LEGAL FEATURES OF THE DRUG ADVERTISING

KWESTIE PRAWNE DOTYCZĄCE REKLAMY PRODUKTÓW LECZNICZYCH

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ABSTRACT

Introduction: In the article discribed current trends of advertising in the pharmaceutical market and foreign experience of legal regulation of these relations. As for the advertising of medicines identified it's symptoms, types, basic rules and prohibitions. Modern pharmaceutical companies can not successfully carry out economic activities without advertising. Besides we can mention some fundamental changes in society (information overload, universal access to internet, social media, freedom of movement of goods, labor and finance), also self-medication becomes more popular. At the same time, the number of deaths after improper and uncontrolled use of drugs ranks fifth in the world among the causes of death.

Aim: Investigate current trends of advertising on the pharmaceutical market, find advertising signs, basic restrictions and prohibitions on advertising of medicines, as well as foreign experience of legal regulation of these relations.

Material and methods: Despite the fact that pharmaceutical advertising were studied by such scholars as M. Abraham, L. Bradley, C. Dunn, J. Donoh'yu, D. Castro, M. Lipski, K. Taylor and others, number of issues related features of drug advertising, remained without proper theoretical studies.

Results: Based on the analysis can come to the conclusion that advertising of medicinal products are the subject of special attention from the state. Drugs, unlike other products, are a group of specialized consumer products. Risks increase when patients under the influence of «aggressive» advertising resort to self-medication. If a complete ban on advertising of medicines is inappropriate, you should set stricter requirements for the content of advertising and product placement rules. That is, in the national legislation to implement regulatory requirements of Directive 2001/83 / EC.

Conclusions: Legal regulation of drug advertising can be improved by such legal means: - should provide for a mechanism of public control over the observance of ethical standards in the advertising of medicinal products; - Prohibit the advertising of medicines for children, as well as drugs for the treatment of infectious, parasitic diseases and pathogens of these diseases, chronic insomnia, cardiovascular diseases, and those costs are reimbursed by government programs or trade names may lead to mix with prescription drugs; - Adopt ethical standards (codes) promotion of drugs for pharmaceutical companies; - Advertising to the public shall not contain any reference to cost or pricing features for medicines.

KEY WORDS: advertising, drugs, prescription, prescription drug, OTC drug regulation, Directive 2001/83/EC.

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INTRODUCTION

Nowadays modern pharmaceutical enterprises can not function successfully without using advertisement. Decrease of the consumer demand on particular segments of the market, necessity to obtain the feedback from a consumer, wish to have measurable results in some spheres of activity and demand new effective approaches to marketing development and information distribution about medicines with the help of advertisement [1]. According to fundamental changes in society, by virtue of colossal informational volume, the absence of borders and easy access the Internet, social webs such as Facebook become the most widespread means of advertisement distribution of different kinds of products, including medicines; it leads to the popularity of self-treatment. According to the WHO data, the death rate from irregular and uncontrolled administration of medicines occupies the fifth position in the world among death causes. Drug advertisement in the world is subject to strict control from the side of the state [2].

AIM

Investigate current trends of advertising in the pharmaceutical market, advertising signs, basic restrictions and prohibitions on advertising of medicines, as well as foreign experience of legal regulation of these relations.

MATERIAL AND METHODS

Despite the fact that pharmaceutical advertising relationships explored such scientists, as M. Abraham, L. Bradley C. Dunn, J. Donoh'yu, D. Castro, M. Lipski, K. Taylor and others, a number of issues related features of drug advertising, remained without proper theoretical studies.

RESULTS AND DISKUSSION

In countries with developed market economies the legal regulation of advertising has come a long way of development, and nowadays it is an effective mechanism that

combines elements of self and government regulation. Developing countries tend to extract lessons from the experience of advanced countries. Also they take into account national, religious, geographic, economic and other features of the native countries.

