



Evaluation of the Ethical Issues for the Direct to Consumer Advertisement in Arabic Satellite Channels

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ABSTRACT

Background: Direct to consumer advertisement (DTCA) is one of the tactics that adopted by pharmaceutical companies for promoting drugs directly to patients and thus increase their sales. DTCA is useful for patient education and should be carefully regulated to avoid misleading patients with inaccurate information.

Aim of the study: evaluation the accuracy of information and the ethical issues for DTCA in some Arabic satellite channels

Methods: A direct observational study to 10 different Arabic satellite channels was done from July to August 2013, to find out the type, accuracy and the ethical status for the DTCA depending mainly on WHO and FDA criteria for medicinal drug promotion

Results: This study showed that DTCA in Arabic channels was only in the form of product claim advertisement.

Dermatological diseases, infertility and sexual dysfunction are the most frequently targeted diseases by DTCA in Arabic satellite channels. There are many ethical problems with DTCA in Arabic satellite channels; most importantly absence of information about the active ingredient of the product, side effects, precautions, cost and the dose, additional ethical problems with DTCA includes claims about guaranteed product effect and safety of product without any medical or pharmaceutical reference.

Conclusion: There are many unethical tactics by DTCA in Arabic satellite channels that may mislead patients and negatively affect their health and in turn having bad economic effects on health care budget.

KEYWORDS: Direct to consumer advertisement, ethical status, Arabic satellite channels

Introduction

Drug Promotion can be defined according to world health organization (WHO) as all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs (1).

Direct to consumer advertisement (DTCA) is one of the tactics that were adopted by pharmaceutical companies for drug promotion besides physician targeted promotion, and data manipulation in clinical trials (2). DTCA can be defined as an effort (usually via popular media) made by a pharmaceutical company to promote its products directly to patients (3). Although DTCA has a long history but it becomes more popular at the late 1990s (4). There are essentially 3 types of DTCA. The first type consists of disease-awareness advertisements, which provide information about a medical condition and encourage people to talk to their physician about available treatments. The second type of DTCA consists of reminder advertisements, which may state the name of a product and may provide information about strength, dosage, form and price but may not mention the product's indication or make claims about effectiveness. Product-claim advertisements are the third type of DTCA. These advertisements combine the brand name with claims about indication and effectiveness and it should also states drug side effects and precautions (5,6).

There is a large debate about DTCA where proponent scientists show an agreement with DTCA due to it's advantages like the ability of DTCA to educate people about health conditions and available treatments and empowers them to become more active participants in their own care, thereby strengthening the health care system (7-9), while others were opponent to DTCA since they found that consumers were not able to identify misleading and inaccurate information (10). Therefore, DTCA should be regulated to ensure not only accuracy but also to ensure ethics in advertisement and thus enhancing patients' health (11). In developed countries like USA, UK, Australia and Canada there are (Codes) which describe regulations and guidelines about printed and broadcast promotional material to control DTCA (12,13), but unfortunately there is no any code regulate DTCA in most arabic countries and Iraq in special so this study aimed to evaluate the accuracy of information and the ethical issues for DTCA in some Arabic satellite channels.

Methods

A direct observational study to 10 different Arabic satellite channels (Iraq medical TV, Konoza altabia, Libya TV shop, Al- Dawaea, JM TV, Arzaq Baghdad, AD National Geographic, Al Arab, Taxi el sahra, and Green life) was done from July to August 2013, to find out the type, accuracy and the ethical status for the DTCA depending mainly on WHO and FDA

criteria for medicinal drug promotion (1,14); Each advertisement was evaluated for the absence or presence of the following points:

1. Type of DTCA (Reminder, disease awareness or product claim)
2. Name of product
3. Active ingredient and excipient if present
4. Indication
5. Side effects
6. Contraindication
7. Reference for the efficacy and safety of the product
8. Cost
9. Dose
10. Emotive themes about the product's effect or the complication of the disease
11. Status indicating that the product is natural
12. Status indicating that the effect is guaranteed and/or within few days
13. Status indicating that by use the product there is no need for surgery or physician consultation
14. Status indicating that by using the product a complete cure of the disease will occur

Results

This study showed that DTCA in Arabic channels was only in the form of product claim advertisement with no any DTCA in the form of reminder or disease awareness type.

Table (1) showed the most frequently targeted diseases by DTCA in Arabic satellite channels.

Table (2) showed the ethical problems in DTCA in Arabic satellite channels.

