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# Controversial advertising of medicines. A comparison between Poland and the United States*

**Abstract**

For many years, the subject of aggressive marketing campaigns conducted by pharmaceutical companies has been raised in Poland. Drug ads are everywhere, on television, the radio, magazines and on the Internet. Therefore, it is extremely important is to ensure both their legal and ethical dimension.

This article will present the differences between direct-to-consumer advertising of medicines in Poland and in the US. The dissimilarities result mainly from differences in legislation. In Poland, the law is much stricter than in the US. For example, in the United States companies are allowed to advertise prescription drugs directly to patients. In the whole of the European Union, and thus in Poland, it is strictly prohibited.

The article will also present other regulations existing in Poland and in the United States and it will compare them. It will offer examples of violations of the law and ethics in the advertising of medicine in both countries. Lastly, it will briefly outline the negative consequences of unacceptable pharmaceutical marketing.

**Keywords**: pharmaceutical industry, advertisement, drugs, law, ethics

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## 1. Introduction

Drug advertisements addressed to the public have very different forms: from television and radio spots through leaflets in clinics to product placement in films and television series. Such advertisement can be defined as "a message created by the marketing department of a pharmaceutical company, which aims at information, persuasion and even involvement of people towards which it is directed in order to influence their attitudes, and then to behave in a desirable manner" (Diehl, Mueller & Terlutter, 2008, p. 100). Companies want to encourage customers to buy a given drug and attach them to their brand so that they can buy preparations from a given manufacturer in the future (Chaniecka & Czerw, 2013, p. 513).

The average American spends 16 hours a year watching TV commercials of drugs (Frosch, Kruger, Hornik, Cronholm & Barg, 2007, p. 6). Companies spend massive amounts of money on the promotion there, because the American drug market is the largest in the world. Compared to it, the Polish pharmaceutical market is small. In terms of size it takes sixth place in Europe, but first place in Central and Eastern Europe (PAIiIZ, 2013, p. 1). In Poland, therefore, investments in advertising are also worth making. In 2014, producers of over-the-counter drugs were the largest advertiser on Polish television (KPMG & IAA, 2015). Advertising influences consumer behavior, as shown by Zarzeczna-Baran's and other researchers (2013, p. 82), 50.6% of respondents considered advertising to be a determining factor in the selection of over-the-counter drugs (OTC).

It is extremely important that the same large pharmaceutical corporations play the main roles in both Polish and American markets (Makowska, 2016, p. 12). It can be assumed that in a similar way they try to influence consumers by using various marketing tools. However, this is not entirely possible due to various legal regulations regarding drug advertising in both countries.

There are stricter laws in Poland because, in accordance with the rules imposed by the European Union, advertising of prescription drugs is not permitted (cf. Journal of Laws of the Republic of Poland 2008 no. 45 position 271, Pharmaceutical Law, art. 57). Advertising of prescription drugs is allowed in the USA; such advertising is called DTCA/DTC (*direct-to-consumer advertising*). In addition to the United States, it is legal only in New Zealand (Mogull, 2008, p. 106). The literature emphasizes that such advertising is a turn in the perception of the patient, because thanks to it he is treated as the partner of a doctor and a person who knows how to look after himself (Faerber & Kreling, 2012, p. 110). The advantages and disadvantages of such a solution are widely discussed in the literature (Stange, 2007; Ventola, 2011, pp. 669–674, 681–684). In Poland, as in the entire European Union, the patient can only receive information on prescription drugs from a doctor or pharmacist.

In the US there are big "pharmacies" (e.g. Rite Aid), where preparations of OTC drugs stand on shelves and you can reach for them yourself. However, the prescription drug must be dispensed by the pharmacist to the patient, which is why they are kept in the "back".

In Poland, there are no such "pharmacy supermarkets" (although the most frequently used OTC drugs are available in grocery stores or petrol stations), and to buy most of the over-the-counter drugs you need to go to the pharmacy, where it will be dispensed from the counter by the pharmacist. The method of sale results in a significant difference in the access to medicines and may also translate into a different ratio of consumers to these resources.

It can be assumed that a stricter regulation regarding the advertising of medicines, a more difficult access to them, translates into greater consumer safety. However, it must be remembered that restrictive government regulations may cause people to stop wondering, do not undermine the legitimacy of advertising drugs feeling that they are well protected. However, when government regulations are weak and consumers know this, they may be more cautious about promoting pharmaceuticals.