Advertising means information about the person, the product (services etc.) distributed in any form and in any manner which is designed to support consumer awareness of advertising and interest in respect of such persons or goods. More specific definition was adopted in paragraph 1 of Article 86 of the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use: advertising of medicinal products shall include any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products; it shall include in particular: - the advertising of medicinal products to the general public, - advertising of medicinal products to persons qualified to prescribe or supply them, - visits by medical sales representatives to persons qualified to prescribe medicinal products, - the supply of samples, - the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind, except when their intrinsic value is minimal, - sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products, - sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith. All parts of the advertising of medicinal product comply with particulars listed in the summary of product characteristics (name of the drug along with the potency of the drug and dosage form, qualitative and quantitative composition of active pharmaceutical ingredients and filler components, dosage form, detailed clinical data, pharmacological properties etc.).

This is the list of information that can not be considered as advertising. In particular, it is: - the labelling and the accompanying package leaflets, - correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product, - factual, informative announcements and reference material relating, for example, pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, as they do not include no product claims, - information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products.

As you know advertisement gives general information about medicines. More detailed information can be recieved from consultation with a healthcare professional and in particular in the case of nonprescription medicines from the product label and leaflet. Incidentally, Directive 2001/83/EC contains rules which are compulsory not only for the EU Member States, but also it is a kind of standard of progressive regulation. The current spectrum of drug advertisements aimed at consumers can be divided into three categories [3]: (1) health-seeking advertisements educate consumers about disease or medical condition; (2) reminder advertisements provide the name of the drug and other minimum information but say nothing about the drug's use, effectiveness, or safety; (3) product-specific advertisements mention a drug therapy by name, describe its therapeutic use(s), and make representations about it's safety and effectiveness [4].

Pharmaceutical policies reflect the enduring tensions between government objectives of supporting economic activity, on the one hand, and ensuring public's access to safe, effective and affordable drugs, on the other [5]. Spectrum of options ranges from non-state regulation to co-regulation and state-based regulation. Typically, states do not provide total ban on advertising of drugs, although government regulations include certain restrictions. Thus, medicine is a specific good and circulation of them is advisable to limit. Therefore approaches to advertisement of medicines in some countries are stricter than in others. It should also be noted that in Europe and the US, some drugs do not promote for ethical reasons, although it is not prohibited. Thus, Article 97 of Directive 2001/83/EC requires from member-states effective means of continuous monitoring of the advertising of medicines (previous system checks the prohibition of illegal advertising).

In Bulgaria requirements to the regulation of medicines advertising spelled in the Human Medicine Act according to which prior to the release advertising material passes matching stage [6]. The Expert Council of the Bulgarian Drug Agency investigates promotional material. This body consists of representatives of the agency, media sphere and public health, consumer organizations. On the basis of the opinion of the expert council the Agency issues decision. Any changes in the approved advertisement will pass appropriate approval before publication.

In the Taiwan (Pharmaceutical Administration Act, Articles 66, 67) any advertisement for over-the-counter drugs must be preapproved by the Department of Health. The entire ad, including all words and images, must be submitted. Once approved, an advertisement may be re-run multiple times for one year, which is the term of an advertising permit. An ad may be submitted for one-year extensions of the permit multiple times. If the permit for an ad is not issued, the ad must be revised and re-submitted prescription advertising for prescription drugs is restricted to academic medical journals. These can be presumably read only by doctors and specialists, and therefore are unlikely to have any sway over consumers [7].

Promotional activities in the People's Republic of China are under a strict regulation of the government (Advertisement Law of the People's Republic of China, Regulation on the Control over Advertisements, Measures for Administration of Printed Advertisements). The laws state that advertisements of pharmaceutical products on radio, television programs, newspapers, periodicals, and other media, as well as other specific advertisements should be tested in the relevant state bodies for legality of their

detention. Otherwise it will not be published. The general requirements for advertisement include the following: - if you use in advertising digital data, statistical data, survey results, excerpts from texts, quotes, you must comply with their authenticity, correctness and identify their primary source; - content of advertising should provide a spiritual and physical recovery of the people, improve quality of goods and services, protect the legitimate interests of consumers, adhere social and professional ethics, protect prestige and interests of the state; - advertisement must not be detrimental to the spiritual and physical health of people with disabilities and minors; - advertisement consists of readily recognizable signs, on the basis of which consumer would recognize it. Advertisement, which is distributed in media, should be specially marked and distinguish from other information, because it must not be misunderstood by consumer [8].

