Direct-to-consumer advertising of pharmaceuticals: developed countries experiences and Turkey

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Abstract

While several major problems concerning drugs occur in the world, the attempts to direct-to-consumer advertising (DTCA) has gained a considerable impetus lately in both developed and developing countries. DTCA has increasingly become an appealing advertising alternative for the pharmaceutical industry as drug companies have come to wrestle with such problems as the expansion of the drug market; the decline of the medical representatives’ work efficiency; drug reimbursement restrictions; and the escalating role of the Internet in the consumer market. Some of the main disadvantages of the DTCA are: increasing drug expenditures, unnecessary drug consumption and adverse effect risks. Even though the influence of pharmaceuticals on health services and the economy hold the same importance in the developed and developing countries, its negative consequences have increased by encompassing developing countries in its grip. Therefore, in this review, using Turkey as an example, the situation of direct-to-consumer advertisements in developing countries is analysed in relation with developed countries.

Introduction

While several major problems concerning drugs such as price policies, patent, promotion activities for physicians, data protection occur in the world, the attempts of direct-to-consumer advertising (DTCA) has gained considerable impetus lately. DTCA is not a mere commercial activity. It also covers a range of issues affecting public health, thus the evaluation of DTCA must be made along with the evaluation of pharmaceuticals in general.

Among developed countries, DTCA is currently allowed only in New Zealand and the United States for prescribed medications. Nevertheless, there have been serious disagreements regarding the attempts to freely allow DTCA in Canada and Europe and organizations of physicians, pharmacists and consumers oppose these attempts by claiming that DTCA increase irrational use of drugs through misrepresentation. The Parliament of the European Union decided that the prohibition of prescribed drugs sold to the public be maintained in 2002, and a similar trend is also being observed in Australia and Canada. In addition to these arguments in various countries, the ethical criteria suggested by the World Health Organization (WHO) in 1988 which emphasizes that prescribed drugs are not to be advertised to the public still remains in effect.

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There is no blanket law covering all avenues of drug advertising in Turkey. The advertisement of prescription drugs to the public was prohibited in Turkey in accordance to the law passed in 1928 and 1994. According to the law of ‘The Foundations and Broadcasts of the Radio and Television’ which was put into effect in 1994, advertising for the non-prescribed drugs was allowed on the condition that it met the following criteria, ‘if they are open, reflecting the facts and can be verified, and protects the individual from harm’. In 1996, The Ministry of Health declared that drugs be classified as prescribed or non-prescribed. Since then, several attempts have been made by the Ministry of Health to allow drug advertising for non-prescribed drugs. However, other state organizations such as the Council of State have come out in opposition to this. As can be seen, while the legal situation of drug advertising remains complex, and at times confusing, serious attempts have been made which go towards incrementally regulating and defining drug advertising in Turkey.

Although pharmaceuticals have the same level of importance in the developed and developing countries, the influence of DTCA on health services and economy varies in developed and developing countries and the negative effects of DTCA may have greater impact on developing countries. Therefore, taking Turkey as the example, the current situation of DTCA in developing countries, as well as developed countries is analysed in our article.

The reasons for the tendency to DTCA

One of the significant characteristics which distinguishes drugs from other merchandise, is that the physician is the determinant factor in its selection, not the consumer. Generally, in the selection of medication for the patient, the physician is the ‘decision maker’ and the pharmacist is the ‘influential’ factor. For this reason, promotion expenses spent for the purpose of affecting the drug preferences of physicians are approximately 15% of total drug sales, exceeding the amount of 77 billion dollars annually throughout the world. Big drug companies allot more than 30% of their income for marketing and administrative expenses, which surpass the amount spent for research and development (R&D) budgets. In Turkey, also, it is pointed out that promotion expenses are approaching enormous amount, i.e. 1 billion dollars, which is many times more than the public resources allocated for preventive health services, family planning, mother and child care and health education.

