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QUALIFICATION WORK

on the topic: «**ANALYSIS OF LEGAL FEATURES OF THE DRUG
ADVERTISING**»

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ANNOTATION

In the qualifying work, the theoretical foundations of advertising are considered. The features of drug advertising and its influence on the prescription and use of drugs are substantiated. The article highlights the state and features of the organizational and legal regulation of drug advertising at the international and national levels. A study of topical problems of the introduction of advertising of medicines in European countries has been carried out. The paper analyzes and summarizes the experience of reforms aimed at creating more rational and efficient health care systems that provide a high level of equity in medical and pharmaceutical care.

The qualification work is laid out on 52 pages, consists of an introduction, 3 sections, general conclusions, a list of used sources.

Key words: advertising, medicines, healthcare system, pharmaceutical industry, regulations, pharmacist.

АНОТАЦІЯ

У кваліфікаційній роботі розглядаються теоретичні основи реклами. Обґрунтовано особливості реклами лікарських засобів та її вплив на призначення та застосування ліків. У роботі висвітлено стан та особливості організаційно-правового регулювання реклами лікарських засобів на міжнародному та національному рівнях. Проведено дослідження актуальних проблем запровадження реклами лікарських засобів у країнах Європи. В роботі проаналізовано та узагальнено досвід реформ, спрямованих на створення більш раціональних та ефективних систем охорони здоров'я, які забезпечують високий рівень справедливості медичної та фармацевтичної допомоги.

Кваліфікаційна робота викладена на 52 сторінках, складається із вступу, 3 розділів, загальних висновків, списку використаних джерел.

Ключові слова: реклама, лікарські засоби, система охорони здоров'я, фармацевтична промисловість, нормативні акти, регулювання.

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ABBREVIATIONS

ABPI - Association of the British Pharmaceutical Industry

ANAM – National Health Insurance Agency

EMA – European Medicines Agency

EC-European Commission

EFPIA - European Federation of Pharmaceutical Industries and Associations

EU - European Union

HA - Health Authority

FDA – Food and Drug Administration

FIP - International Pharmaceutical Federation

GMP – Good Manufacturing Practice

ICESCR - International Covenant on Economic, Social and Cultural Rights

MENA - Middle East and North Africa

MP-Medical Products

NMRAs - National medicines regulatory authorities

NHS - National Health System

NDP - National Drug Policy

NEMLs - National Essential Medicines Lists

OPs – Online Pharmacy

OTC - Over-the-counter

PC - Pharmaceutical Care

POM - Prescription-only medicines

HTA – Health Technology Assessment

OECD – Organisation for Economic Cooperation and Development

RAs - Regulatory authorities

WHO - World Health Organization

INTRODUCTION

Relevance of a subject. Healthcare advertising is becoming increasingly important in raising awareness about various diseases and health issues, as well as the drugs and procedures needed for treatment. Unlike advertising in other industries, healthcare advertising is unique and subject to a plethora of regulations. Research on EU regulation in the field of pharma medical advertising focuses mainly on the rules applicable to the advertising of prescription drugs intended for healthcare professionals. Less has been learned about the other types of medicines that are part of the EU health market and about the advertising restrictions that apply to the marketing of these products to consumers. Although the restrictions on advertising of over-the-counter (OTC) drugs are not as detailed and strict as those that exist for prescription drugs, it is nonetheless important to be aware of the regulatory framework applicable to consumers of advertisements for such products.

The European market for OTC consumer health products consists of more than 2000 companies [1]. In our paper, we analyzed the general framework of legislation and industry codes of practice that exist at the EU level to regulate the advertising of these categories of products to consumers, with examples from national approaches.

At the EU level, the Unfair Trade Directive 2005/29/EC governs business-to-consumer relations relating to all types of products and services, including medicines, medical devices and foodstuffs. The directive contains a broad ban on misleading and offensive advertising [6]. For these purposes, an advertisement is misleading if it contains false information or is in any way misleading or likely to deceive the average consumer and cause or may cause them to make a transactional decision they would not otherwise make. Aggressive commercial practices include advertising that exerts undue influence or pressure in a way that limits the consumer's ability to make an informed decision. There are also restrictions on comparative advertising set out in Directive 2006/114/EC3 that apply to advertising directed at consumers.

In this work, we have identified the main problems of regulation and development of drug advertising in the world. We analyzed the changes in the advertising market, its types and growth prerequisites in the context of the COVID-19 pandemic.

To achieve the put purpose the following **tasks** of the research were definite:

- to study of historical aspects of the global experience of advertising research;
- to analyzed the advertising policy of the pharmaceutical sector;
- to investigation of the legal framework for the regulation of advertising: world experience.

The subject of the study is administrative and legal regulation of healthcare advertising.

The objects of the study were:

- statistical and informational materials of health authorities;
- data from WHO, as well as other international organizations on the organization of the work of pharmacy advertising;
- legislative and normative acts regulating advertising.

Methods of researches. The research used a system-overview, analytical and structural-logical methods of analysis.

The practical significance of the work. An analysis of the organization of advertising in the health care system of the United States and EU countries made it possible to identify factors contributing to this situation in relation to developing countries.

Scientific novelty. Attractive and negative factors of advertising when buying medicines are highlighted.

Structure and volume. The qualification work consists of the introduction, three chapters, conclusions and the list of the studied literature. The total amount of the qualification work makes 52 pages of the text, including 10 tables and 11 drawings. The bibliography contains 48 names of the studied literature.

CHAPTER 1. THEORETICAL PRINCIPLES OF ADVERTISING AND ADVERTISING CAMPAIGN EVALUATION METHODS

1.1 Historical aspects of the global experience of advertising research.

In many ways, modern advertising is the most important contribution to world culture. Advertising is a collection of stories that companies tell customers about their products to differentiate them from each other. By collectively listening to commercialized gossip and purchasing related products, consumers engage with images and stories.

The cultural dimension of advertising came of age in the 1920s. Agencies and publicists no longer sought to simply convey objective facts about products - they sought to associate products with a certain lifestyle, give them glamor and prestige, and convince potential consumers that buying a product can be a personally fulfilling and enriching experience. [1]. Advertising images try to both resonate with those who bought the products and help them define a lifestyle. Advertising reinforces the feeling of belonging to a group and shows that the advertised company also "gets it".

Advertising supports basic principles: freedom of speech, competition and democracy. Advertising is a source of important information about an open market economy. "Advertising is a powerful tool of competition. It provides valuable information about products and services in an efficient and cost-effective manner. In this way, advertising helps the economy to function normally - it supports low prices and facilitates the market entry of new products and new firms" [6].

