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Direct-to-consumer advertisement as a factor influencing the pharmaceutical market: Legal and theoretical aspects of DTC (the Polish case)

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Abstract: In the following paper a brief review of the current government regulations on the Polish pharmaceutical market will be provided. The Polish pharmaceutical market has its own features and peculiarities. This is the only market in the European Union where advertising of pharmacies is prohibited.

Since 12 January 2012, by Article 94a of the Pharmaceutical Law Act issued 12 May 2011, it is forbidden to advertise pharmacies, pharmacy points, and their activities in Poland. In such a situation the role of direct-to-consumer advertising increases. The purpose of this study is to describe the existing situation in the Polish pharmaceutical market, to indicate the gaps and to highlight its controversial nature. A theoretical framework of direct-to-consumer advertising and its benefits has been outlined in the paper to determine the impact of direct-to-consumer advertising. The methodological framework of the study is comprised of a legal practice and statutory regulations overview, as well as analytic reports from statistics databases.

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Reklama skierowana bezpośrednio do konsumenta jako czynnik wpływający na rynek farmaceutyczny. Aspekty prawne i teoretyczne reklamy bezpośredniej (przykład Polski)

Abstrakt: W niniejszym artykule został przedstawiony krótki przegląd aktualnych przepisów prawnych dotyczących polskiego rynku farmaceutycznego. Polski rynek farmaceutyczny jest bowiem szczególny — to jedyny rynek w Unii Europejskiej, na którym reklama aptek jest zabroniona.

Od 1 stycznia 2012 roku — zgodnie z art. 94a ustawy z dnia 12 maja 2011 roku o refundacji leków, środków spożywczych specjalnego przeznaczenia żywieniowego oraz wyrobów medycznych — obowiązuje zakaz reklamowania aptek, punktów aptecznych i ich działalności w Polsce. W takiej sytuacji zwiększa się rola reklamy skierowanej bezpośrednio do konsumenta. Celem tego badania jest opisanie aktualnej sytuacji na polskim rynku farmaceutycznym, podkreślenie jego kontrowersyjnego charakteru oraz wskazanie występujących luk w przepisach prawnych. Aby określić wpływ reklamy skierowanej bezpośrednio do konsumenta, w artykule przedstawiono teoretyczne aspekty reklamy skierowanej do konsumenta i jej korzyści. Zakres badań obejmuje praktykę prawną i przegląd przepisów ustawowych oraz raporty analityczne ze statystycznych baz danych.

1. Introduction

The European pharmaceutical sector has been recognized as strategic by the European Commission.¹ Though in European countries there are general regulations (Directives), the pharmaceutical market of each country is unique, because it has its statutory regulation, economic and demographical factors which influence it.

To ensure high standards of people's quality of life and healthcare, there are supranational regulations in the EU.

The national legislation of each Member State of the European Union must be harmonized with EU Directives. On a supranational level (Council Directive 92/28/EEC of 31 March 1992 on the advertising of medicinal products for human use) — advertising of prescribed medicine is forbidden in the EU:

Article 3

1. Member States shall prohibit the advertising to the general public of medicinal products which:
— are available on medical prescription only, in accordance with Directive 92/26/EEC (8),
— contain psychotropic or narcotic substances, within the meaning of the international conventions [...].²

Moreover, Council Directive 89/552/EEC of 3 October 1989 regulates the broadcasting of advertising of pharmaceutical products and “Member States shall, by appropriate means, ensure, within the framework of their legislation, that

¹ <https://ec.europa.eu/docsroom/documents/7649/attachments/1/translations/en/renditions/native> (accessed: 23.07.2019).

² <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31992L0028> (accessed: 24.07.2019).

television broadcasters under their jurisdiction comply with the provisions of this Directive.”³

The Polish pharmaceutical market has its own features and peculiarities. Although the advertising of prescription-only medicines is prohibited in Poland (according to the EU Directives), this is the only market in the European Union, where advertising of pharmacies is prohibited by national law.

In the following paper a brief review of the current government regulations on the Polish pharmaceutical market is provided.

To determine the impact of direct-to-consumer advertising there has been provided a theoretical framework of direct-to-consumer advertising (DTC) and its benefits in the paper.

The framework of study contains legal practice and an overview of the statutory regulations, as well as statistical reports of the scientific databases.