Following the strategic path aimed with the purpose of expanding drug consumption, makes drugs no longer a part of health services, but on the contrary, it makes health services be a part of the pharmaceutical world. The key steps of this strategy can be outlined as: the realization of the prescribed and non-prescribed drugs distinction after the extension of the non-prescribed medicines respectively; the removal of the license of non-prescribed drugs; bringing the sale of non-prescribed drugs out of the pharmacy and finally providing the possibility of public-orientated ads for all the non-prescribed medicines first; followed by those for the prescribed ones. In this respect, DTCA may be an important turning point to increase sales and to protect high levels of profit for pharmaceutical companies. In addition to several recent problems occurring in the expansion of the drug market, the decline of the medical representatives’ work efficiency, which has had an important impact in terms of offering promotions, drug reimbursement restrictions and the increase of Internet use are some other factors that have made public-orientated advertisement more appealing to the drug companies.

Problems concerning the market

Problems such as strict competition in drug markets, the increasing difficulty in finding new pharmaceuticals and competing medications coming to the market in a short interval of time have been attempted to be resolved by corporate mergers and acquisitions, but these corporate moves seem to be insufficient and perhaps somewhat ineffective. While in the
USA, which comprises half of the world’s drug market, drug companies’ profits are three times more than other companies’ median, in order to maintain their current profitability, drug companies would have to introduce 24–34 new pharmaceuticals into the market every year.18,19 However, quite to the contrary, there is a trend indicating a decrease in the number of new pharmaceuticals introduced to the marketplace every year. While in the USA, 56 new molecules’ entities could be licensed in 1996, this figure decreased to 17 in 2002 and 21 in 2003. In general, this situation is found throughout the world. Although today’s annual R&D expenditures of companies have tripled since the 1990s, the number of new active substances approved in markets have decreased by 50%.20,21

In addition, while the growth of the global pharmaceutical market has slowed down, some developing countries such as Turkey, China and Mexico have gained greater importance in terms of pharmaceutical market expansion.22,23 For example, Turkey’s Pharmaceutical market which was the second fastest growing market in the world grew 7.1 times between 1987 and 2003. In the same period, the world market grew by just 3.5 times.24–27 DTCA is an important tool for these developing countries for a more rapid expansion of the pharmaceutical market and this may be the answer as to why DTCA has gained prominence and an increasing importance in pharmaceutical companies’ marketing strategies.

The problems of the medical representatives’ work

Along with the decline in the number of new pharmaceuticals, the length of time required by research in the drug sector and generic drug competition, large pharmaceutical companies have been forced to entrust their profitability into a small number of best-selling drugs in order to maintain their profit margin.5 In such matter, the efficiency of the promotion effort is of great importance. Yet, there has been an increase in the number of medical representa-

Drug reimbursement restrictions

As the share of drug expenses have increased within the total health expenses in most countries including Turkey, the institutions, employers and insurers who reimburse for drug purchases have recently started to set limits on these expenses.16,39–41 Restrictions on the prescriptions of physicians have been the easiest and the most frequent method of imposing such limits.41,42 This situation is one of the important reasons which led drug companies to implement new advertisement strategies in terms of DTCA, by opening a new ‘front line’ in the promotion wars aiming to gain public support.42,43
The Internet impact

The widespread use of the Internet has also been an important factor in the direct advertising of drugs to the public. For instance, 25% of information on the Internet in the USA is associated with health, and more than half of adults using the Internet make use of it to acquire information concerning health issues. It is also known that some of these Internet users have requested to obtain certain drugs later from their physicians.44 The increasing usage of the Internet in Turkey has caused a similar trend. In addition, it is estimated that there are more than 300,000 Internet sites related to the sales of almost all kinds of pharmaceuticals over the Internet. In Turkey too, there is a growing interest in this type of pharmaceutical sales.45

The aims and methods of DTCA

As it is widely known, advertising is one of the basic methods of marketing products.42 Advertising has been defined by Leacock as ‘the science of arresting the human intelligence long enough to get money from it’ and it is mostly aimed at persuasion rather than dispensing information.38,46,47 The ads can be in the form of spots where the title of the drug is given or in the form of announcing new treatment alternatives for diseases, as well as combining both forms together.2 The advertisement because of its form and content delivers superficial and limited information which emphasizes only a fragment, but not the entire truth about the product.48–50

