promote a dialogue with their healthcare provider & also promoting heightened awareness & detection of adverse drug reactions.^{4,10}
- It helps in reducing stigma associated with a disease/condition for e.g.; ad campaign for erectile dysfunction (ED), benign hypertrophy of prostate (BHP), depression, etc.^{4,10}
- Reduces under treatment & under diagnosis by raising the awareness of the patients regarding their condition / disease & thus

encouraging them to seek treatment & have a dialogue with their healthcare provider for the treatment options available.^{4,10}

- It encourages competition between the products & thus lowers drug price, supporters for DTCA argue that it leads to competition & therefore manufactures tend to lower the price for their products so as to appeal the consumers, also by encouraging early medical treatment the cost-saving are high by avoiding a surgical intervention which the patient may have to bear if treatment is sought at a later stage of a disease.⁴

The arguments made by the opponents of DTCA are as follows:

- Mislead the patients by overemphasizing the benefits of the product while underestimating its risks & side-effects.^{4,7,10}
- Provide incomplete information regarding the products, & making false claims by suggesting that only medication can improve the patient's health & not lifestyle modification.^{4,5,7}
- Strains patient-clinician relationship as these ads influence the patient who many-a-times may ask for prescription of the advertised drug, even if their healthcare providers don't feel the drug is fit for the patient. Clinician may have to spend precious amount of time to make a patient understand why the particular drug or treatment is not appropriate for them.^{4,7}
- Promotes disease mongering & encourages drug overutilization for e.g.; in cases where a male patient has normal physical variation in sexual performance, may seek medication for erectile dysfunction (ED).⁴
- DTCA appeals to consumers emotions leading them believe that a certain product can cure their ailments which may not be a reality.^{4,5,7}
- Many a times consumers may misinterpret an ad & make a self-diagnosis.⁵
- Certain minor ailments do not require medication as patient's immune system takes care of it but the consumers starts to self medicate that could prove to be harmful for them.⁵
- The consumers are drawn towards costly medicines only because of drug brand ads while other cheaper, generic alternatives are

just as effective as then costly ones leading to higher health care costs.^{4,5,7}

- Promotes new drugs even before their safety profile is fully known putting the public health at risk.^{4,7}

Current status of DTCA in India: In India DTCA is allowed for OTC (over the counter) drugs only, though OTC does not have a legal recognition in India, all the drugs that are not included in the list of 'prescription drugs' are considered as non-prescription drugs (or OTC drugs).⁸

DTCA is not allowed for the drugs falling under the schedule H & schedule X of Drug and Cosmetics Rules, 1945. Drugs falling under Schedule G require the following compulsory warning on the label: *"Caution: It is dangerous to take this preparation except under medical supervision"* and hence are not allowed to be advertised directly to the consumers because of their toxicity & their potential for harm due to inappropriate & unnecessary use. The OPPI (organization of pharmaceutical producers of India) also does not voluntarily advertise these drugs to the public.^{5,8,9}

The main Acts influencing and regulating pharmaceutical advertising and marketing in India are: *The Drugs & Cosmetics Act, 1940* and *Drugs & Magic Remedies (objectionable) advertisements Act, 1954*.

The Drug & Magic Remedies (Objectionable Advertisement) Act mentions a list of ailments for which no advertising is permitted. It also prohibits misleading advertisements, which, directly or indirectly, give false impressions regarding the true character of the drug; make false claims, or are otherwise false or misleading in any particular respect. It also prohibits the advertisement of certain purposes of remedies. This Act defines an advertisement to include print items, and any announcements oral or produced by light, sound or smoke. It also defines a drug and a magic remedy (talisman, mantra, kavacha, etc.) too. The Act provides a schedule of various diseases or disorders or conditions for which drugs cannot be advertised.^{5,10,11}

However with the increase in literacy rate, increased awareness, telecom & internet

revolution in India this scenario is changing fast & the pharmaceutical companies have started to recognize the emerging role of internet & social media because of its potential to transcend geopolitical boundaries thus increasingly exposing Indian population to advertising for prescription drugs also. DTCA of prescription drugs still persists despite legal prohibitions.^{1,5,12}

India is currently ranked 11th in the global OTC market in size, with an expectation that it will get to the 9th position within five years.^{5,8} Currently the Indian OTC market (i.e. non-prescription advertised medicines) is estimated to represent approximately Rs.104 Billion growing at roughly 8-9%.³ It is expected to grow at a CAGR of approximately 18% till 2013-14.⁹ OPPI 46th Annual report states that the Pharmaceutical industry in India is growing at around 16% per annum. Currently, India ranks 3rd in the global pharmaceutical market in terms of volume and accounts for 1.5% of the total global pharmaceutical production by value.¹³

Eyeing this potential of Indian OTC market, more & more pharmaceutical companies are trying to bring their prescription products under the OTC umbrella. This switch protects their drug molecule even after the patent expiry & as OTC drugs do not require prescription for purchase they can be sold at any grocery store & do not require drug license for sale. This has helped pharmaceutical companies to reach the areas & consumers that were earlier inaccessible.^{5,9}

India earlier had only 12 drug molecules in OTC market but now the number has crossed 33 & is still growing.⁹ In India some of the OTC medicines that can be seen advertised on TV such as;^{8,9,10,13} Digestives, Antacids, Antiflatulents, Oral contraceptives, Cognition & memory enhancing drugs, Sexual performance enhancing drugs, Cold rubs and analgesic balms/creams, Vitamins/tonics (especially herbals and Ayurvedic-registered), Medicated skin treatment, Skin fairness creams, Analgesic / cold tablets, Analgesic / Antiseptic creams/liquids, Glucose powders, Cold & Cough liquids, Throat lozenges, Medicated dressing (band-aids), Baby gripe water, etc.