Advertising plays a significant role in the business cycle, helping to stimulate economic growth. In a country where consumer spending determines the future of the economy, advertising encourages people to spend more. By encouraging more purchases, advertising contributes to both job growth and productivity growth to help meet rising demand and enable each consumer to spend more [48].

The main key role that advertising plays in the economy and what effect it causes, we have shown in the table 1.1.

Table 1.1

Key roles played by advertising in the economy

The effect of advertising	Contents	Consequences
Economic	<ul style="list-style-type: none"> • provides consumers with useful information about choosing products and services, as well as comparing features, benefits and prices; • with more complete information, consumers and businesses often decide to purchase additional products and services. 	<ul style="list-style-type: none"> • generates net income from direct sales and jobs through the promotion of industry products and services; • generates indirect sales and jobs among first-tier suppliers for industries that bear advertising costs; • creates indirect sales and jobs at all other levels of economic activity.
Consumer	<ul style="list-style-type: none"> • by providing information, advertising reduces consumer search costs, reduces harm from choosing the wrong products. 	<ul style="list-style-type: none"> • description of new products; • notifying consumers about the availability of the product and the place of purchase; • help differentiate competitive choices; • provide information about prices and advertising opportunities; • saving consumers money by encouraging competition.
Ethical	<ul style="list-style-type: none"> • advertising can affect a person's self-esteem when it uses a powerful instinct to assess physical and mental state 	<ul style="list-style-type: none"> • reinforces offensive ethnic and racial stereotypes; • violates confidentiality; creates false needs that make you crave brands and material goods.

One of the major questions in the history of advertising is whether advertising reflects existing cultural values and views on gender or whether it constructs and creates these views. Some analysts consider advertising to be only a "mirror" of culture. Others argue that advertising is a "distorted mirror" that both reflects and shapes our culture [25]. The advertising industry likes to say that advertising simply reflects existing values, because this view absolves advertisers of the guilt of maintaining unrealistic standards.

The history of advertising has gone through several major milestones, from the advent of the printing press in the 1440s to the enormous influence of television. From its earliest beginnings, advertising has had to constantly adapt and change to meet new media and increasingly savvy audiences [1,23,29].

The first television advertisement appeared on screens in 1941 in America. At that time, advertising was an integral part of society. Although the 1950s were a tense decade for America during the Cold War, television viewers felt optimistic and began to loosen their wallets as prosperity began to rise. Characters were built around the products to create the appearance of a connection between the audience and the brands, and famous faces were brought in to sell everything from washing machines to cigarettes [29].

According to the Business Dictionary, advertising is defined as: "Paid, non-personal, public communication of affairs, goods and services, ideas, organizations, people and places through such means as direct mail, telephone, print, radio, television and the Internet" [30].

Advertising is always there, although people may not know it. In today's world, advertising uses every possible medium to get its message across. This is done through television, print (newspapers, magazines, magazines, etc.), radio, press, Internet, direct sales, advertisements, mailings, contests, sponsorships, posters, clothing, events, colors, sounds, images and people.

The advertising industry consists of advertising companies, agencies that create ads, media outlets that place ads, and a host of people such as editors, visualisers, brand managers, researchers, creative directors, and designers who drive

the last mile to the client or recipient. A company that needs to advertise itself and/or its products hires an advertising agency.

The company informs the agency about the brand, its image, ideals and values behind it, target segments, etc. Agencies transform ideas and concepts to create visuals, text, layouts and themes to communicate with the user. Once approved by the client, the ad is aired according to bookings made by the agency's media buying department [43]. Therefore, advertising is a means of communication with users of a product or service. Advertisements are messages paid for by those who send them and intended to inform or influence the people who receive them.

The essence of advertising can be expressed in two stages (fig. 1.1).

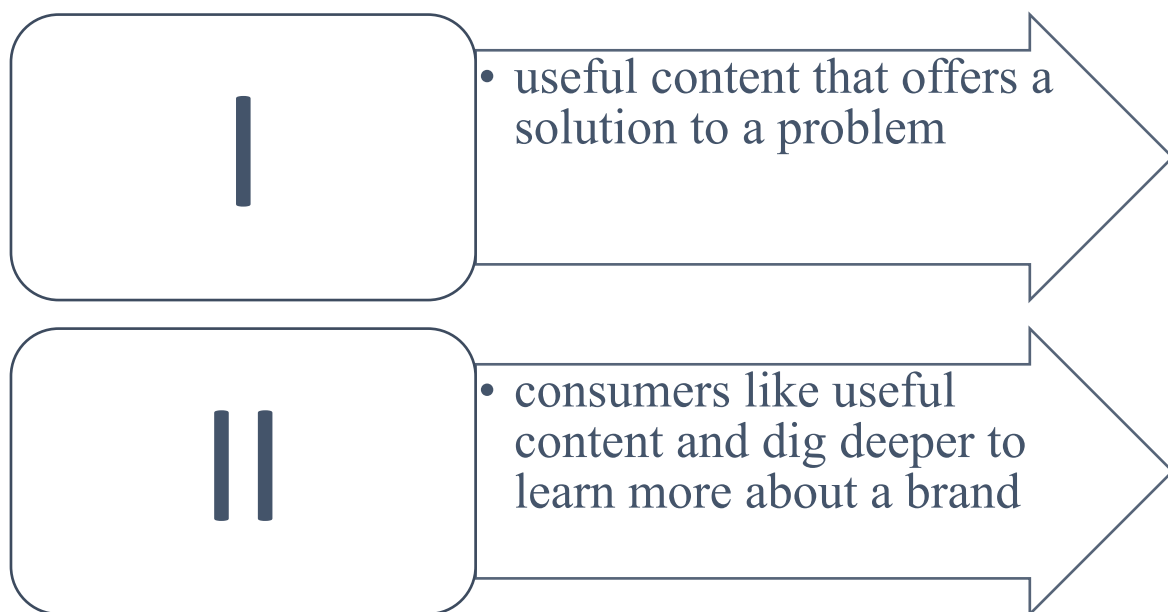


Fig. 1.1 Stages of the advertising creation process.

Over the years, the evolution of advertising has gone through several important stages, as it has had to constantly adapt and change according to new media and audiences. Most importantly, it has become much more personalized throughout history. The single medium that has had the greatest impact on the history of advertising and ad personalization is the Internet and its ability to collect billions of data points about users.