Direct-to-consumer advertising covers activities which aim at the widespread use of drugs within a society by brand recognition and the brand loyalty associated with them. Different marketing methods are used to influence the public, patients and patient groups. DTCA, particularly in developed countries, is performed through various marketing strategies such as written, audio-visual communicative media, drug samples, free telephone lines, the sponsorship of activities, internet sites and direct contact (e.g. letters) to consumers.4

Together with the complicated legal situation of DTCA, some hidden and illegal methods of drug advertising such as using news and television programmes hosted by famous health authorities, novelists, journalists containing messages advocating the use of certain drugs to the public has been used increasingly in Turkey.51–55 There are many interesting examples on this subject. For instance, in a TV serial an actor who play a chemist has shown a drug box and has repeatedly told this vitamin drug’s brand name while trying to convince the consumer to buy it.55 In another example, a famous writer under the direction and sponsorship of a pharmaceutical firm, has written a novel where the name of a menopausal drug is not only mentioned by brand, but it is found in the novel in several passages that advertise it.56 Whether the name of a drug is mentioned or not, this type of hidden advertising is being prepared in order to influence healthy or unhealthy individuals towards the consumption of drugs.

Despite the policy of WHO warning which points out that the material prepared for promotion should not be designed to mask its real properties, and again as the policy of WHO which does not permit post-marketing surveys, campaigns and scientific studies to be employed as a masked promotion style, such examples of these types of open or masked public-orientated ads which force the legal limits and ethical regulations continue to be presented to consumers today.6 In Turkey, several drug companies have screening programmes such as ‘lipid determination, osteo-scanning for osteoporosis, etc.’ aimed at advertising their drugs and in the writing of prescriptions.57 The screening project of attention deficit and hyperactivity disorder at schools which is supported by the Ministry of Education leads to quite a lot of arguments because of the risk of enhancing drug consumption and regarding some children as ill.58 Especially in developing countries such programmes and projects are important tools used to increase drug consumption. For example, through self-assessment questionnaires
contained in ad brochures, many people start using drugs by diagnosing their own or their friends’ illnesses as depression. 59

Pharmaceutical companies not only use some masked methods of DTCA but also direct drug advertising to public has been observed in Turkey. For example, the license of a medication containing ‘bupropion’ which was used in the treatment of cigarette cessation had been widely advertised to the public, but suspended for 3 months due to the fact that it violated drug-advertising regulations. 60

The actual and potential effects of DTCA

Pharmaceutical sales and consumption

It is obvious that DTCA has had an undeniable impact on medication sales. According to some researches 1 dollar spent for the public-oriented ad returns as 1.69–4.20 dollar. 39,61 While the rise of 10% in the public-directed advertising expenditures brings about a rise of 1% in the sale of a group of medication, the same increase in the physician-directed ad in that group is 0.2–0.3%. 61,62 In addition, it has been estimated that because of the ads the prescription of the advertised drugs is written mostly when a patient demands. 63

Although DTCA has not been as widely used in Turkey as in some developed countries, it is clear that masked advertising has been playing an increasingly important role in shaping public demands and pharmaceutical consumption. Turkey has a wealth of examples which illustrate the rapid increase of pharmaceutical consumption. According to sources of drug companies in Turkey, the consumption of medicine which was seven packs per person a year in 1989, was 16 packs in 2003. 21,64 During the same period, there was no increase in the consumption number of the packs in the developed countries such as France and Germany. 65,66 While drug expenditure among the total health expenditures increased to 22% in 1990, and 35% in 1998, it rose up to 55% in 2003. 9,27,67,68 Per capita pharmaceutical expenditures in Turkey are roughly two times higher than countries with middle income average. 16,69 Also an indication of the widening of the market is that while there were 6488 drugstore in 1980, the number reached 21 000 in 2002, which shows that Turkey is ahead of many developed European countries such as Germany and England in the number of pharmacies in relation to population. 3,11,70