The purpose of this article is to describe and compare the main legal regulations that apply to the advertisement of medicines to the public in Poland and the USA. Examples of violation of legislation and illustrations of violation of ethical rules that occur in both countries will be presented. Next, the consequences of inappropriate pharmaceutical marketing will be discussed.

## 2. Advertising of OTC drugs in Poland

At the time of the Polish People's Republic, pharmaceutical companies operating in Poland were only state-owned. Pharmacies lacked medicine. "Own methods" for the production of expensive foreign medicines were developed (Szuba, 2003, p. 285). There was no need for marketing. This changed after the systemic transformation, which initiated changes in the Polish pharmaceutical market. The patents' rights began to be respected and the foreign drug corporations began to enter the Polish market with their products and their ways of their promotion.

For many years, the promotion of drugs in Poland was prohibited by law (cf. Journal of Laws of the Republic of Poland 1991 no. 105 position 452, Act on pharmaceuticals, medical materials, pharmacies, wholesalers and pharmaceutical supervision, art. 4. point 2) and it was not until 1993 that advertising of over-the-counter preparations was allowed (cf. Journal of Laws of the Republic of Poland 1993 no. 47 position 211, The Act on Combating Unfair Competition, art. 29).

After the TV spot of a drug, the pharmacies experienced a real invasion on patients trying to buy it (Szuba, 1994, p. 386). With time, as consumers became sceptical, this marketing began to lose its importance. Nevertheless, it still plays a very important role, which is particularly evident in the fact that many people in the pharmacy—without remembering the name of the drug—instead of trying to remember it, they tell the pharmacist the content of the advertisement (Sudak, 2015).

In 2014, the value of the Polish market of over-the-counter drugs was estimated at 11.5 billion PLN, an increase of 2.5% compared to 2013 (Kula, 2015). Most—68% of expenditures—companies spend on advertising on television, then on radio—23%, while in magazines—6.3% ("Koncerny farmaceutyczne…," 2017).

The currently applicable Act of September 6, 2001—Pharmaceutical Law—introduced provisions on the advertising of drugs to the public. First of all, it prohibits such publicity advertising, which concerns medicinal products issued only and exclusively on the basis of a prescription, containing psychotropic substances and intoxicants and placed on lists of reimbursed drugs. It also prohibits the advertising of medicines by well-known public persons, scientists, people who have medical or pharmaceutical training. It also suggests that the actor appearing in the advertisement has such education. The advertisments cannot include content that suggests that:

(1) one can avoid visiting a doctor or surgery by taking a given medicinal product;
(2) taking a given drug will significantly improve the patient's health, and not taking it can worsen the condition of a healthy person;
(3) the medicinal product is a food or cosmetic;
(4) the effectiveness and safety of a given medicine results from natural origin.

In addition, advertisements cannot ensure that taking a medicine will always be effective and will not have any side effects, and the effect will be better or the same as treatment with another preparation or other method. The content of advertisements also cannot give a detailed description of the disease and its symptoms. It is also forbidden to advertise that contains information incompatible with the Summary of Product Characteristics.

## 3. Advertisements of RX and OTC drugs addressed directly to customers in the USA

The history of advertising of drugs addressed to the public in the USA dates back to the beginning of the 20th century (they were then printed in newspapers and on posters). The first federal regulations regarding advertising appeared in 1906, they were detailed in 1938. In 1951, the governmental distinction for OTC and RX drugs was introduced for the first time. Previously, it was up to the drug manufacturer to decide whether it was sold with or without prescription. From that time on, medicines were to be issued based on prescription if they had harmful effects, were potentially dangerous, difficult to dose, and dangerous in receiving. In 1962, the Kefauver-Harris amendment was introduced, which required the medicine manufacturer to provide proof of the effectiveness and safety of the product before it was released into the market (it was the result of the tragedy caused by taking talidomide) (Donohue, 2006, p. 670). Since 1972, the so-called OTC Drug Review has been taking place. Because over 300,000 over-the-counter drugs are sold on

the US market, it would be impossible to describe and classify each one, which is why it is done for certain classes of drugs (e.g. for painkillers). For each category, a monograph is published. It contains information such as acceptable ingredients, dosage, formulas and labelling. If the drug meets the recommendations of the monograph, it is considered safe and effective, and companies can create and sell it without additional approval by the Food and Drug Administration (FDA). Drugs that are not compatible with the monograph must be verified by New Application Drug Process (FDA, 2015a).