The Internet has made an incredible revolution in advertising [26]. This has changed not only the way advertising is broadcast, but also the way consumers relate to it.

1.2 Essential characteristics of advertising and features of advertising on the Internet.

When analyzing advertising claims, it is necessary to take into account the fact that this is a complex and ambiguous concept, which is interpreted with the help of a complex study. There are different approaches in terms of scope, and different countries interpret this judgment differently. This word is of Latin origin and is translated from the original language as "chant", "assert", "shout", all words with a clear active and persuasive color [16].

In the world, advertising has become a large and important service industry. Analysis of the information provided by foreign experts allowed us to formulate two main laws of advertising (fig. 1.2).

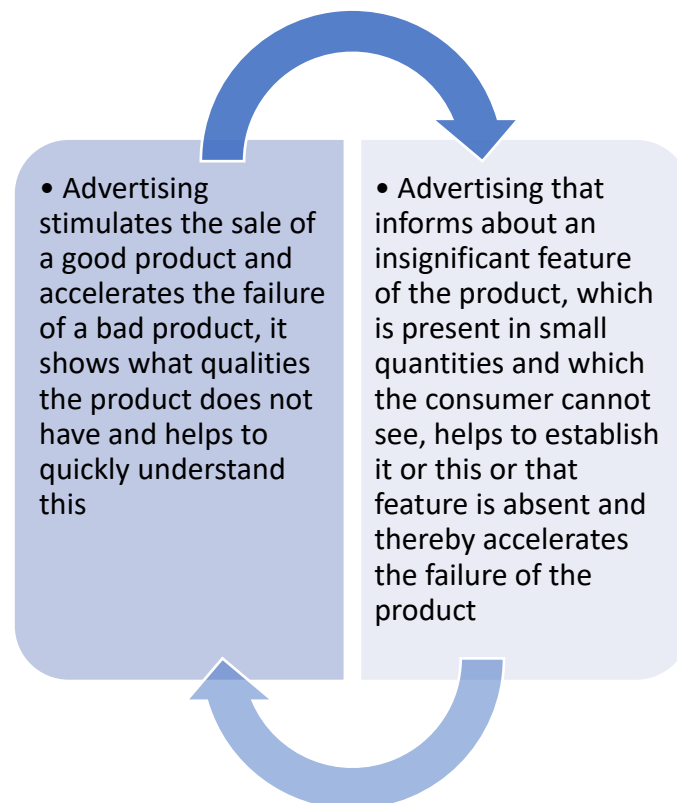


Fig. 1.2 Basic laws of advertising.

Scientists and practitioners in their research offer completely different sets of approaches to defining advertising. If you highlight the main ones and find the intersection, you can highlight the following (tabl. 1.2) [23,24].

Table 1.2

Approaches to defining advertising

Approach	Judgment	Function
Marketing (economic)	the most important tool of promotion, marketing communications	promotion of goods, services or ideology, which is reduced to informing, popularizing, increasing demand and loyalty, achieving the ultimate goal
Creative	creative process, product of intellectual activity	a bright, unexpected and attractive idea for advertising activities in order to stand out from the competition

Advertising is always aimed at the consumer, including the potential one, it is aimed at informing him about new goods and services and their consumer properties by various means.

The goals of advertising activity must be clearly defined in terms and expressed quantitatively, this approach to the formation of goals allows you to control the effectiveness of advertising activity [23]. Advertising goals can be very different, but the main goal of advertising is to increase the company's revenue by increasing the demand for services provided or products sold (fig. 1.3).



Fig. 1.3 Task of advertising activity.

Advertising performs a number of very important functions. The main ones presented in the table. 1.3.

Table 1.3

Main functions of advertising

Function	Value
Economical	Advertising stimulates the sale of goods and helps increase profits, speed up the buying and selling process.
Educational (informational)	Advertising acts as a learning tool: the consumer not only learns about goods and services, but also finds ways to improve life.
Communicative	With the help of surveys and questionnaires, analysis of market processes and internal research, the feedback of the company (company) with the market and the consumer is supported.
Controlling	Manages the processes of forming preferences of consumer groups for various products.
Demand management (marketing)	Using the possibilities of targeted influence on the consumer, advertising not only forms demand, but also manages it, reducing or increasing the volume of advertising information and planning its distribution
Public (social)	With the help of advertising, a message is transmitted to many people, a positive phenomenon, event, attraction is promoted, an anniversary in the life of the company is remembered, a warning is given about the negative consequences of certain events, etc.
Stimulating	Reminder, incentive to buy, contact
Psychological	Influence on emotional and mental processes, on the formation and development of needs, on the sense of self-worth, prestige, opinions and preferences of consumers, on their aspirations.

The Internet connects marketers with customers across the country and around the world. When advertising online, there are rules and guidelines that protect consumers and also help businesses maintain their trust in the Internet as a marketing

tool. In addition, advertising integrity standards apply when selling computers, software, drugs, or other products or services.

The term "Internet advertising" includes all types of advertising that are designed to be placed on the Internet and work with the target audience, it combines traditional image advertising with the dissemination of information and sales through the global Internet network".

Internet advertising - advertising placed on the Internet, mainly on well-recommended and popular websites (for example, Google), presentation of goods, services or enterprises on the Internet, addressed to the mass consumer and has a persuasive character [13].

There are several main types of advertising on the Internet, which differ in the scheme of interaction of the parties, the complexity of setting up and conducting the campaign, placement and other resources. Understanding their essence, advantages and disadvantages will avoid the risk of "losing money", as well as understand which option is definitely suitable and which is not.

The main types of advertising on the Internet and their features are presented in fig. 1.4.

