



The Ethical and Legal Evaluation of Pharmaceutical Products Advertising

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Abstract

Advertising is a mandatory condition for goods sales and is the main tool for competitive struggle in the market economy. The aim of advertising and providing information about pharmaceuticals do not differ from advertising of any other product – it is to convince people to buy promoted goods. However, pharmaceutical advertising has some features. This is explained by the characteristic aspects of objects related to medicine and health, which makes us consider the influence of advertising on people not only from the point of view of commerce but also through the prism of public and personal security of citizens. The purpose of the work is to evaluate the ethical and legal aspects of pharmaceutical advertising in the Russian Federation, as well as to study the influence of this advertising on consumer's choice. Materials and methods: advertising of pharmaceuticals and product specification file, comparative analysis, content analysis. Results and discussion: a pharmaceutical drug is a socially important product designed for health support of a patient and preventive health care of the population, hence the advertising of such a drug is subject to strict control by the government. Pharmaceuticals are advertised using different techniques. At the same time, the health of people depends on the quality of drugs and the accuracy of the treatment; therefore, knowledge and observation of the ethical and legal aspects of regulating advertising are significant and relevant at any time. Advertising legislation in the Russian Federation takes into account the features of medicinal products. However, it is established that there are many faults concerning the advertising of pharmaceuticals. Conclusion: based on the research findings it is determined that the most important component of the advertising activity control system is the state regulation which is implemented through the creation of a broad legislative framework. However, faults in the legal regulation and ethic aspects allow us to suggest some methods for improvement of advertising control.

Keywords: advertising, ethical principles, legal violations, medical product, Russian advertising code.

INTRODUCTION

Pharmaceutical advertising is pertinent to the health of society and its members. Currently, the advertising of pharmaceuticals has become the factor that increasingly affects their manufacturing and sale.

In the Russian Federation, the advertising of pharmaceuticals, dietary supplements, and medical goods is regulated by the Federal law "On Medicine Circulation" No 61-FZ [1] of 12.04.2010 (<http://www.rg.ru/2010/04/14/lekarstva-dok.html>), as well as the Federal law "On advertising" No 38-FZ [2] of 13.03.2006 (<http://www.consultant.ru/popular/advert/>), which specifies requirements both to advertising in general regardless of advertised product/service and to special cases, for example, advertising of medical products. The Federal law "On fundamental healthcare principles in the Russian Federation" No 323-FZ [3] of 21.11.2011 (<http://www.rg.ru/2011/11/23/zdorovie-dok.html>), as well as the Order of the Ministry of Health of the Russian Federation No 647-n of 31.08.2016 "On approval of regulations of Good Pharmacy Practice of the medicinal product for human use" [4] also indirectly make their contribution. Unfortunately, nowadays, there is a constant violation of advertising legislative regulation. According to general requirements, advertising must be honest and true. However, unawareness of end consumer about such a special product as a pharmaceutical drug give advertisers ample opportunities for providing flawed information about the product.

In our work, we have studied some potential faults from the point of view of the ethical and legal aspects of pharmaceutical advertising in the Russian Federation and carried out the positioning of legal infringements in advertising of medicinal products.

MATERIALS AND METHODS

Materials: pharmaceutical advertising, product specification file regulated the issues on advertising and information on pharmaceuticals.

Methods: comparative analysis and content analysis.

RESULTS AND DISCUSSION

One of the main peculiarities of a pharmaceutical drug as a product is the inability of a consumer to evaluate its quality

accurately. Any patient who takes a pill can see its color and shape, perhaps, he/she can smell and taste it. As a rule, this completes his/her knowledge about the properties of the given pill. Such fundamental concepts as "effectiveness" and "safety" of a drug are irrelevant for a patient and he or she cannot determine by himself/herself whether the properties of this pill correspond to his/her needs or not. Therefore, consumers in their choice have to be guided by other accessible properties relying on some pictorial cues.

Naturally, some chronic diseases can be an exception when it comes to choosing a drug. For example, in cases when a consumer previously has the prescript design of therapy or he/she deals with some periodical mild diseases which he/she knows how to fight against. Nevertheless, in most cases, consumers are guided by incoming information, for example, advertising.