OTC advertising must meet the three basic requirements imposed by its Federal Trade Commission. First, the producer must prove before the ad's admission that the claims used in the advertisement are objective and truthful. Secondly, the FTC considers how "real recipients" will react to advertising and how they will interpret it. Even if the ad uses "truthful assertions" but omits or suggests something that may lead consumers to misinterpret the facts, the FTC may forbid such promotion. Thirdly, the FTC may be against advertising that exposes the consumer to harm (Consumer Healthcare Products Association, 2015). OTC advertising must be true and not misleading. All the indications contained in the advertisement must comply with the approved indications: if the product is sold as compatible with the given monograph, its indications must be consistent with it (Blinkoff & Tabela, 2015).

Obviously, in the United States over the years, the advertising of RX drugs has been more controversial than OTC. The law authorizing the advertising of prescription drugs to the public has existed in the US since the 1980s. Paradoxically, what enabled DTCA development is the idea of "management of health care" (managed care), which was to reduce costs while increasing efficiency. The patient was to participate in the process of his treatment to a greater extent, and among other things, he had to participate in deciding what medicines the doctor prescribes to him. It was decided that thanks to RX drug advertisements, patients will demand more modern, newer, better-acting drugs, not those to which a pharmaceutical sales representative will convince a doctor during dinner (Kravitz, 2000, p. 221).

Because at the same time there were social movements that demanded more information about therapy for the sick, equalizing disproportions between the knowledge of the doctor and the patient, they were cleverly used by pharmaceutical companies in the fight to enable advertising of prescription drugs. The DTCA was supposed to educate patients, prepare for a conversation with a doctor, so patients themselves when talking about their illness, can co-decide on what drugs they would take (Donohue, 2006, p. 682).

Initially, companies were reluctant to use this form of advertising. Only 24 products were promoted in this way in 1985–1990 (Donohue, 2006, p. 680). It was believed that it could bring more damage and negatively affect the patient-doctor relationship. The main method of marketing was still the influence on doctors, which were massively visited by pharmaceutical sales representatives, leaving numerous gifts (Kravitz, 2000, p. 221). It was not until the early 1990s that DTCA commercials were aggressively developed. It happened thanks to, among others,

the spread of the Internet. In 1991, 55 million USD was spent on such promotion, in 1995—363 million (Donohue, 2006, p. 683), in 2009—4.51 billion, and in 2014—4.53 billion (Mack, 2015). This is more than it spent on the advertising of OTC drugs. For example, in 2009, it was 3 billion (Faerber & Kreling, 2012, p. 110).

FDA watches over correct prescription drug advertisements. There are three categories of DTCA: the *product claim ad*, the *reminder ad,* and the *help-seeking ad*. These three categories are subject to different legal recommendations and different requirements as to what they must contain (FDA, "Prescription Drug Advertising").

## 4. Controversial advertising campaigns for OTC drugs in Poland—examples of violations of law and ethics

The Chief Pharmaceutical Inspectorate (GIF) deals with the control of pharmaceutical advertising campaigns in Poland (cf. Journal of Laws of the Republic of Poland 2008, No. 45, position 271). Manufacturers are increasingly complacent with the Polish laws because in 2007 GIF stopped advertising 115 times, in 2010—47 times, and in 2015 only 8 times (Chief Pharmaceutical Inspectorate, "Decisions and messages"). In addition, the promotion of drugs is promoted by the Committee of Advertising Ethics (KER), which reviews advertising messages in terms of compliance with the Code of Ethics for Advertising.

The ban on RX drug advertising is sometimes broken in Poland. For example, by the decision of the Chief Pharmaceutical Inspectorate of April 2012, the Kadefam was ordered to stop distributing the *Menopause* brochure. *A guide for women whom the doctor prescribed for Cliovelle*. In addition to informational and educational material for patients, this guide included advertising elements encouraging the purchase of Cliovelle, such as printing prominently on the information that when taking this product, there is no significant weight gain. The brochure also contained a promotional slogan and a graphic sign identical to that on the package of the drug intended for sale on prescription (Chief Pharmaceutical Inspectorate, 2012). The advertising of medicines should be very carefully distinguished from information on medicines. However, it must be remembered that the line between information and commercial text can be very thin, and it should be caught by the appropriate supervisory authorities. However, it cannot always be done.