While 95% of physician consultations conclude with the prescription of some pharmaceuticals in Turkey, this ratio is 56% in Holland, 73% in Italy, 53% in UK and 66% in USA. 71–73 More than half of the patients (52.5%) do not go to health centres to have themselves examined, but to have drugs prescribed for them. 11 There were even physicians in Turkey who were accused of ‘not giving prescriptions’, and there continues to be still there some other doctors facing similar complaints. 74 Further, some studies indicate that while the average number of pharmaceuticals prescribed per patient is 0.9 in Australia, 1.3 in the United States and 1.4 in Norway, it is 2.9 in Turkey. 11,72,75 However, WHO has recommended that the standard value of drug numbers per doctor–patient encounter is 1.6–1.8. 24 As in other developing countries, there is also tendency to polypharmacy in Turkey. Furthermore, one survey in Turkey reports that almost one-third of the public goes to pharmacies to get medicine rather than seeing a physician in case of an illness, and that two-third of them first use the medicine at home, and that more than half of them have spare or extra drugs at home. 74

The face of pharmaceutical consumption has also undergone some changes in Turkey. In 1988, the list of the 10 highest sold pharmaceuticals (by value) constituted seven antibiotics and three painkillers. However, the list in 2003 was dramatically different. Only two antibiotics remained whereas in the rest of the list were antidepressants, antipsychotics, anticholesterol pharmaceuticals, cardiovascular pharmaceuticals, antiasthmatics and osteoporosis preventive pharmaceuticals. 76,77 Although Turkey has the profile of health problems bearing the characteristics of developing countries, it has been becoming into a market which closely resembles
the pharmaceutical consumption profiles of western countries. Even though there is a pattern of growth and misuse of the consumption of drugs in Turkey, there appears to be no clear policy in place to regulate the rational use of drugs.

**Benefits and risks of drugs**

In general, the unnecessary use of drugs is one of the main problems in the field of health. The use of pharmaceuticals without indication or not using the necessary pharmaceuticals and ‘using the right medication in the wrong course of time’ are all the examples of inappropriate use of pharmaceuticals. It is stated that more than 50% of drugs prescribed, distributed or sold in the world are done so inappropriately, and that nearly half of this medication is also used incorrectly.78

In Turkey, there has not only been an increase of pharmaceutical consumption, but also inappropriate pharmaceutical consumption. Approximately 200 million prescriptions have been filled annually and according to some research more than half (up to 68%) of the medication prescribed for patients is not right for them.79–81 Again, 67% of prescriptions written at primary care centres contain antibiotics and almost half of them are not appropriate for correct use.79 The ratio of over-the-counter pharmaceuticals comprises theoretically only 3.5% of all pharmaceuticals in Turkey. In practice, however, medications of all kinds, except narcotics, are easily purchased without requiring a prescription, and this fact plays a hugely significant role in the increase of unnecessary consumption.9,82 It is quite common for several medications in Turkey to be also sold in supermarkets, etc. apart from pharmacies.83

It is also a significant fact to re-emphasize that all drugs are toxic in some way, but as a healing tool, the toxic effect is kept on tolerable levels so as not to overcome its useful effect. Today, the profit-oriented production and improper consumption of medication hinders the examination of side/adverse effects of a medication which should be done before and after obtaining its license.84,85 It is estimated that 51% of several serious side-effects of medicines were undetermined before licensing was obtained.86 After introducing them on the market, 20% of new medications show signs of severe side-effects which necessitate the adding of serious warnings to its consumption at a later time or their complete withdrawal from the market.2 The recent example of such a case was the heavily advertised and used Vioxx (rofecoxib) which was withdrawn from the market due to its serious side-effects which had been known by its manufacturer for a long time.87,88 As records over these matters are inadequate and insufficient in developing countries, the dimensions of the situation are uncertain and critical. In Turkey, for many years there has not even been a medication side-effect report, nor has there been any necessary survey carried out on this matter, which is an annoying fact.89

According to the learned intermediary rule, drug companies are compelled to present all information about drugs to the medical society, and physicians are responsible to know the effects of the drugs they prescribe.90,91 An additional important point is that the validity of the learned intermediary rule will be removed by the application of DTCA, and drug companies will have more responsibility over problems which are likely to occur during the use of medication.90