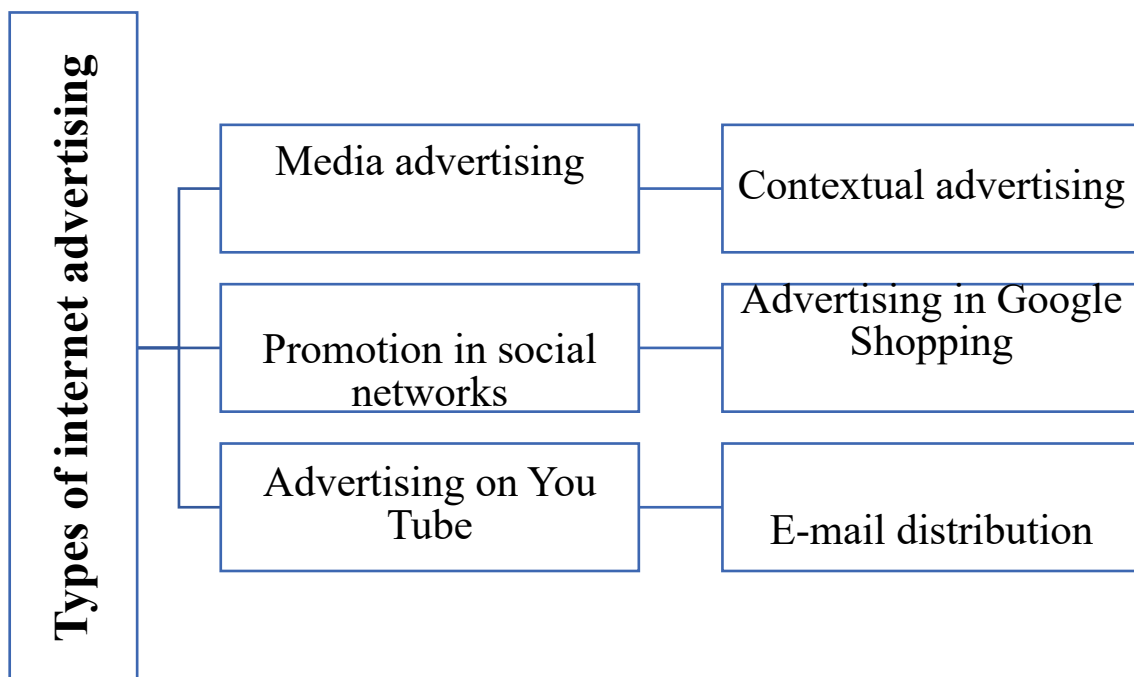


Fig. 1.4. The main types of Internet advertising.

Advertising is the structured and composed non personal communication of information, usually paid for and usually persuasive in nature, about products (goods, services, and ideas) by identified sponsors through various media. Direct to Consumer Advertising involves promoting products directly to consumers by the use of popular media. Historically, advertisers have used the traditional mass media - radio, television, newspapers, magazines, and billboards- to send their messages. But these are largely being replaced by Internet advertising. In today's world, advertising has a profound impact on the society of which consumer is a part. It is a powerful force that shapes the attitudes and behavior of the people.

1.3. Theoretical principles of advertising and advertising campaign in the world.

An advertising campaign is a set of coordinated advertising activities (events, appeals, publications) implemented by the company over a certain period of time and pursuing a single, clearly defined goal, connected by an identified topic.

"A successful advertising campaign is a combination of a successful advertising appeal and the right choice of media, as well as the timing of the appeal." It is possible to highlight the main variables of an advertising campaign - it is time, place and content, as shown in fig.1.5.

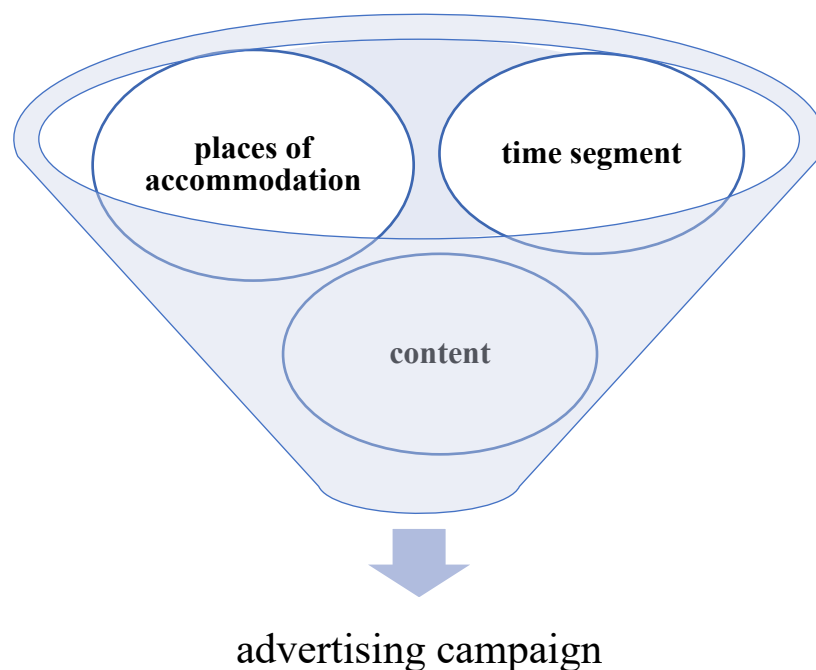


Fig. 1.5 – Components of an advertising campaign.

The development and implementation of an advertising campaign traditionally includes five main stages.

Stage N 1. *Research.*

Volumetric stage, which includes the collection of data about sites, enterprises, competitors and the target audience of the resource. At the same time, the main emphasis is on the analysis of the target audience, since the effectiveness of advertising depends, first of all, on the reaction of users to it. Conducting segmentation of Internet users using basic and connecting needs as segmentation features allows the campaign to significantly narrow or expand its target group, depending on the tasks, which can become an additional competitive advantage.

Stage N 2. *Setting goals and drawing up a strategy.*

At this stage, the company must clearly understand the purpose of advertising, that is, why the advertising campaign will be carried out. The goal may be to build the name and prestige of the company in order to later take a strong position in the market. The goal may simply be to sell the product. In other words, objectives may be economic or non-economic, or advertising may be purely economic or non-economic in nature. The campaign budget is formed on the basis of the received data. Marketers develop a company's promotion strategy based on its ability to stand out among competitors in the general market, providing consumers with a unique type of service or emphasizing in every way the high qualification of its workers, specific product properties, product or service advantages over other firms. It is important to find what the consumer is most sensitive to, as well as what will allow the most effective use of the advertising budget.

Stage N 3. *Media planning.*

A more detailed work plan is formed for short periods of time, where a complete list of all advertising communications is worked out, sites for placing ads are selected. The choice of the type of Internet advertising is carried out taking into account the specifics of the enterprise (company, firm), its goals and objectives, as well as advantages and disadvantages of each individual tool. The organization,

depending on its goals and tasks, should choose the optimal sites and means of Internet advertising.

Stage N 4. *Implementation.*

Development of advertising (creating videos and writing text for ads, creating creative), as well as setting up targeting displays, launching campaigns.

Stage N 5. *Calculation of efficiency.*

Analysis of results, calculation of performance evaluation and correction of impressions, as well as the ads themselves.