Advertising is understood as any material which is published or broadcast using any medium or any activity, and that draws the attention of the public in a manner calculated to promote an advertised object and introduce it into the market [5]. The task of any advertising is to present the goods in the most favorable light, to create a desire of the consumer to buy it. The aim of advertising of pharmaceuticals does not differ from the usual advertising – it is to persuade a visitor of pharmacy organization to buy the advertised item. Advertising influences the formation of the emotional and rational elements of the consumer decision-making process for purchasing a medicinal agent or medical appliances.

According to general requirements, advertising must be honest and true; it must provide accurate and verifiable information about the benefits of pharmaceuticals and their bad effects. Moreover, unfair advertising is advertising that contains a comparison of the advertised product with others in the marketplace manufactured by competitors; also, it can be the kind of advertising the object of which is prohibited from being advertised in that particular manner. Unfair advertising refers to the use of false or misleading statements in advertising leading to misrepresentation of the concerned product [6]. Concerning the advertising of pharmaceuticals, relevant information is related to the benefits of the advertised product among those produced by other manufacturers or sold by other sellers; official or public recognition and the results of the trials are also important.

In advertising it is not allowed:

- to use the images of health workers and pharmacists, excluding the following cases: advertising of medical services, personal-care products aimed exclusively at health workers and pharmacists as its consumers, advertising published in places of conducting some medical or pharmaceutical exhibitions, seminars, and conferences, advertising published in print media designed for health workers and pharmacists;
- to reference to health properties of the advertised object (positive effect on disease progression), excluding such notification in advertising of pharmaceuticals, medical services including prevention techniques, diagnostic aids, health practices and aftercare, medical products.

It is not allowed in advertising to omit significant information concerning the advertised object, its purchase or use conditions if the information content is distorted or the consumers are misled by this advertising.

There are some individual requirements for the advertising of pharmaceutical products. According to the Federal law "On advertising" № 38-FZ of 13.03.2006 chapter 3, article 24, the advertising of pharmaceutical products must not:

- 1) appeal to minors;
- 2) contain reference to an individual case of full recovery, improvement in one's health as a result of the treatment with the advertised object;
- 3) contain expression of gratitude to physical persons in relation to the advertised object;
- 4) form an idea about the advantages of the advertised object using the references to the clinical trials which are mandatory for obtaining of marketing authorization;
- 5) contain the statements or assumptions about the existence of any deceases of consumers;
- 6) encourage healthy people to feel the need for application of the advertised object;
- 7) form the feeling of unnecessariness of visiting a doctor;
- 8) guarantee a positive effect of the advertised object, its safety, effectiveness and lack of bad effects;
- 9) represent the advertised object as a dietary supplement or anything other than a pharmaceutical product;
- 10) contain the statements about the fact that safety and effectiveness of the advertised object are guaranteed by its natural origin;

When defining the product promotion strategy (including pharmaceutical products) one should always take into account the risks associated with the opportunity of application of advertising legislation, as well as competition legislation. Therefore, we can highlight the following examples of the unfair promotional and PR activities according to the data of the Federal Anti-Monopoly Service of the Russian Federation [7]. (Table 1).

Based on the data of the Federal Anti-Monopoly Service of Russia we have carried-out the positioning of legal infringements in pharmaceutical advertising. Using the results of the study the following parameters of positioning were selected and classified including the most popular types of infringements in advertising of the studied products: assurance of the pharmaceuticals' positive effect; formation of the feeling that a dietary supplement has some health properties; absence of a warning about contraindications; having an illegible preventative superscription in print media; giving information about advantages of the advertised object by way of reference to the fact of carrying out the research that is mandatory for obtaining of marketing authorization; tendency to emphasize the secondary properties of the product rather than its main medicinal effect.

There was an inverse ranking of the positioning parameters at the next stage of the study where each factor corresponds its rank ("1" – lowest value, "5" – highest value). We

tabulate (R_i и R_n) the ranking results (Table 2). Determine the price of the rank (C) according to the formula:

$$C = 1 / \sum_{i=1}^n r_i \quad (1)$$

where: C – rank price; r_i – rank; n – numbers of factors.

Further, we calculate the weight (W_i) of each factor according to the formula:

$$W_i = r_i \cdot C \quad (2)$$

where: W_i – factor weight i ; r_i – rank; C – rank price; i – rank serial number.