In this case, there is an emphasis on the importance of the evaluation of differences between education and the ads regarding medication. Although drug companies would like to demonstrate DTCA in the form of an educational activity, this activity actually stands to bring down public health education to a commercial level and to make it a part of a sale-based activity.92 Public-oriented drug advertisement bears the function of transforming the public’s insufficient knowledge and education of health into a ‘false and insufficient knowledge’ of ads.3,46,93 The information in the ads claims to aim at persuading the public to make informed choices but in fact, often it tends to produce demands for certain drugs rather than providing objective information over risks, benefits or
treatment choices with/without medication. Exaggerating the benefits and minimizing the risks of drugs is one of the main characteristics of DTCA. If the goal is education, the health education of patients or physicians is too vital to leave it to drug industries through deceitful educational campaigns which aim at merely the marketing of the drugs. Physicians are capable of obtaining sufficient information and interpreting this information through their own experiences and accumulated knowledge. Patients, on the other hand, lack such sophisticated knowledge and therefore may deal with consequences that contain more risks of suffering harm due to DTCA.

Nevertheless, information that patients receive about drugs from physicians and pharmacies is also quite inadequate. In studies carried out in Turkey, it is stated that more than half of the physicians do not inform their patients about their illness and that the same number of them do not give the name of the drug they prescribe to the patient. In his medical appointment, the patient is not in the role of information-gatherer but rather of an information-giver. The brevity of this interview period, the limited 3 or 5 min, between physician and patient is one of the significant facts underlying these problems. While according to one research the interview period with a doctor per patient was determined less than 5 min in Turkey, it is estimated that in Germany it is 7.6 min, in Holland 10.2 min and in Switzerland 15.6 min. One research estimated that, while physicians and patients spend time alone for an average of 3.9 min (nearly the total interview period in Turkey), discussing medications, the total average encounter length was more than 20 min in USA.

The use of non-prescribed drug receives either overt or covert support from the pharmaceutical industry and health authorities because it provides savings in the health budget by reducing visits to the physician, but at the same time increases drug consumption. Despite the risks involved, such as the interaction with other medications, contraindications, side-effects and hindering the early diagnosis by masking the symptoms of an illness, it is reported that self-medication is becoming more and more common. Nevertheless, public-oriented ads for non-prescribed medications is a matter of concern in terms of misuse of drugs.

The belief that the negative effects of ads could be prevented by only allowing advertising for prescription medication also holds significant contradictions. While these types of ads aim to create a demand in individuals, taking some measures to prevent meeting these demands is a paradox and illogical. Unfortunately, meeting this demand depends on the physician’s giving-in to the pressure of the patients who have been affected by DTCA. Thus, research findings suggest that the most common reason of improperly written prescriptions is the ‘patient demands’.

Nevertheless, drug prospectuses are one of the sources that patients can refer to in furthering their information on medication. However, it is a known fact that the drug prospectuses are written for healthcare staff rather than patients and that is why they are far from being understandable by the patients. Besides, it should also be kept in mind that the rate of literacy in Turkey is 87.5%. In this context, because the prescribed drug-related regulations and education in Turkey are insufficient, DTCA furthers the risk of improper drug consumption on account of the fact that patients can buy drugs directly from the pharmacies without prescription.

In developing countries where education of health and pharmaceuticals are insufficient, the drug ads/commercials mislead people and function as a factor to reinforce the belief that pharmaceuticals are ‘remedies for all troubles’. The media, then presents ‘hero’ medications referring to new discoveries which ‘eradicates’ cancer, or does away with rheumatism and puts an end to stomach problems. The created beliefs that diseases may be cured through medication rather than the efforts made to acquire the right knowledge, attitude and behaviours on health, also serves to increase inappropriate drug consumption and polypharmacy. Especially in
developing countries this tendency is common among patients as well as physicians, and present through symptomatic treatment. Within this general framework, it can be stated that pharmaceuticals in our daily lives have the function of acting in our homes as the front outposts of modern medicine. A high-ranking executive of a big pharmaceutical company declares that more than 90% of medication is successful in treating only 30–50% of the patients. As a result, it is hard to say that the situation mentioned above is taken into consideration in the rational consumption of the pharmaceuticals.