You can independently assess the effectiveness of the created advertising campaign in detail and make forecasts regarding the improvement of the quality of the online store, using various statistical and analytical services. After each end of the advertising campaign, it is necessary to evaluate the effectiveness and analyze the results.

It should be noted that calculating the effectiveness of advertising through an Internet resource is the most difficult, and this is due to the fact that the number of visits to the Internet resource correlates (with a high positive correlation coefficient) with the number of responses to other advertising means .

Advertising activity, compared to other types of activity, is more associated with risk, since there is practically no full guarantee of a positive result.

Advertising is a tool for generating income in business by increasing sales. However, when using this tool it is necessary to constantly monitor costs and evaluate the effectiveness of investments. So that advertising generates revenue that will exceed all costs. Otherwise, the funds received from the sale of goods and services will not cover the costs incurred and all the company's work will become unprofitable.

There are many types of advertising products. Depending on the goals and objectives of advertising, the following types are distinguished [23,24]:

- commercial or economic;
- image advertising;
- stimulating advertising;

- political advertising;
- business advertising;
- social advertising and others.

Public or social advertising is a type of advertising activity that is closely related to society, that is, society. The focus of attention is on models of human social behavior. The main goal of social advertising: to influence habits that are harmful from the point of view of society, forming behavioral patterns useful for society. In general, social advertising contributes to the humanization of society, therefore it is actively used by state structures, as well as all kinds of non-profit organizations. Advertising of medicinal products can be classified as a type of social advertising.

The development of the pharmaceutical industry in the world was parallel to the development of the advertising industry, and they were deeply intertwined. Patented medicines gained popularity among the public, manufacturers invested more and more money in their advertising. Advertising, in its early days, was widely stigmatized in society, undergoing rapid transformation into the main facet of the global economy we see today. At the beginning of the 20th century, drug advertising became a multi-million dollar market [28,29].

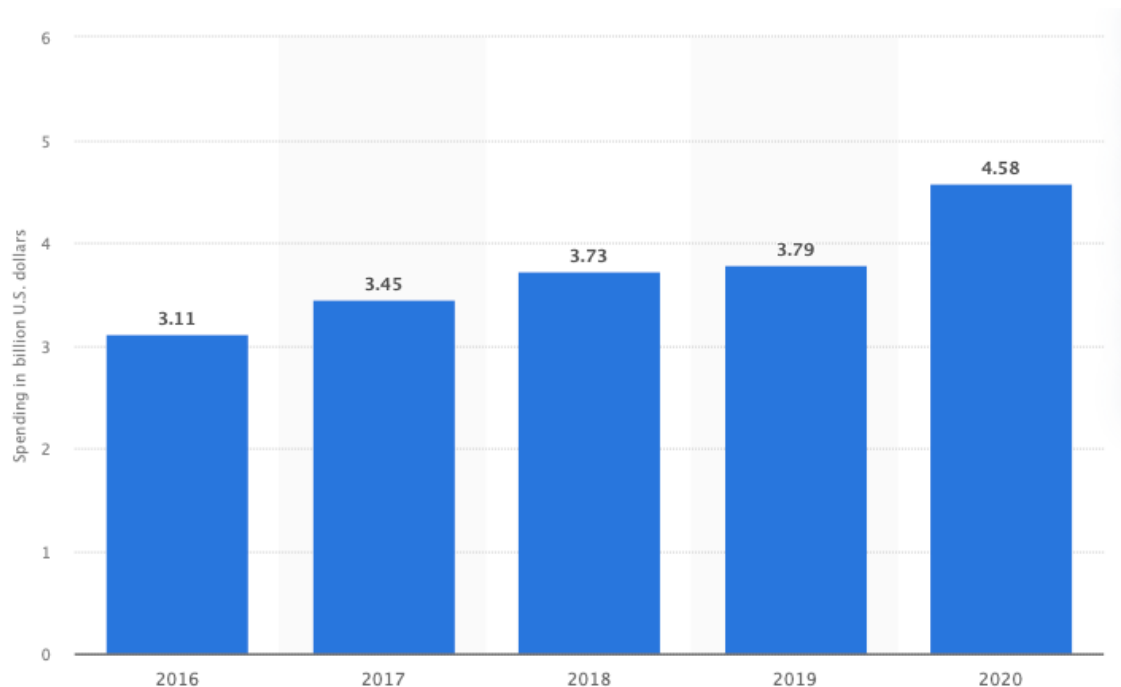
In the 19th century, there were no clear rules for the production and advertising of medicines. Pharmaceutical firms could voluntarily adhere to the American Medical Association's Code of Ethics, which stipulated that firms should sell and advertise their products only to the medical profession and not to the general public [47]. Because it was a voluntary choice, very few drug manufacturers actually followed the Code of Ethics. Patent drug manufacturers pioneered modern American advertising, which we continue to see today in both pharmaceutical and other commercial markets [37].

Drug marketing is big business, and companies are willing to spend a lot of money to offer you an easy solution to a health problem that a person may or may not have. In 2021, lifestyle and entertainment was the industry with the highest spending on television advertising in the United States, reaching US\$10.1 billion.

Pharmaceuticals and medical are in second place with spending of 5.6 billion, and food and beverages round out the top three with advertising spending of 4.5 billion [48].

From 2015 to 2020, annual prescription drug advertising spending across all media (except digital) increased from \$3.2 billion to \$5.2 billion, and that number is expected to continue to grow [2].

In 2020, the pharmaceutical industry spent 4.58 billion U.S. dollars on advertising on national TV in the United States, unsurprisingly representing a big shift in spending compared to the 2019 pre-covid market. In 2020 TV ad spending of the pharma industry accounted for 75 percent of the total ad spend (fig.1.6).



Source: Statista 2023.

Fig.1.6 Pharmaceutical industry TV advertising spending in the United States from 2016 to 2020 (in billion U.S. dollars).

The top-spending pharma companies in MediaRadar's study were Pfizer, AbbVie and GlaxoSmithKline. Pfizer spent most on brands Chantix and Eucrisa, while AbbVie spent on Humira, Orilissa and Mavyret. GSK spent more of its TV dollars on prescription product Breo Ellipta, but also on consumer brands Sensodyne and Flonase.

The pandemic upended everything in healthcare, even advertising. Spending on digital channels surged in 2020 and again in 2021. Now, marketers are grappling with a new landscape where consumers access treatment through video visits, mobile apps, and text messages.

Fierce Pharma reported according to data from Standard Media Index (SMI), pharma ad spend on linear TV fell by 4% YoY in 2022 while digital's share of the media mix rose from 49.6% to 52.6%, marking a possible tipping point in the transition to digital pharma advertising.