Among the most frequent GIF complaints about advertisements, there are accusations of the use of words and advertising slogans that mislead consumers. An example of an advertising campaign, which was paused for this reason, is the Ibuprom Max Sprint produced by USP Zdrowie advertisement, which was broadcast in the form of TV commercials. GIF stated that the slogan: "Even such a sharp back pain does not ruin your plans" introduces consumers to error because it should present the product in an objective manner and inform about its rational

use. In the characteristics of this medical product, there is no treatment for acute pain, but only for pain with mild to moderate intensity. Another slogan: "Take the strongest and the fastest Ibuprom Max Sprint" could suggest that this drug works the fastest and is the strongest. This ad also contains a footnote with the content: "the maximum plasma concentration is reached within 32.6 minutes; for tablets within 90 minutes." However, there was no indication of the source of this claim. In addition, this suggested to the consumer that the drug works three times faster than other painkillers (Chief Pharmaceutical Inspectorate, 2014).

In 2013 KER dealt with a similar case of the drug Teraflu produced by Novartis, because the TV spot contained the slogan: *Theraflu No. 1 for influenza in the world**. At the bottom of the screen, a lot of text as a reference to the footnote appeared, which no one would be able to read in a short time. KER's adjudicating team stated that the ad was attributed to the product features in support of which the company did not provide sufficient evidence and using the slogan misleads consumers (Committee of Advertising Ethics, 2011).

Ads can also affect human feelings too much. In 2014, for this reason, KER considered consumer complaints about the advertisement of Polocard by Pfizer Trading Polska Sp. z o.o. The grandfather disappearing during this ad aroused the audience's fears of death (Committee of Advertising Ethics, 2014).

Product placement is a very interesting form of advertising which is often used by manufacturers. For example, in 2011, GIF recommended the limited partnership "Teatr Kamienica" to remove the incorrect advertising of the product Acard from the play "I tak Cię kocham" ["I love you anyway"]. In the scenario, the phrase: "And let my heart remember Akard (Acard)" was spoken, the address of the drug's producer, Polpharma, also appeared in the dialogue of the play (Chief Pharmaceutical Inspectorate, 2011).

A specific form of advertising is found in large campaigns aimed primarily at educating the patients. GIF tries to prevent this by using the google test. It is checked whether the average Internet user after entering the name of the educational campaign about the disease and its sponsor is able to identify the name of the drug (Michalski, Sławatyniec, Duczyńska & Kęska, 2013, p. 132). An example of a campaign in which both GIF and KER found violations was organized by GlaxoSmithKline (GSK) action on the prevention of cervical cancer. Its aim was to persuade women to do a Pap smear to detect the disease early. At the same time, GSK is the producer of Cervarix, a vaccine which prevents cervical cancer (Makowska, 2010, pp. 113–114).

It is important that the patients themselves report advertisements that will be inappropriate for them because the competent authorities are not always able to discover all the irregularities. Pharmaceutical companies also participate in pointing out errors in advertisements, which, if they want to weaken competitors, often point to their violation of the rules.

## 5. Advertising campaigns for drugs in the USA—examples of violations of law and ethics

In the United States, as in Poland, pharmaceutical companies advertising their products do not always comply with applicable laws and ethics. The FDA deals with the violation of regulations related to prescription drug advertising. One of its departments, The Office of Prescription Drug Promotion, sends warns to pharmaceutical companies when they violate the principles of drug marketing and advertising. In 2007, 18 such warning letters regarding promotional materials were sent, in 2010—46 letters, and in 2014—10 (Food and Drugs Administration, 2015b).

Federal Trade Commission (FTC) deals with monitoring the observance of regulations related to the marketing of OTC drugs. The FDA and FTC adopt the same definition of false and misleading advertising, although their interpretation in practice is slightly different. The FTC does not require giving so much information about the adverse effects that a drug can cause. It is also not necessary to provide accurate information about evidence (e.g. clinical trials) of the effectiveness of the drug. Thus, the false statements are common in OTC ads (Faerber, Kreling, 2012, p. 227).

In addition to government regulations, there are organizations such as the National Advertising Division (NAD), Council of Better Business Bureaus and National Advertising Review Board (NARB) that deal with consumer complaints about advertising.

Faerber and Kreling (2012, p. 229) investigating drug advertisements appearing on American television between January 2008 and December 2010 stated that up to 57% of the main statements used in them can be considered as misleading consumers.