2. Characteristics of the Polish pharmaceutical market

The pharmaceutical market is made up of all buyers on the demand side, all bidders on the supply side and, most importantly, the moderators of the pharmaceutical market — country authorities, who have an impact on the conditions in which the purchase transaction takes place.⁴

Similarly to other European countries, the Polish pharmaceutical market is in the phase of maturity by the limited increase in sales. According to the latest report of IQVIA, in the year 2017 the total value of the Polish pharmaceutical market (including prescription medicines, hospital and mail-order sales of pharmacies), calculated in retail prices was 38.3 billion PLN, which means growth of about 4.9% or about 1.8 billion PLN in money equivalent. Although prices for medicines vary significantly within the European Union, Poland remains the country with the lowest prices on the pharmaceutical market, demonstrating high affordability for consumers. The average price is about 4–6 EUR per pack.

According to the Pex PharmaSequence monthly report,

the average retail drug price in June 2019 was 21.4 PLN and was 0.9% lower than in the previous month, and 1.9% higher than the average price in June 2018. The average retail price of reimbursed prescriptions was 28.3 PLN, 26.4 PLN for non-reimbursed prescriptions and 16.2 PLN for products sold without a prescription.⁵

³ Article 3, Council Directive 89/552/EEC of 3 October 1989 on the coordination of certain provisions laid down by Law, Regulation or Administrative Action in Member States concerning the pursuit of television broadcasting activities.

⁴ K. Krążyńska, “Apteczny rynek farmaceutyczny i konsumpcja leków w Polsce,” *Konsumpcja i Rozwój* 2013, no. 2 (5), p. 109.

⁵ https://www.pexps.pl/files/upload/files/PEX_MonthlyReport_WWW_20190730K.pdf (accessed: 18.07.2019).

Another key point in the Polish pharmaceutical market is that any kind of advertising of pharmacy has been completely forbidden since 2012. Therefore we can admit that the health sector is strictly regulated, but in the case of Poland, it is regulated more strictly than in other countries of the European Union.

Since 1 January 2012, by Article 94a of the Pharmaceutical Law Act issued 12 May 2011, it is forbidden to advertise pharmacies, pharmacy points, and their activities in Poland. The ban, which was in force until the end of 2011, applied only to the advertising of pharmacies, which related to reimbursable drugs or drugs with the same name as covered by a refund. The current Pharmaceutical Law applies to all activities of pharmacies. Under the Pharmaceutical Law, Article 94a:

1. It is forbidden to advertise community pharmacies and pharmaceutical dispensaries and their activities. The information about the location and opening hours of the community pharmacy and pharmaceutical dispensary is not advertising.

1a. Advertising of non-pharmacy turnover units and their activities concerning medicinal products or medical products is prohibited.⁶

Nevertheless, Polish pharmaceutical law does not define the term “advertising of pharmacy and its activities.” However, it is indicated that “every action is directed at the public, aiming to boost sales of medicinal products and medical devices offered by a given institution.” Such a definition of advertising is understood very broadly in practice and can be misleading for all participants in the market.

Pharmacies are not allowed to issue newsletters about price cuts, participate in loyalty programs, and use promotional information of the name (e.g., “cheap medicines”). The Supreme Administrative Court recognized that encouraging the use of a sphygmomanometer is also a form of a pharmacy’s advertising. However, the law allows the providing of information regarding the address of the institution and its working hours.

The entry into force of the above law violates the legal norms of the European Union. Moreover, at the beginning of 2018, the Presidium of the Supreme Medical Council (Prezydium Naczelnej Rady Lekarskiej) appealed to the Polish Minister of Health (Minister Zdrowia Łukasz Szumowski) with a petition to consider a total ban on advertising of OTC drugs, for the reason that the Polish pharmaceutical market is on the verge of global change. The above-mentioned petition was published on the official website of the Polish Ministry of Health (Ministerstwo Zdrowia) on 23 January 2019. The Presidium of the Supreme Medical Council mentioned the report prepared for the National Council of Radio and Television (Krajowa Rada Radiofonii i Telewizji) “Broadcasting commercial communications of health products and medicines in television programs,” saying that the

⁶ The law of 12 May 2011 on the reimbursement of medicines, food products of special nutritional purpose and medicinal products (Journal of Laws of 2011, No. 122, it. 696 as amended) — (Polish).

number of advertisements for health products and medicines in four nationwide channels increased in the period 1997–2015 more than 20 times.