Advertisers are exploring tools like first-party data and contextual targeting to stay connected to consumers and clinicians alike.

Conclusions to the I Chapter

According to the scientific literature, we analyzed the current state of the global advertising sector. The main definitions of advertising, its functions and main directions of development were highlighted. In the first chapter, the theoretical base of advertising activity, the theory of advertising campaigns is worked out. The main definitions of concepts were considered, the goals and tasks of advertising were considered. The features and trends of modern advertising of medicinal products are analyzed.

It can be noted that due to the variety of forms of advertising, it serves different purposes and has a great impact on the economy, ideology, culture, social climate, education and many other spheres of public life. However, the main purpose of creating and spreading an advertising campaign is to sell a product or service and make a profit for business owners.

CHAPTER 2. ORGANIZATIONAL AND ECONOMIC ISSUES OF LEGAL REGULATION OF DRUG ADVERTISING.

2.1 Advertising as a source of information provision of society with rational pharmacotherapy.

Modern pharmacy cannot be imagined without advertising, just like any industry that provides services to the population. Pharmacists, conveying information to patients, paying attention to medicines, create a positive image for the pharmacy. Therefore, effective advertising is very important.

Medicines can cure acute illnesses, treat chronic conditions, relieve symptoms, and prevent future health problems. However, any decision to use medication involves weighing the potential benefits against the potential harms. To make an informed decision, a person needs information about the goals of the treatment, how it works, how to use it properly, the likelihood of benefit and harm, and how the drug compares to other available treatment options or the option of not treating, and relative cost-effectiveness. The quality of information accompanying medicines can make the difference between 'poison and medicine', between uses that lead to improved health and uses that are more likely to result in harm [3,18,31].

As important as information about medicines, inaccurate information about diseases and disease risks can cause harm if patients seek medical care when it is not needed, leading to unnecessary use of medicines and potential exposure to harm caused by taking medicines.

Irrational use of medicines is widespread in the world. This includes use when the medication is not needed, off-label use, selection of excessively harmful or ineffective options, concurrent use of products that should not be combined, use by patients for whom there is no scientific evidence of benefit, overdosing, and use of more expensive equivalent options.

Underuse can also be a problem, for example, if an inadequate dose or duration of use leads to ineffective treatment or the development of resistance, or if a person does not adhere to or does not receive the necessary therapy. Many factors

contribute to the misuse of medicines, including not only a lack of information, but also inaccurate and misleading advertising.

The World Health Organization defines pharmaceutical advertising as "all informational and persuasive actions of manufacturers and distributors, the result of which is an inducement to prescribe, supply, purchase and/or use medicinal products" [45,50].

Not all advertising necessarily leads to the misuse of medicines. However, there is a tension between the competitive pressures manufacturers face to increase product sales and the maintenance of limited, judicious use of the most cost-effective alternatives available. An analysis of the 25 most advertised drugs in the US from August 2013 to December 2014 found that only one-third were rated as innovative, and only one was on the WHO Essential Medicines List [48-50].

The instructions that are covered by the advertising of medicinal products are presented in figure 2.1.

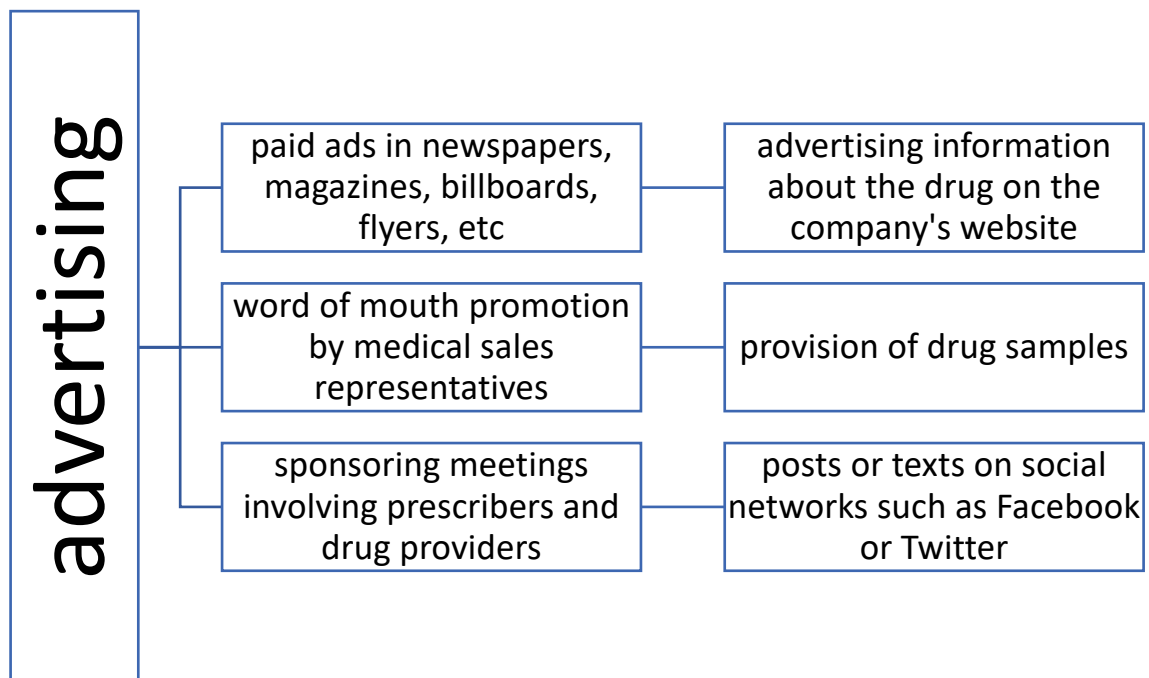


Fig. 2.1 Types of instructions to which drug advertising applies.

The new system emphasizes a shift from a product focus to a consulting focus. The development of information technologies in the field of health care and their impact on pharmaceutical practice shows the following statements [32]:

- a. to remain competitive in the future, the community pharmacy should become more of an information center;
- b. in order to become a point of contact for any health-related problem, pharmacists need appropriate sources of information about medicines that should be easily accessible, up-to-date, reliable and meet the needs of patients who need quick access to information;
- c. as patients have access to the same sources of information as healthcare professionals, pharmacists should be able to support patients in interpreting information;
- d. as the importance of information available on the Internet is growing, pharmacists must be familiar with new information technologies;
- e. websites approved by independent agencies should become the main sources of drug information for pharmacies;
- f. knowledge acquired at university often becomes obsolete after a few years. Pharmacists should participate in continuing professional development programs to update their knowledge in order to provide the best possible service to their patients.