The FDA in 2014 dealt with the case of Exparel produced by Pacira Pharmaceuticals, Inc. Exparel. It has been approved by FDA for use as injections for local anaesthesia and indicated for use in postoperative activities. The object of the study was printed drug advertisement and educational cards for medical personnel.[1] The advertisement uses the sentence "Pain control, which lasts up to 72 hours," although the study has not proven that the drug has been active for more than 24 hours. This statement was false and misleading. On the educational cards, it was suggested to use the drug in the case of colectomy and laparoscopic cholecystectomy, although it was not proven to be effective with them (*off-label use*). Instructions for using the medicine for the uses studied were used, not for the new ones indicated. The FDA demanded the immediate discontinuance of the distribution of these advertising materials (Food and Drugs Administration, 2014b).

[1] The educational cards contained information about the physician, patient characteristics, instructions for dosing the drug, other information and information about safety. Promotional material can be found under the link: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM416514.pdf.

The FDA also makes sure that there is no lack of information on the adverse effects of the drug in advertisements. An example of a warning letter with such a thread sent in 2014 may be the one addressed to OptumInsight Life Sciences, Inc. on the drug Kapvay. This drug has been approved by the FDA as an integral part of the treatment of ADHD. Its use is associated with many risks, such as hypertension, bradycardia, excitement, fatigue, drowsiness, allergic reactions, sore throat, insomnia, nightmares, emotional disorders and others. In the telephone conversation script that the company's sales representatives were to conduct with various health care providers, important information about the risk of taking the medicine was skipped. It is true that the interlocutor was informed that full information on the medicine may be sent to him by e-mail, or he may read them on the website and asked which of the two forms he prefers. Nevertheless, the FDA did not consider it sufficient. In addition, the producer was accused of using a statement in the marketing script: *Kapvay, a drug for ADHD*, which is misleading, because the FDA approved this drug only as one of the elements of the treatment of this disease. Weaknesses were also found in information on the use and dosage of this remedy reported during the interview. The generic name of the drug was also not given in the script, which is a violation of US law. The FDA demanded a written reply to the letter and discontinuation of advertising conducted in this way (Food and Drugs Administration, 2014a).

The pharmaceutical companies themselves report to the National Advertising Division (NAD) the doubts regarding the competitor's advertising. In 2009, NAD alerted by Pfizer Consumer Healthcare dealt with the case of OTC drug Excedrin Extra Strength produced by Novartis Consumer Health, Inc. The ads used the statement that Excedrin works faster to relieve headaches than Advil, but the company did not provide any evidence. Ads using such an argument appeared on television and the Internet. Novartis did not want to give up so easily, because it had research conducted on a panel of 201 people confirming his advertising slogans and referred the case to the National Advertising Review Board, which in early 2012, like earlier NAD, ordered the company to stop its advertising (ASRC, 2012). In a study submitted by Novartis, no support was found for the general statements used in the advertisement. Novartis publicly stated that it disagrees with NAD and NARB, but he will comply with their recommendations. This case is an example of the efficient operation of self-regulatory organizations in the US (ASRC, 2012).

## 6. Conclusion

Advertisements often present drugs as "miraculous" remedies for everyday ailments. They work instantly and are able to solve all problems. Buying and applying them is even necessary for proper functioning.

American society is bombarded with commercials of pharmaceuticals, which is driving the gigantic profits of pharmaceutical corporations in this market. Although Poles are more "protected" from pharmaceutical marketing due to more stringent legislation, including the prohibition of the advertising of prescription drugs in our country, however, our society is increasingly seen as medicine-addicted (Sudak, 2015).

And while of course one can point to the good sides of drug advertising—raising the knowledge of consumers about the available preparations (you do not have to go to a doctor with every trifle), education about certain diseases, accustoming the ailments, even those which are shameful (e.g. excessive sweating, mycosis), encouraging a consultation with a doctor or pharmacist – they also have a lot of side effects. They are additionally compounded by the irregularities in the ads described above. Aggressive promotion of pharmaceuticals may lead to the medicalisation of society, pharmacologisation, self-diagnosis and self-treatment. Drug manufacturers are accused, inter alia, of not respecting ethical standards when cooperating with doctors; applying pressure on governments in particular countries to adopt beneficial system solutions for them; creating new diseases (e.g. meteopathy, restless leg syndrome); making even healthy people take medications.

Big pharmaceutical companies are lobbying for DTCA in the European Union as well (Arnold & Oakley, 2013, p. 505). They argue that such advertising plays a very important educational role regarding diseases and appropriate treatment (p. 506). So far, European leaders are resisting such argumentation. On the other hand, there are appeals in the US to prohibit the advertising of prescription drugs. Usually, the voices of opponents of this type of advertising are drowned out with the help of simple arguments to respect American freedom, and thus not to prohibit the producer from advertising their products (Ventola, 2011, p. 671).

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