At the same time in international law we can find tendency to unification of national laws in different states, and therefore developed uniform rules of advertising regulation in force regardless of frontiers. As examples of international documents regulating advertising activity can lead the International Code of Advertising Practice of the International Chamber of Commerce (1986), the European Convention on Transfrontier Television (1989), the Madrid Agreement Concerning the International Registration of Marks (1891), the Agreement on Cooperation states-participants of the Commonwealth of Independent states in the field of advertising regulation (2003). States do not adopt common rules for regulation of advertising, but also create common official bodies to resolve disputes, provide legal assistance for each others in detection and prevention of violations.

An important role in this context plays the European Convention on Human Rights (1950), which recognizes the right to freedom of expression, and also set an effective mechanism for the implementation of this right. Article 10 «Freedom of Expression» states the following: «1. Everyone has the right to freedom of expression. This right shall include freedom of opinion's expression and distribution of information and ideas without interference by public authority and regardless of borders. 2. Exercising of these freedoms may be subject to such formalities, conditions, restrictions or penalties as are prescribed by law and necessary in democratic society in the interests of health protection or morals, protection of other's rights» [9]. That is, advertising is guaranteed by the right of freedom of expression, however, has a lower level of protection in comparison with non-profit views. Restrictions under advertising must be prescribed by the law, comply with legitimate goals and be necessary in democratic society. For example, the aim of protecting the reputation and rights of others were set as justified to limit advertising.

Thus, we can identify three systems of supervision (control) over the advertising of medicinal products: (1) preliminary assessment (before placing advertisement); (2) common control, that acts after placing advertising according to the clearly formalized procedures or market surveillance; (3) complete lack of control over advertising. The last one in the cotex of drugs is unacceptable.

It is necessary to mention advantages and disadvantages of advertising.

The benefits of advertising include: - provide additional awareness for patients on medications that they are interested in; - encourage patients to turn official sources of information about drugs (texts which are not intended on getting about drug will be banned); - patients will pay more attention to their health status, people become more informed about morbidity; - provide current information for patients about new drugs, their properties, or manufacturers; - make visibility of brands (trademarks); - helps consumers in choosing needed products; - encourage the development of competition on the quality and price of products; - ensure responsible use of medicines and awareness of patients for more skilled communication with medical staff; - urge additional investments in promotion; - patients become more actively involved in the healing process. Similarly, the advocates of drug advertising argue that advertisements are useful because they educate consumers. On their opinion, consumer advertisement empower patients in speeking with their doctors [10], also that prescription drug ads is an appropriate and highly valued source of information for health care consumers [11]. In other words, advertising ensure the right of every citizen on information. Any advertisement can not provide comprehensive information, but it should stimulate interest in looking for broader information. Therefore advertisement must contain reference on package leaflet or counsultation of physician, pharmacist.

The disadvantages of medicine's advertising include: (1) possibility of unfair promotion of medicinal products to the general unprepared audience. American consumers are bombarded daily with advertisements for prescription drugs that treat high cholesterol, diabetes, depression, pain, erectile dysfunction, and a host of other conditions. While the majority of pharmaceutical promotional expenditures still aimed at physicians [12]; (2) patients often practice self-treatment and rarely go to doctor. However, the civilized world 20 years ago adopted concept of responsible self-treatment to curb public spending on health. Advertising can not prevent healing process when the health system guarantees the availability of health services for people; (3) pharmaceutical companies control ways of information obtained by doctors, pharmacists, patients and persons involved in sector of research and development. Scepticists say that pharmaceutical industry co-opted these movements (the patients «and consumers» rights movements in health care) by means of DTCA, using the language of individual rights to support commercial activities [13]. However, companies are ultimately responsible to their shareholders, not to patients, and shareholders «desires for increased sales are often at odds with patients» needs for rational drug prescribing, there is an inherent conflict [14]; (4) expenses on advertisement influence at higher prices on drugs; (5) irrational use of drugs may worsen patient's conditions. Around 100,000 of people die every