Modern pharmaceutical companies cannot function successfully without the use of advertising. A decrease in consumer demand in certain market segments, the need to receive feedback from the consumer, the desire to have measurable results in certain areas of activity, and the need for new effective approaches to developing marketing and disseminating information about medicinal products through advertising [15,18].

Adequate information about medicines is vital for their correct use. Common pharmacy situations, such as adverse drug reactions, drug interactions, or use of drugs during pregnancy and breastfeeding, require access to sources of drug information. Information sources must be relevant, accurate, user-friendly and trustworthy. The image of the profession of pharmacists shows that the pharmacist is responsible for advising other medical professionals and patients on drug therapy and health issues.

A recent study of the use of drug information sources in Switzerland showed that pharmacists mainly use reference books and textbooks as sources of drug information. Also, in Spain and Hong Kong, official directories were the most common sources of information [41,46]. In Japan, pharmacists received information about drugs mainly from medical representatives of pharmaceutical companies [31].

All advertising of medicinal products must also meet quality standards (tabl. 2.1). Public advertising of pharmaceuticals that are for pharmacy or general sale is allowed. Advertising should not be directed exclusively or primarily at children [39].

Table 2.1

Quality Standard for the advertising of medicinal products.

	Standard	Quality requirements
I.	correspond to the information given in the product summary	clearly state that this is an advertisement for a medicinal product and state the name of the product and, if there is only one, the name of the active substance
II.	objectively present the product without exaggerating its properties and encourage rational use of the product	include information necessary for the correct use of the product and a clear invitation to read the instructions on the package or in the package instructions
III.	do not mislead	do not indicate that the effect of taking the product is guaranteed, is better than other identified treatment methods, or that the product has no side effects
IV.	not claim or imply that the product is "safe"	do not refer to the recommendations of scientists, medical professionals or celebrities who may encourage the consumption of drugs

Consumers value pharmacists who provide information about the proper use of medications and confidence that prescriptions are being filled correctly. Pharmacists are considered to provide valuable advice on a range of health issues

when requested. In accordance with the fundamental changes in society, thanks to the enormous amount of information, the lack of borders and easy access to the Internet, social networks such as Facebook are becoming the most common means of distributing advertisements for various types of goods, including medicines; this leads to the popularity of self-medication [17].

According to the WHO, mortality from irregular and uncontrolled drug use ranks fifth in the world among the causes of death. Advertising of drugs in the world is subject to strict control by the state [50].

Advertising of medicines, medical equipment, methods of prevention, diagnosis, treatment and rehabilitation helps to increase the competitiveness of the products of the companies producing the corresponding goods and services. And under conditions of competition, such companies will improve the quality of their goods and services in order to increase the number of consumers.

Also, one should not forget about the social significance of advertising of medicines, methods of prevention, diagnosis, treatment and rehabilitation - such advertising has a positive effect on the consumer's awareness in this area, provides him with information about the nature, assortment of such goods and services, etc. This, for example, allows a person who does not understand medicine to easily find his way around and choose the medicine he needs. In a democratic society, a person should have information about the product, in particular about the advertised medicinal product, and, having the information, gets the right to choose. It is impossible to deprive a person of the right to such information.

2.2 Analysis of advertising policy in pharmacy in the countries of the world.

Pharmaceutical regulation sets scientific standards and frameworks for obtaining high-quality, safe and effective medicines for patients. It is a critical component of the process that turns the spark of an idea into a licensed therapeutic that can change the lives of patients around the world.

In countries with a developed market economy, the legal regulation of advertising has gone through a long path of development and today is an effective

mechanism that combines elements of self-regulation and state regulation. Developing countries tend to learn from the experience of advanced countries. They also take into account the national, religious, geographical, economic and other characteristics of the native countries.

At the second stage of the work, we analyzed the policy of advertising medicinal products in EU countries, as well as in a number of other countries. Studying the experience of the EU is necessary for countries that are just starting this path and as a result of the European integration vector of development, their national legislation is gradually being harmonized with EU practices.

The regulation of advertising of medicinal products in the EU countries is quite uniform. This is due to the fact that the national legislation regulating the advertising of medicinal products in all EU countries is harmonized with Article VIII of Directive 2001/83/EC. It is in this document that the requirements for regulating the advertising of medicinal products are prescribed. The Directive is a set of key requirements and prohibitions. National legislation may not contradict them, but may contain unprincipled additions.

Directive 2001/83/EU of the European Parliament and the Council of the EU dated 06.11.2001 "On the consolidation of Community laws on medicinal products for humans" approved the consolidation of rules governing the production, classification of drugs, their labeling, advertising, placing on the market, wholesale and retail trade, pharmacological supervision, etc. [36].

According to Directive 2001/83/EC (Article 97), advertising of medicinal products is subject to effective and adequate monitoring [36]. According to the Directive's article 98, the Marketing Authorization Holder (MAH) must set up a scientific service to handle the information about medicinal products and make sure that the authorities or bodies in charge of monitoring the advertising of pharmaceuticals are following their decisions. However, the Directive gives some freedom to the Member States (MS) in the monitoring as it does not exactly elaborate on the rules for the control of pharmaceutical advertising. Nevertheless, the Directive does not contain precise rules on the control of pharmaceutical advertising,

leaving a certain degree of freedom to MS in carrying out such monitoring. The national legislation of the member countries that have ratified the Directive must comply with the provisions set out in it. However, each of them can approve additional rules, for example, regarding the advertising of medicinal products [40].

Each country has transposed the European Directive into national legislation and regulatory guidelines with local adaptations, so all MS have taken further special measures regarding the advertising of medicinal products. Thus, depending on the MS, pharmaceutical promotion may be controlled by the government, national competent authority or not, an approach called "self-regulation" [36].

As part of self-regulatory activities, monitoring and control in the absence of designated national competent authorities can be delegated, for example, to national pharmaceutical industry associations, stakeholder groups or the company responsible for the advertising itself. Such associations and organizations develop their own codes and can evaluate and approve advertising. Promotional activity is a key part of the business strategy of biotech and large pharmaceutical companies after obtaining marketing authorizations and as they prepare to launch their new drugs in Europe.

European countries can rely on different manuals/codes to follow the principles of good promotion practice, especially in the context of self-regulation of the company itself. Published by the WHO in 1988, "Ethical Criteria for the Advertising of Medicinal Products" provided the basis for the development of guidelines and measures to ensure ethical advertising practices [45].