Among all other justifications for providing a complete ban on advertising, it is worth mentioning the following: “irresponsible advertising of over-the-counter drugs leads to their abuse and increases the frequency of complications associated with this.” Moreover, in this petition the authors demanded to implement a total ban on the sale of products which are not related to the treatment process in pharmacies.⁷ The answer to this petition was published by the Ministry of Health on 27 April 2018, with the following statement:

The Department of Pharmaceutical Policy and Pharmacy informs that in light of the content of the petition sent, other posts sent by public partners and knowledge possessed from the office, as well as in the context of law analysis at the national and EU level, it should be stated that the demand for a total ban on advertising of over-the-counter medicinal products, medical devices, and dietary supplements is unjustified. Referring to the application for the introduction of provisions regulating the advertising of medicines available without a prescription, medical devices and dietary supplements addressed to doctors, the Department of Pharmaceutical Policy and Pharmacy informs that these regulations have already been introduced and can be found in Chapter 4 of the Act of 6 September 2001 Law pharmaceuticals.⁸

The claim of the total ban on the sale of products which are not related to the treatment process in pharmacies was completely rejected by the Ministry of Health as unfounded.

It has been highlighted in the answer by the Ministry of Health to this petition that pharmaceutical law strictly regulates the advertising of medicinal products in Poland. For instance, Article 53, chapter 4 of the Pharmaceutical Law says:

1. Medicinal product advertising shall not be misleading, should present the medicinal product objectively and should inform on its reasonable use.
2. Medicinal product advertising shall not involve offering or promising any indirect benefits for purchasing the medicinal product or for delivery of evidence that the medicinal product has been purchased.⁹

It is worth mentioning that according to Pharmaceutical Law, there is a special body — the Pharmaceutical inspectorate (Państwowa Inspekcja Farmaceutyczna) which performs control under all public advertising and according to Article 63:

Upon request of the Pharmaceutical Inspection bodies, the Marketing Authorization Holder MAH must make available:

1. A specimen of all advertising addressed to the general public, along with the information on the method and data of its distribution;

⁷ <https://www.gov.pl/web/zdrowie/petycja-o-calkowity-zakaz-reklamy-lekow-dostepnych-bez-recepty-wyrobow-medycznych-oraz-suplementow-diety> (accessed: 24.01.2019).

⁸ *Ibidem*.

⁹ <http://prawo.sejm.gov.pl/isap.nsf/download.xsp/WDU20011261381/U/D20011381Lj.pdf> (accessed: 24.07.2019).

2. Information on all advertising addressed to persons qualified to prescribe medicinal products and to persons supplying medicinal products.¹⁰

Thus, assessing the local legal requirement on the Polish pharmaceutical market we can admit that there is strict control from the Ministry of Health and Main Pharmaceutical Inspectorate, whose mission it is to ensure patient safety by exercising supervision and control over the manufacture and marketing of pharmaceutical products. Nevertheless, there is no strict definition of pharmaceutical advertising, though a good solution would be for example, a catalog of non-advertising activities.

3. Direct-to-consumer advertising on the Polish pharmaceutical market

Taking into account local legal requirements in Poland and a total ban on the advertising of pharmacies and pharmaceutical dispensaries — when a retailer or wholesaler can create a message to customers in order to attract them to make a purchase in a particular pharmacy or pharmacy chain, there is another way to increase sales on the pharmaceutical market — direct-to-consumer advertisement (DTC). In the case of DTC advertising, the main players are the manufacturers (pharmaceutical companies) both local and international.

Direct-to-consumer pharmaceutical advertising (DTCPA) — can be defined as an effort (usually via popular media) made by a pharmaceutical company to promote its prescription products directly to patients.¹¹ The most common channels for DTCPA are the following:

- television;
- radio;
- newspapers, magazines;
- online advertising (websites, social media);
- brochures (despite the fact they are usually given by pharmacies or other healthcare professionals).¹²

DTC has numerous benefits, prominent among them including the possibility to set up direct contact with consumers, fast information about new products on the market (informational function), encouraging consumers to take preventive measures (motivational function) and creating the positive image of a pharmaceutical company. It is impossible to overestimate the educational function of DTCPA. DTCPA provides an educational function, informing patients about

¹⁰ Ibidem.