year from the adverse effects of prescription drugs. This number is higher than of all murders, auto accidents, airplane crashes combined [15]. According to the WHO data, the death rate from irregular and uncontrolled administration of medicines occupies the fifth position in the world among death causes. Drug advertisement aimed to make control more strict from the side of the state [16]; (6) advertisement mislead consumers into taking costly prescription drugs that they do not need. Pharmaceutical marketers seek all ways to sell products. They turn normal human experiences with things like hair loss or shyness into diseases [17].

We would like to define the following types of advertisements:

1) advertisements for unspecified range of people that usually apply to OTC drugs, which have been recognized as safe and effective for use by patient alone without medical supervision. In developed countries advertisement of OTC drugs is allowed, but it tightly controlled by authorities in the field of health. Prescription and some OTC drugs have banned in most countries. In particular, such lists include as followings: (1) medicinal products contain narcotic drugs, psychotropic substances and precursors; (2) using of drugs can cause a syndrome of addiction, except drugs for external (local) application; (3) drugs are intended for using by women during pregnancy and lactation; (4) drugs are intended to treat tuberculosis, sexually transmitted diseases, especially infectious diseases, HIV/AIDS, cancer and other tumoral diseases, chronic insomnia, diabetes, adiposity (including drugs for weight loss), impotence (erectile dysfunction) etc. These drugs in the form of separate list must be approved by authorized authority in the sphere of health protection. Such body passes the decision on classification of the drug (advertising of which is prohibited or allowed) after public registration (re-registration) of medicinal product.

For example, in Great Britain the Cancer Act (1939) prohibited any advertisement to public that contains offer to treat any person for cancer or to prescribe any remedy for this, or to give any advice connected with treatment. Medicines which contain psychotropic or narcotic substances cannot be advertised to general public, with the exception of products listed in schedule III to the Narcotic Drugs Convention [18]. According to the article 66 of the Danish Medicines Act, advertising to general public shall not be allowed for medicinal products that: - are available only on prescription; - are inappropriate for use unless patient has firstly consulted with doctor to prove diagnosis or treatment, or - are comprised by Act on Euphoriant Substances. The general public means anyone who is not a doctor, dentist, veterinarian, pharmacist, nurse, veterinary nurse, pharmaconomist, midwife, bioanalyst, clinical dietitian, radiographer or a student within one of these fields. The purpose of the Act is to ensure that the citizens: - have access to safe and effective medicinal products of a high quality; - have access to objective and adequate information about medicinal products, and - are protected against misleading advertising and other illegal forms of marketing medicinal products. Also Article 87 of the Directive 2001/83/EC contains the following prohibition on advertising of medicines in such situations: - marketing authorization on the drug has not been granted in accordance with the Community law; - if the expenses on certain drug can be compensated from the budget; - if the drugs are distributed directly by pharmaceutical manufacturers with the purpose of advertising (vaccination measures approved by the competent authorities of the Member State can be qualified as an exeption).

Incidentally, the total ban on advertising of medicines, including OTC drugs, does not comply with the European practice. This measure should be accompanied by exercising of drugs only on prescription. According to the theory, prescription drug ads should be banned. However, some researchers [19] admit that advertising of prescription drugs is a form of free speech that should never be restricted, unless it will be fraudulent. All EU members permitted advertising of OTC drugs. In some countries there are small restrictions. It does not include drugs dispensed by prescription. In Ukraine, just as in EU, advertisements of prescription medicines are prohibited. Moreover, Ukraine has already stricted regulation – adopted the list of criteria which prohibit the promotion of certain OTC drugs.