Impact of DTCA (Discussion): Some of these drugs may provide relief to the patient's but in the long run they can lead to serious adverse effects. There is a risk of drug abuse also.

If a hypertensive patient takes an antacid that has sodium bicarbonate in it, he/she can load himself/herself with extra sodium which may prove to be detrimental to his/her health.

The use of oral contraceptive pills that can cause menstrual irregularities, breast tenderness.

Cold & cough tablets & syrups containing opioids can be a cheaper & more readily available form of drug abuse.

Drugs promising enhanced sexual performance can lead to stroke & cardiac arrest in patients with cardiac ailments.

Advertisement claiming that a certain device if used in one's footwear can help to increase height. Apart from putting the consumers under health risks they also put extra burden on the patient's expenditure. Advertisement of other products like fairness creams, apart from having health, financial implications, also give a false impression that "fair is superior and it is either a prerequisite or a guarantee to success and fame". This affects the self esteem and morale of not so fair persons especially females negatively and also raises the negative values in the society.

Other products such as tummy trimmers, bands to control blood pressure & gadgets for increasing height also have similar implications. Nowadays even lifestyle modification drugs such as, antiobesity drugs, antistress drugs & nutraceuticals and functional foods are emerging as OTC medicines in India.¹³

Some commonly used lifestyle drugs are; viagra (sildenafil citrate), norethisterone, anabolic steroids, orlistat, sibutramine, minoxidil, finasteride, amphetamines, antioxidants, botulinum toxin, cyproheptadine, food supplements, vitamins, height increasing pills, etc.¹⁴

Conclusion: DTCA if implemented & used correctly can lead to decrease in healthcare costs, promotion of responsible self medication, good source of health information to general public. It will also be helpful in early diagnosis, better treatment & improved patient compliance. However due to lack of strict implementation of laws, Indian consumers are being constantly exposed to advertisements for prescription as well as non prescription via television, internet, social media & other forms of media.

The Drugs & Magic Remedies (objectionable) advertisements Act, 1954 needs amendment so as to allow manufacturer's / importer's to share information which educate the consumers about the product & also helps them to understand the procedure involved in treatment administered upon them by the healthcare provider, it will also help in removing stigma associated with a disease. A multipronged approach is needed involving the pharmaceutical companies, government agencies as well as the consumers to curb the inappropriate use of DTCA. There is also an urgent need for Amendments in IT Act, 2000 and enactment of Cyber Law for prevention of unlawful DTCA over internet in India.

Uncontrolled dispensing of prescription drugs by pharmacists on demand of consumers without the prescription should be stopped. Lastly, the victim i.e. the consumer (patient) should be careful, informed and act more wisely about their decisions related to their health.

References:

1. Khosla P, Khosla A. Direct to consumer advertising of prescription drugs on internet: A Boon or a Curse. *Indian J Pharmacol* 2011;43:483-4.
2. Boden WE, Diamond GA. DTCA for PTCA: Crossing the line in consumer health education? *N Engl J Med* 2008;358(21):2197-2200.
3. Kravitz RL. Direct-to-consumer advertising of prescription drugs. *West J Med* 2000;173:221-222.
4. Ventola CL. Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic? *Pharmacy and Therapeutics* 2011;36(10):669-684.

5. Meshram SK, Ambade VN, Tumram NK, Borkar JL. The Critical Appraisal of Drug Advertisement Directly to Consumers: A Mockery of Drugs and Magic Remedy (Objectionable Advertisements) Act. J Indian Acad Forensic Med 2014 January-march;36(1):61-66.
6. Basics of drug ads [Internet]. U.S. Food and Drug Administration. Cited 2014 Nov 28 Available from: www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm072077.htm.
7. Kusuma SK, Nunley RM, Mehta S, Genuario JW, Kennedy J, Washington Health Policy Fellows. DTCA: Improving Patient Education or Simply Increasing Pharmaceutical Profits?. December 2007 AAOS. Cited 2014 Nov 13
8. Available from: <http://www.aaos.org/news/bulletin/dec07/reimbursement1.asp>.
9. Bhangale V. OTC Marketing of Drugs. Proceedings of the International Conference on Marketing and Society; 2007 Apr.8-10; Kerala, India: IIMK, 397-402.
10. Saha PG. Indian Otc Drug Market: Opportunities and Challenges. GJRA, October 2013;2(10):61-63.
11. Sen K. India. Advertisement Of Drugs In India: An Overview. Cited 2014 Dec 24 Available at <http://www.mondaq.com/india/x/265212/food+drugs+law/ADVERTISEMENT+OF+DRUGS+IN+INDIA+AN+OVERVIEW>
12. Gupta VK, Gupta CD, Patel JR. Assessment of Awareness and Attitudes towards Over-the-Counter (OTC) Drugs amongst Urban Population: A Questionnaire Based Study. RJPBCS. April – June 2012;3(2):1037-44.
13. Vats S. Impact of Direct to Consumer Advertising Through Interactive Internet Media on Working Youth. International Journal of Business and Administration Research Review. Nov-Jan2014;1(2):88-99
14. Gupta S. Emerging Indian OTC Markets. Apeejay - Journal of Management Sciences And Technology. Oct - 2013;1(1):24-29.
15. Rahman SZ, Gupta V, Anupama S, Khunte Y. Lifestyle Drugs: Concept and Impact on Society. Indian J Pharm Sci. 2010;72:409-13.
16. Reddy P, Gosavi D, Reddy S. Lifestyle Drugs. Int J Pharm Pharm Sci. 2012;4 suppl.5:43-45.

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