¹¹ G.A. Abel et al., “Direct-to-consumer advertising in oncology,” *The Oncologist* 11, 2006, no. 2, pp. 217–226.

¹² C.L. Ventola, “Direct-to-consumer pharmaceutical advertising: Therapeutic or toxic?,” *Pharmacy and Therapeutics* 36, 2011, no. 10, p. 669.

health conditions and available treatments.¹³ Moreover, setting the prices of medicine in the advertising helps to control product prices in retail.

The controversial nature of DTCPA is that the pharmaceutical product differs significantly from other consumer products, therefore the quality of information and message delivering in DTCPA is highly important.

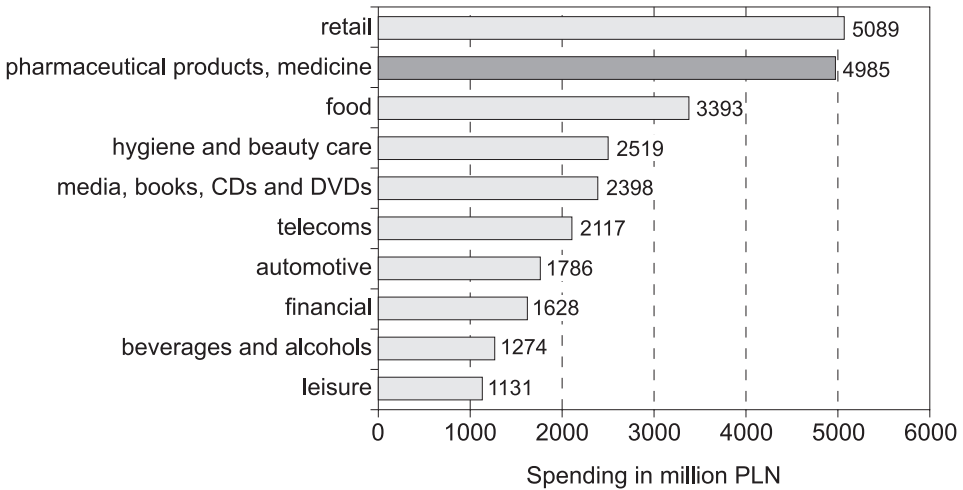


Fig. 1. Advertising expenditure in Poland by industry sector in 2016 (in million PLN)

Source: Statista, 2018 (accessed: 5.01.2019).

The current situation in the Polish pharmaceutical market on the one hand, and the quick positive response of consumers on the other, have led to the fact that the advertising expenditure of pharmaceutical companies has increased many times over.

According to the database Statista, in the year 2016, advertising expenditure in Poland in the pharmaceutical products and medicine sector reached 4.985 million PLN. Such expenditure almost equals the retail sector in Poland (5.089 million PLN). Furthermore, advertising expenditure on pharmaceutical products in Poland, exceeded the expenditure on food products, beauty care and the automotive and financial sector (Fig. 1).

Providing a comparative analysis with 2017, using the latest statistical data (available from 1.07.2019), we can state that advertising expenditure in the pharmaceutical sector in Poland has increased and reached 5.623 million PLN, in percentage terms the increase was 12.8%, whereas the annual inflation rate in Poland

¹³ D.L. Frosch et al., "A decade of controversy: Balancing policy with evidence in the regulation of prescription drug advertising," *American Journal of Public Health* 100, 2010, no. 1, pp. 24–32.

in 2017 was 2.6%¹⁴ compared to 2016. The pharmaceutical industry remains second after the retail industry (6.933 million PLN) considering advertising expenditure. By indicating such results we can assume that increasing advertising expenditure for manufacturers and wholesalers was caused by the fact that advertising leads to positive customer response and an increase in sales (Fig. 2).