Table 1: Frequency of disease status that targeted by DTCA

Disease targeted by DTCA	Frequency N (percent)
Erectile dysfunction	3 (7.5%)
Vitiligo	4 (10%)
Alopecia	4 (10%)
Obesity	5 (12.5%)
DM	2 (5%)
Varicose vein	2 (5%)
Migraine	1 (2.5%)
Wrinkle	2 (5%)
Infertility	4 (10%)
Hemorrhoids	1 (2.5%)
IBS	1 (2.5%)

Back pain	1 (2.5%)
Bone pain	1 (2.5%)
PCOS	1 (2.5%)
Asthma	1 (2.5%)
Gall stone	1 (2.5%)
Hepatic disease	2 (5%)
Rapid ejaculation	1 (2.5%)
Melasma and cholasma	1 (2.5%)
Black comedones	1 (2.5%)
Hyperlipidemia	1 (2.5%)

Table 2: Frequency of ethical problems in various DTCA

Disease targeted by DTCA	Frequency N (percent)
Name of product not mentioned just mention telephone number for call to purchase the product	22 (55%)
Active ingredient not mentioned	40 (100%)
Contraindications or precautions not mentioned	40 (100%)
Dose and of drug not mentioned	40 (100%)
Cost of drug not mentioned	40 (100%)
Side effects not mentioned	23 (57.5%)
No any side effects or safe	17 (42.5%)
Safe because of its natural origin	9 (22.5%)
Natural products	17 (42.5%)
Guaranteed effect	16 (40%)
Effect will appear within days – weeks	8 (20%)
Emotive themes	12 (30%)
No need to surgery just by using this product	2 (5%)
Complete cure and you will stop any treatment in the future	2 (5%)
Reference for product efficacy and safety zero	0 (0%)
Licensed from Ministry of health without license number	4 (10%)

Discussion

DTCA can be done through the radio, television, newspapers, magazines, and recently using the internet (15); Yet DTCA using TV is still one of the most common tactics for drug promotion, at which big pharmaceutical companies spent million of dollars on it (16). Heavy direct-to-consumer (DTC) advertising strongly correlates with increased sales for the promoted drugs but, in terms of both money and health, may not be in the best interest of patients (2). DTC advertising has been vehemently debated in the literature (17). The primary argument in favor of DTC advertising is a form of patient education with the potential for more informed patients and better health care (18), and it is well known that only disease awareness type (extremely informative type) provide patients with education about a disease or medical condition and let people know that treatments exist for a medical condition (6).

This study showed that all of the examined DTCAs in the Arabic satellite channels were in the form of product claim, which means that the advertisement mentions the indication of the product, whereas disease awareness and reminder advertisement don't mention product indications. This fact means that DTCAs in Arabic world were not aimed to benefit the patient since no any DTCA in the form of disease awareness, but instead DTCA aimed to increase products' sales (6).

Table (1) showed that DTCA targeted many types of diseases, yet it focuses on sexual dysfunction and fertility issues (22.5%) besides dermatological problems (30%) more than other conditions; similarly other studies found that DTCA focuses on cosmetic issues and trivial ailments (19, 20). Furthermore one of the known advantages for DTCA is that it can reduce the stigma associated with health problems that could be embarrassing to the patient like erectile dysfunction, rapid ejaculation, infertility and PCOS (20), which may be an advantage to arabic patients with such problems, but surely if the medical product is proven to be effective and advertised in an ethical manner since Pharmaceutical practicing Law no. 40 at 1970 (article 18) prohibit any advertisement that oppose the morals of society.

Table (2) showed that there are many ethical problems for DTCA in Arabic satellite channels, first of all absence of information about the name of the product in more than half of the studied DTCAs, instead a

telephone number was given in all DTCA in order to call the company to purchase the product, close to this finding A toll free number was available in 93.3% of DTCA in other study (21); The lack of suitable basic information about advertised products is an ethical problem for the DTCAs in this study since FDA at 1997 announced that adequate provision of information for the drug is sufficient, more information of drugs can be obtained through toll free telephone number (22). Additionally table (2) showed that no any DTCA were mentioned the active ingredient of the product, even so some of them (42.5%) mentioned that the product is natural with no any additional data regarding its content, according to WHO (1) criteria for promotion of medicinal products both the name of the product and its active ingredient should be mentioned, this in turn means that there is a big ethical problem in all of the studied DTCAs.

This study as shown in table (2) showed that cost was not mentioned in 100% of DTCA, similarly Woloshin S et al in his study found that no one of the 67 studied DTCA mentioned product cost (23). Additionally Critics about DTCA say that cost information that could benefit consumers is rarely included in DTCPA (24).

Furthermore, the dose and product strength was also no mentioned in all advertisements, which may be explained in absence of scientific and practical data regarding these products, similarly Woloshin et al found that most advertisements described the benefit of medication with vague, qualitative terms (23).