Health services and outcomes

The main approach in the reasonable application of pharmaceuticals which have an important role in health services, is that it should be applied when needed, with required amount and in the right required manner. Also reducing the problems, likely to occur in drug use, to minimum is only possible by giving priority to prevention and health promotion rather than saving or making money in health services. Unfortunately, the expenses made for the purpose of preventing and developing health, even in the most developed countries, remain on a very limited level. There are many conspicuous examples in this topic: among the health services in Switzerland, France and England, the percentage of preventive health expenses is 2%, while in Turkey this is about 1%. Almost every person of four in the USA is in the obese category; what’s more, expenses for cholesterol-reducing medications in this country are more than the total health expenses in Turkey. Again, the total expenditure of vaccination in Turkey almost equals the expenditure of a drug used for erectile dysfunction.

In today’s developing world, including Turkey, health services have been mainly reduced to drug-prescribing services. Required lab work or offering suggestions in life-style changes in diet and exercise are said to be neglected in medication-focused patient–physician interviews. The instantly available drugs have also provided the temporary concealment of the problems created by inadequate and unreachable health services. In this respect, it can be said that medication is also used as if to mask problems and inadequacies in the field of health. Rather than working to remove and resolve health problems in society through their ads, drug companies make it possible for diseases to be known, but only those for which their products would provide the remedy.

Direct-to-consumer advertising inevitably causes increasing and unnecessary usage of drugs and health services. Furthermore, the discussion of information which is brought by the patient from the ads, increases the physicians’ workload. About 25% of physicians in the USA claimed that they were under significant pressure owing to such demands. Public-oriented drug ads have led to the creation of some important problems in health services and physician–patient relationships.

The final remarks

Today’s world has entrusted the private sector completely for drug production, which has become the most profitable sector in health services. This leads to excessive amounts of profits in the pharmaceutical sector, irresponsibility by drug companies and health providers towards public, and also leads to problems related to unnecessary drug use by people. Among the ill effects of DTCA are that they are performed for the purposes of enhancing drug consumption, to increase the share of drug expenses in health expenditure, to the unnecessary consumption and to adverse effect and risks. Along with these, practices over drug ads are still being argued, and the DTCA regulations are becoming more flexible in Turkey for the sake of meeting the standards of the European Union. After such an arrangement which is only about non-prescription drugs, similar attempts over prescribed drugs would not be a surprise at all. DTCA for non-prescribed drugs in Turkey is an important part of pharmaceutical companies’
strategy to get their foot in the door, and later lead to DTCA aimed at prescribed drugs. Thus, while restrictions are made in the health expenses of government, regulations encouraging drug use of individuals on their own, bears the risk of the improper use of resources. In today’s world, where the effort in Turkey is to reach and be on a same level with the European Union especially in terms of regulations, in many areas there remain urgent issues that must be resolved in the field of health, prior to the direct introduction of DTCA. It should be remembered that, in Turkey, the rate of infant mortality remains five times more than that of the country with the worst conditions among the countries of the European Union and per capita health expenditures as approximately seven times less than European Union countries’ averages.\textsuperscript{113,114}

It must also be taken into account that instead of procedures including similar regulations ruling DTCA which are used in the European Union, the actual determinant here, is how their application will be realized.\textsuperscript{115} While problems faced within the course of the promotion of drugs for physicians still remain unresolved despite the ethical principles and legal regulations which have existed for 15 years, it is not very difficult to guess as to what extent the consequences of DTCA will be.\textsuperscript{9}

While the quality of health services remains unchanged and even declines as its cost increases, the improper use of limited sources threaten public health.\textsuperscript{4} It goes without saying that the advertisement of drugs will have a significant effect in increasing consumption. However, on what level it will contribute to the solution of health issues or whether it will speed up these problems are important questions which remain unanswered. Today, the basic need for the rational use of drugs is not its advertisement, but in providing adequate health services and sufficient education.

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