Who will receive all benefits after banning the advertisements of medicines? It may be advantageous for manufacturers of medicines that have not already passed technological improvements. Besides they do not maintain standards of quality, and therefore suffer more competition from high-tech drugs on the market. As a result of the prohibition of advertising manufacturers will more likely maintain their level of sales for some time, because people would not be able deprive the information about existing and applying other medicines with similar storage. Also such initiative is associated with redistribution of the media market. However, the idea of maximum limitation of medicine's advertisements was approved by medical professionals who extended a monopoly on prescriptions. U.S. family physicians believed that DTC advertising was not a good idea [20]. Drugs, which are designed and intended for use without medical intervention for diagnostic purposes, destination or monitoring of treatment, if necessary - on the advice of a pharmacis, can be legally advertised to population. That is, advertisements of prescription drugs can not be aimed at the end consumer, but must be addressed to medical prescribers.

2) advertisement designed for professionals in the sphere of healthcare (physicians and pharmacists). In particular, the restrictions on public advertisement do not apply to advertisement of medicines, which are placed in specialized publications for medical institutions and doctors, and are distributed at seminars, conferences on medical topics. Active means of promotion are as follows: exhibitions, conferences, symposia, congresses with the participation of pharmaceutical companies, which inform practitioners about their products.

In the Directive 2001/83/EC mentioned the following rules of promotion of medicinal products for professionals

in the sphere of health protection, namely: (1) employers must provide adequate training for medical sales representatives; (2) medical sales representatives can not supply, offer or promise gifts, pecuniary advantages or benefits to persons qualified to prescribe or supply medicines, unless they are inexpensive and relevant to the practice of medicine or pharmacy; (3) the marketing authorization holder shall establish, within his undertaking, scientific service in charge of information about the medicinal products which were placed by him on the market; (4) free samples shall be provided on an exceptional basis only to persons qualified to prescribe them and on the following conditions: (a) the number of samples for each medicinal product every year must be limited; (b) any supply of samples shall be in response to a written request, signed and dated, from the prescribing agent; (c) those supplying samples must maintain an adequate system of control and accountability; (d) each sample must be no larger than the smallest presentation on the market; (e) each sample must be marked as «free medical sample – not for sale» or with another text, which have the same meaning; (f) each sample shall be accompanied by copy of the summary of product characteristics; (g) no samples of medicinal products containing psychotropic or narcotic substances within the meaning of international conventions, such as the United Nations Conventions of 1961 and 1971, may be supplied.

Gifts to physicians have been, for many years, a foundation of pharmaceutical marketing. Gifts can be offered to physicians in exchange for giving attention at promotional material or presentations [21]. Some critics of drug ads argue about the negative effect on physician-patient relationships because doctors may not prescribe medicines to their patients, which they have seen in the ads. Some detractors of drugs advertisements perceive a heavy promotional expenditure made by pharmaceutical companies as an indicator of increased drug prices [22].

Requirements on drug advertising were developed worldwide with great rigor and detalisation. The problem is that some advertising spots exaggerate the effectiveness of medicines and medical equipment. Such activities can be qualified as offences. Also in advertising spots we can often see so-called «happy» patients, which supposedly solved chronic diseases by using these drugs. This policy misleads buyers and damages their legitimate interests. Advertisers often exaggerate safety or therapeutic properties of medicines, or suggest on the exclusivity of the drug. In this field there are two issues that must be solved. The first one is an anticompetitive action of advertisers that violate competition rules. And the second one is violation of consumer's rights.