As one can see from our study, the largest factor weight of legal infringements (0.286) is accounted for assurance of pharmaceuticals' positive effect, while the lowest value (0.048) is accounted for the tendency to emphasize the secondary properties of the product rather than its main medicinal effect.

Within the conditions of explosive development of the pharmaceutical market advertising plays a very important role but the consequences of its impact on consumers directly depend on its quality and truthfulness. Advertising legislation in the Russian Federation takes into account some peculiarities of pharmaceutical products circulation. However, interestingly, there are many infringements related to pharmaceutical advertising: unacceptable comparisons, promotion beyond the instruction for medical use (absence of a warning about contraindications), other inaccurate information. All this does not just mislead consumers but can also cause irreparable damage to their health [8].

The ethical regulation of medicines developed in the pharmaceutical market is primarily aimed at preventing promiscuous belief of the population in a panacea, in the indispensable effectiveness and absolute safety of the advertised medicines and, ultimately, in preventing a negligent attitude towards pharmaceuticals and their application [9]. Ethical promotion of pharmaceutical products is the activity carried out in the process of promoting safe, effective and high-quality medicines, medical products from the developer and/or the manufacturer before consumer use and taking into account the criteria of the World Health Organization and the European Union [10] Ethical criteria for promotion should ensure that the practice of pharmaceutical advertising is consistent with generally accepted ethical standards.

According to some authors [11], the possibility of ethical violations in advertising is taken into account even before the development of the advertised product; responsibility for them lies with the advertiser; the measures to combat ethical violations are proactive. Nevertheless, the actual practice of advertising requires consideration of parameters for estimating its ethical feasibility. We should stem from the norms of advertising ethics contained in the Russian advertising code of the Advertising Council of Russia – the professional code of advertisers (<http://www.investgazeta.net/praktika/kodeks-chesti-reklamista-133881/>) [12]. It is, primarily, lawfulness. Important standards of the Russian advertising code are honesty and truthfulness. Honesty obliges the advertiser to provide information about the goods, their quality, and advantages that correspond to reality [13]. Truth and reliability in advertising are considered as the central ethical principles of business dealing.

The Association of International Pharmaceutical Manufacturers (AIPM) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) pay much attention to advertising ethics. In addition, in Russia, there are a number of ethics codes - documents containing self-regulation norms concerning the advertising of pharmaceutical products:

- Ethical criteria for the promotion of medicines by WHO (1988).
- International Code of Advertising Activities of the International Chamber of Commerce (1986).

- Code of Marketing Practice of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) (1981).

These codes serve as guidelines: public organizations are currently forced to rely on them when identifying cases of improper advertising since the legislative framework is not full in Russia.

Unawareness of the end consumer about such a distinctive product as a drug provides advertisers with ample opportunities. This is where the question arises about socially irresponsible marketing, when, in the absence of knowledge in the field of medicine, the consumer becomes dependent on external sources of information about the product; moreover, he/she has to take this information for granted. Both real and imputative properties of the drug become indistinguishable for the patient. An important thing here is the balance between such concepts as "persuade someone to buy a product" and "deceive someone". The advertisers say that there is no need to talk about the deception of the consumer; as a rule, in their own defense, they refer to the conviction "mendacity is in the eye of the beholder" [14].

The advertiser can emphasize the safety of the drug, timing of onset of pharmacological effect, its depth or benefit for the disease progression, but in all cases, the consumer is unable to verify and evaluate the reliability of these claims. This involves some cases of the obsolete drugs advertising, which touches a chord of nostalgia offering a "time proved remedy", as well as some cases of pharmaceutical products advertising with ambiguous effectiveness.

The time-saving factor works for advertising. The world is turning faster and faster; self-medication becomes preferable for people, as it does not take time to go to the clinic, there is no need for waiting in queue to have an appointment with the doctor. It is much easier to cope with the disease by yourself dropping in a pharmacy after hours and buying everything necessary for

treatment, according to the advertisement or the opinion of a pharmacist.

The main technique of unfair competition for professionals is the use of deliberately false information in advertising [15]. It is difficult to mislead an expert with a variety of emotional teasers or plausible statements, but it is easy to do that with a patient. An unfair technique used both for professional and non-professional customers is the assignment of the advertised product properties and benefits that are proven for another, albeit similar product.