The results of this study (Table 2) showed that in more than half of total number of studied DTCA, side effects were not mentioned; this result is not strange since it is well known that a common complaint with DTCA is omitting important information (25). Similarly, content analytic studies have found that most DTC ads emphasize drug benefits over risks (24), and nearly 84% of the regulatory letters for DTCPA cited ads for either minimizing risks (e.g., omitting information about side effects) or exaggerating a drug's effectiveness, or both (25).

In this regard the Iraqi pharmaceutical professional practicing Law 40 at 1970 (article 17) states that drug side effects should be mentioned during advertisements in journals or magazines but since the law is outdated and not updated so there is no any point regarding TV DTCA.

Additionally this study showed that 42.5% of DTCA states that the product safe or with no any side effects, Similarly, in one study in USA regarding DTCA, Six point one percent (61%) of the advertisements contained no side effect warnings (21). This result may be explained in that consumers were considerably more likely to recommend or purchase a drug when the description was accompanied by an incomplete risk statement instead of a complete risk statement (26).

Moreover, this study (table 2) showed that 22.5% of DTCA stated that the product is safe and effective since it is natural, this claim is non ethical since it is well know that herbs and natural products with many problems, adverse and side effects is one of these problems, herbs are not devoid from side effects and they may cause even serious side effects like cancer, besides that herbs have many interaction with medicines (27). Secondly, Herbs are natural products and their chemical composition varies depending on several factors, such as botanical species, used chemotypes, the anatomical part of the plant used (seed, flower, root, leaf, and so on) and also storage, sun, humidity, type of ground, time of harvest, geographic area; and merchandized products containing on the label the same product varying in their content and concentrations of chemical constituents from batch to batch; This variability can result in significant differences in pharmacological activity: involving both pharmacodynamic and pharmacokinetic issues (27). So it is the cardinal responsibility of the regulatory authorities to ensure that the consumers get the medication, which guarantee with purity, safety, potency and efficacy (28); That's why the general company for drug and medical alliances in Iraq states that herbal drugs and other supplements should not be used or marketed in Iraqi pharmacies or drug stores unless the product is registered in Iraqi ministry of health because if its side effects on patients (29).

According to medicine act, any advertisement that suggests that the safety and efficacy of the medicinal product is due to the fact that it is

natural, should be prohibited (30).

This study also showed a problematic claims in the examined DTCA, at which 40% states that the effect of the product is guaranteed, whereas 20% states that the effect will appear within short period of time and 5% of DTCA states that complete cure will occur by using the advertised product and there is no need for surgery; However no any one of these advertisement coupled its claims with a suitable medical or pharmaceutical reference as shown in (Table 2), which may be explained in a way for convincing patients by misleading data just to increase the product sales. Furthermore, the two DTCA which promise of complete cure of disease were focusing on Vitiligo (31) and diabetes mellitus (32) at which there is no know therapy to cure them.

According to medicine act any advertisement that suggests that the effects of taking the medicinal product are guaranteed, should be prohibited, Moreover any advertisement which gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a telephone number should also be prohibited because of its unethical cover (30).

Many researchers who were opponent to DTCA found that consumers were not able to identify misleading and inaccurate information (33), and since there are many un ethical issues in DTCA in Arabic satellite channels this means that most of these DTCA should be prohibited.

Some DTCA claimed that there product is licensed from Ministry of health, to persuade patients to purchase a safe and effective product since it is licensed by MOH, but this data may not be correct or even ethical since it is not associated with license number to confirm these

claims.

Finally this study showed that emotive themes was used in 30% of DTCA, Similarly Woloshin et al(23) found that emotional appeals is one of the common tactics for DTCA. Sufrin and Ross state that emotional appeals overshadowed factual information which lead to more patients seeking out medications that they did not necessarily need. Consumers are drawn to the emotional appeal of the advertisements and not necessarily the true capabilities of the drug (34). Because of consumers' limited knowledge, critics have claimed that benefit-oriented advertising leads to overestimation of efficacy and suitability, and prompts requests based on hope and emotion, neither of which provides a rational basis for prescribing (35).

This study has some limitation in the small number of examined DTCA through limited number of the examined satellite channels, but on the other hand it is the 1st and the only study regarding DTCA ethical evaluation in arabic world and the middle east.

This study suggests that a self-regulatory approach, complemented by parallel government monitoring, provides an efficient and responsive system that promotes responsible and ethical advertising (36).

In conclusion to the finding of this study, there are many un ethical tactics by DTCA in arabic satellite channels that may mislead patients and negatively affect their health and consequently having bad economic effect on health care budget.

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