We would like to mention the following manifestations of unfair competition. Firstly, unlawful use of trademarks, advertising materials without permission (consent) of entity which previously has started using them in economic activities that lead or could lead confusion with activities of the entity. Secondly, comparative advertising contains a comparison of the goods, works, services or activities of another entity without permission. Comparisons will not be consider as illegal, if presented information on goods, works, services confirmed on actual data was reliable, objective, useful for consumer. Thirdly, dissemination of misleading information under which we mean the report about incomplete, inaccurate, false information about entities which can affect or may affect behavior of individuals regarding buying or selling goods and services of the entity.

Such misleading information, in particular, include the following data: - incomplete, inaccurate or false information about product, manufacturer, origin, seller, method of manufacture, source and way of acquisition, quantity, consumer properties, quality, completeness, suitability for use, standards, characteristics, and also essential terms of the contract; - incomplete, inaccurate or false information about financial status or economic activities of the entity; - information about relations which are not existing; - references to the production, purchase, sale or delivery of goods, works and services, which were not presented on the day of dissemination of information. Advertisement content should be controlled and this information must not mislead, at the same time it can display data about healing properties of the drug. Usually advertising should contain objective information about drug, medical device, method of prevention, diagnosis, treatment, rehabilitation. It must be clear that the message is an advertisement and advertised product is medicinal tool, medical device, a method of prevention, diagnosis, treatment or rehabilitation. Also must be indicated special requirement to consult with physician before using of medicinal product or medical device, and recommendation for mandatory review instructions to the drug with disclaimer as follows: «Self-medication can be harmful to your health», which takes at least 15 percent of the area (length) of all advertisement.

Legislation in most countries contains such restrictions on advertising of medicines: - advertisement can not include references to therapeutic effects in relation to disease that is difficult to treat; - it is forbidden to post messages stating that consultation with physician or pharmacist is not necessary or that therapeutic effect of the drug or medical device guaranteed; - it is forbidden to call some drugs as the most effective; - it is prohibited to post images of changing humans body (parts) as result of disease or injury; - it is prohibited to suggest statements that contribute to occurrence or fear of getting sick, if we will not use particular drugs; - it is prohibited to allocate statements that promote capabilities for self-diagnosis and self-treatment; - it is banned to show any participation of physicians or references on specific cases of successful use of drugs, or gratitudes, letters, excerpts of them with recommendations, stories about using advertised goods or services. Also it is not allowed to publish names or images of popular people.

CONCLUSION

Advertisements of medicinal products are the subject of special attention from state. Drugs, unlike other goods, belong to the group of specialized consumer products. Their

improper use can determine significant health damage. These risks increase when patients under the influence of «aggressive» advertising begin self-treatment. Restricting advertising of OTC medicines is a significant step towards solving problem of self-treatment. Legal regulation of drug advertising can be improved in several ways: - gain control over entities to monitor observance of legislation on advertising, particularly by introduction stringent sanctions for violations of the law and creation of effective forms and means of control over medicine's advertisement; - special authority of state control in the sphere of drugs turnower or health protection should monitor the compliance of legislation on advertising of medicinal products. It does not alter the activity of authorized bodies on competition protection, consumer rights or television and radio; - should be provided a new specific criteria for banning advertisements of medicines and mechanism of public control over the observance of ethical promotion and advertising. Also should be set state control platform for the resolution of ethical issues; - provide the prohibition on advertising of drugs for children of all ages; - provide ethical standards (codes) on promotion of medicines for pharmaceutical companies. At least this is the most effective tool for resolving disputes in advertising of medicines if the laws on these issues were not settled; - should be banned an advertising of drugs for dangerous infectious and parasitic diseases and carriers of pathogens of these diseases, chronic insomnia, sleep disorders and cardiovascular diseases; - advertisements of prescription drugs can be allowed only for specialists in the sphere of healthcare; - advertising of reimbursement OTC drugs and those, trade names of which coincide with prescription drugs should be banned. The same consequences apply to sampling of free samples, aimed at the end user, as well as the distribution of any coupons for received free medicines; - provide the prohibition of medicine's advertising, proposition on which may create the impression that there are numerous cases of serious transmission diseases.

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