All the aforesaid gives ample opportunities for manipulating the consumer; a phenomenal occurrence appears that is characteristic only for the pharmaceutical industry when under pressure the consumer can be given an inappropriate drug or just something that is not even a medicine but is perceived in that way. This phenomenon is widespread in the sale of dietary supplements: they look like medicines, are sold in pharmacies, their advertising is similar to the advertising of medicines, and they are often recommended by pharmacy workers. All this makes most consumers perceive them as medicines [16, 17]. However, dietary supplements are not intended for the treatment of diseases [18]. The principle distinction between medicines and dietary supplements, used in some European countries, which is that the former are for patients, and the latter are for healthy only, does not find a broad response in Russia.

Pharmaceutical products are socially significant products; the health of the population depends on their properties. The pharmaceutical industry is responsible for providing the public with real information about pharmaceutical products. In this case, it is necessary to take into account the risk to which public health can be subjected in the absence of necessary regulation of the procedure for providing this information.

Table 1 – The risk matrix related to the violation in advertising of pharmaceutical products

Description of risk	Example	Reason
According To Advertising Content		
Using in advertising an image similar to the image of a pharmacist or a health worker	The image of a man wearing a white jacket was used in the advertising leaflet of a pharmacy	Para. 4 of Part 5 of the Clause 5 of the Federal law "On advertising"
Unacceptable comparison of products with placebo	The statement "twice as fast. Clinically proven" was used in the advertisement video concerning the product's effect, wherein the video sequence was accompanied by the explicative reference "in comparison with the group of placebo"	Para. 1 of Part 2 and Para. 1 of Part 3 of the Clause 5, Para.4 of Part 1 of the Clause 24 of the Federal law "On advertising"
According To Advertising Recipient And Its Placement		
Placement of pharmaceuticals advertising in TV or radio programs intended for minors	Placement the video with a pharmaceutical product for children on air of "Detskoye radio"	Para. 1 of Part 5 of the Clause 24 of the Federal law "On advertising"
Placement of advertising article about prescription drugs in the unspecialized mass media.	Speaking about contraception in TV program anchormen have demonstrated some packages of the prescription drugs and described their positive effects and health properties	Para. 8 of Part 1 of the Clause 24 of the Federal law "On advertising"
According To Key-Words		
Using the words "effective and safety" in advertising	Placement in a magazine the advertising of pharmaceutical products with the statement "effective for seasonal preventive measures and safety treatment of influenza"	Para. 8 of Part 1 of the Clause 24 of the Federal law "On advertising"
Using the word phrase "number 1"	Posting on the website of the statement that a certain manufacturer's silicone gel is "the number one choice of plastic surgeons from around the world"	Para. 2 of Part 1 of the Clause 14 of the Federal law "On Protection of Competition"

Table 2 – The results of calculations of rank price and factor weight

Ser. №	Factor	Rank(r_i)	Rank price(C)	Factor weight(W_i)
1	Assurance of pharmaceuticals positive effect	6	0.04762	0.286
2	Formation of the feeling that a dietary supplement has some health properties	5		0.238
3	Absence of a warning about contraindications	4		0.190
4	Having an illegible preventative superscription in print media	3		0.143
5	Giving information about the advantages of the advertised object by way of reference to the fact of carrying out the research that is mandatory for obtaining of marketing authorization	2		0.095
6	Tendency to emphasize the secondary properties of the product rather than its main medicinal effect	1		0.048

CONCLUSION

Advertising and promotion of pharmaceuticals is a delicate and complex matter because such things as the ability to draw attention to the product, ethical principles and mandatory norms of the legislation on advertising and protection of competition intersect in this area. The advertising segment of the Russian pharmaceutical market, in comparison with the Western European market of medicines, can be considered as not fully formed regarding both legislative and ethical regulation [15]. To date, the advertising of pharmaceutical products is carried out using all possible media. The most important component of the control system of advertising activities is the government regulation. It is implemented through the creation of a broad legislative framework. The ethical norms of the pharmaceutical market prohibit direct communication between the manufacturer and the patient. Most advertising devices, such as television, radio, local newspapers, are not used to promote prescription drugs.

Some faults in the legal regulation and ethical aspects allow us to suggest some methods for improvement of advertising control.

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