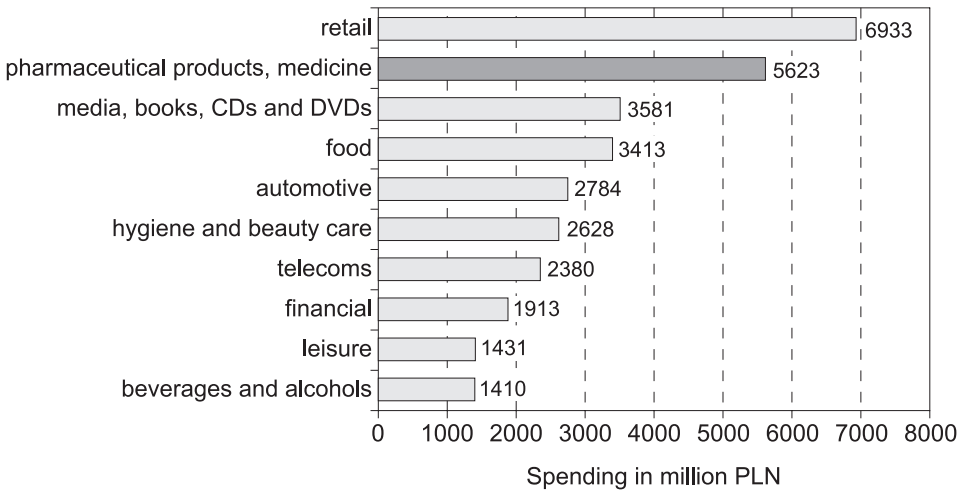


Fig. 2. Advertising expenditure in Poland by industry sector in 2017 (in million PLN)

Source: Statista, 2019 (accessed: 25.08.2019).

A negative impact of DTC advertising on the Polish pharmaceutical market can be:

- over-consumption of non-prescribed drugs;
- possible side effects of using inappropriate drugs;
- providing misleading information to the customers;
- increasing the cost for patients (advertising costs are included in the cost of the product).

In their research “Content Analysis of False and Misleading Claims in Television Advertising for Prescription and Nonprescription Drugs,” Adrienne E. Faerber and H. Kreling found that 57% of drug advertising on television was misleading: “potentially misleading claims omitted important information, exaggerated information, made lifestyle associations, or expressed opinions.”¹⁵

¹⁴ <https://stat.gov.pl/obszary-tematyczne/ceny-handel/wskazniki-cen/wskazniki-cen-towarow-i-uslug-konsumpcyjnych-pot-inflacja-/roczne-wskazniki-cen-towarow-i-uslug-konsumpcyjnych/> (accessed: 15.07.2019).

¹⁵ A.E. Faerber, D.H. Kreling, “Content analysis of false and misleading claims in television advertising for prescription and nonprescription drugs,” *Journal of General Internal Medicine* 29, 2014, no. 1, pp. 110–118.

In most cases, DTCPA on the Polish pharmaceutical market focused on the promotion of over-the-counter (OTC) drugs. In the case of OTC drugs, consumers can find the directions for use on the packaging and follow them, but it is important to ask for medical advice from a specialist in each individual case. Therefore “DTCA may motivate consumers to seek a physician’s care,”¹⁶ and does not force them to treat diseases without professional medical care. According to Article 8 of the Code of ethics in advertising: “Advertisements should not abuse the trust of the recipient or exploit his lack of experience or knowledge.”

Article 19 of the mentioned Code says: “In advertising for products which, in the case of normal use, pose a real danger, it should be legibly informed of the potential danger associated with their usage.”¹⁷

The above-mentioned articles should prevent the potential harmfulness of the promoted products, especially concerning pharmaceuticals.

The code of ethics in advertising obligates manufacturers to follow the rules of running advertising campaigns. Despite that, there are many lawsuits in the court against pharmaceutical companies, which have not abided by the advertisement standards.

“Advertising certainly has the power to reflect, cultivate, and amplify values and behaviors in our culture. However, how the values are selected and whether the selected values are appropriate are concerns to some critics.”¹⁸ There is no doubt that advertising shapes modern society, which is why it is so important to find the right values and follow ethical standards, especially when they are related to public health.

Nevertheless, such a big share of advertising expenditure creates competition on the market, which in turn leads to lower prices in the pharmaceutical market.

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¹⁶ A. Lyles, “Direct marketing of pharmaceuticals to consumers,” *Annual Review of Public Health* 23, 2002, no. 1, pp. 73–91.

¹⁷ Code of ethics in advertising, Warsaw, 18.01.2019.

¹⁸ K.B. Sheehan, *Controversies in Contemporary Advertising*, Thousand Oaks 2013.

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