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) regularly publishes a Code of Practice that sets global guidelines for the promotion of pharmaceutical products. Section 12.3 of the IFPMA Code of Practice 2019 states that a designated company employee with sufficient knowledge and appropriate qualifications should be responsible for approving all advertising communications (Qualified Academic Staff) [38]. Consumer protection laws play an important role in a robust market economy, the main ones are presented in table 2.2.

Table 2.2

European regulatory environment for pharmaceutical advertising.

Main legislative acts	Contents
Resolution WHA39.27. "Ethical criteria for the promotion of medicinal products", WHO,1988 [45].	Provide a framework for creating rules and policies to ensure ethical advertising practices.
Directive 2001/83/EU of the European Parliament and the Council of the EU dated 06.11.2001 "On the consolidation of Community laws on medicinal products for humans"[36].	The summary of rules governing the production, classification of drugs, their labeling, advertising, introduction to the market, wholesale and retail trade, pharmacological supervision, etc. was approved.
Directive 2005/29/EU of the European Parliament and the Council of May 11,2005 ‘Unfair Commercial Practices Directive’ [35].	Relation to unfair business-to-consumer commercial practices in the domestic market governing consumer advertising; -applies to any action or omission directly related to the promotion, sale or supply of the product by the trader to consumers. Thus, it protects the economic interests of consumers before, during and after a commercial transaction; - ensures the same level of protection for all consumers, regardless of the place of purchase or sale in the EU.
Directive 2006/114/EU of the European Parliament and the Council of December 12, 2006 [34].	Applies minimal and objective criteria for determining whether an ad is misleading for misleading and comparative advertising.
Directive 2010/13/EU of the European Parliament and of the Council of December 12, 2006. dated March 10, 2010 “Audiovisual Media Services Directive “ [33].	Coordination of certain provisions laid down by legislation, regulations or administrative acts in the Member States regarding the provision of audiovisual media services.
Regulation (EU) N 2006/2004 of the European Parliament and the Council of October 27, 2004 [44].	Cooperation between national bodies responsible for the implementation of laws on the protection of consumer rights.
Code of the European Federation of Pharmaceutical Industries and Associations (EFPIA) [38].	Companies operating in Europe refer to the relevant codes of practice. EFPIA Code of Practice on Relations between the Pharmaceutical Industry and Patient Organizations.

The unifying feature of the legislation of all EU states is the distinction between advertising of medicinal products aimed at the end consumer and at health care professionals. The regulations stipulate the different requirements for advertising to the general public and healthcare professionals.

Advertising of drugs for a wide range of consumers and information about medicinal products, presented in specialized publications, materials for specialized conferences, seminars, etc. Specialized publications are an integral part of the health care industry with a narrow target audience that is not the final consumer of the products about which the information is distributed.

Advertising can be presented in several forms, including:

- medical journals – scientific/professional/medical magazines;
- newspapers;
- television advertisements;
- internet advertising;
- posters.

The scope behind the regulation of advertising is to:

- encourage the rational use of the medicines, by presenting it objectively and without exaggerating its properties;
- ensuring that they are honestly promoted with regards to their benefits by complying with the particulars listed in the summary of product characteristics of the medicine; and
- not be misleading.

According to Directive 2001/83/EC, "advertising" includes a wide range of activities designed to promote the prescription, supply, sale or use of medicinal products. According to EU legislation, drug advertising is any form of direct provision of information by medical representatives, conducting population surveys or incentives that promote the prescription, supply, sale, or use of drugs.

We highlighted the main concepts that include drug advertising (fig. 2.2) [36].

-
- The concept of advertising
 - advertising aimed at the end consumer;

 - aimed at persons authorized to prescribe or supply drugs;

 - visits by medical representatives to persons authorized to prescribe medicinal products;

 - provision of product samples;

 - stimulation, encouragement to prescribe or supply drugs in the form of gifts in the event that they may be related to practical medical or pharmaceutical activities;

 - financial support of activities that contribute to the increase in the volume of sales of products, with the participation of persons authorized to prescribe or supply medicinal products;

 - financial support of scientific conferences attended by persons authorized to prescribe or supply drugs, including payment of related travel and living expenses.

Fig.2.2 Advertisement of medicinal products includes the following concepts.

Persons authorized to prescribe or supply medicinal products must have access to objective sources of information about the drugs presented on the market. It is worth noting that only those of them for which a trade license has been issued can be advertised.

The general legal regime of circulation of medicinal products [5,19]

The general principles included in the Code of Medicinal Products for Humans are as follows:

- Unauthorized drugs may not be advertised to any person (including the medical profession).

- It is forbidden to advertise prescription-only drugs, as well as drugs containing psychotropic or narcotic substances.
- All permitted advertising must be consistent with the product brief.
- All permitted advertising must encourage rational use and must not mislead.
- Member States may decide to prohibit the advertising of medicinal products for which the cost is paid.
- Companies should create their own scientific service. They must keep copies of published notices and provide them to the authorities upon request.

In addition to the directives and regulations specific to the pharmaceutical industry, the following four general directives and regulations apply:

Legal regime of sales to consumers [36]

Articles 87 and 88 of Directive 2001/83/EC on the Community code relating to medicinal products for human use require Member States to prohibit advertising:

- Medicines without a trade license.
- Consumers of prescription drugs.
- Consumers of products containing psychotropic or narcotic substances.

Medicinal products intended for use without the intervention of a medical practitioner may be advertised to the public, but must:

- It is clearly indicated that the advertised product is a drug.
- Include the name of the product and its generic name if the medicinal product contains only one active substance (member States have the possibility to derogate from this and allow reference only to the name of the product and the International Nonproprietary Names (INN)).

Directive 2006/114/EC on misleading and comparative advertising applies to all comparative advertising, but without specific reference to pharmaceuticals. This area is regulated in more detail in relation to medicinal products by the national legislation of EU member states [34]. A product advertisement is the only type of advertisement that includes the name of the drug and discusses its benefits and risks. However, these advertisements must not be false or misleading. The legislation

encourages companies to use plain language in product advertisements aimed at consumers (tabl.2.3).

Table 2.3.

Basic requirements for advertising according to users

Users	Requirements
End consumer	Advertising of prescription drugs, as well as drugs for the treatment of tuberculosis, sexually transmitted diseases, other dangerous infectious diseases, malignant neoplasms and other oncological pathologies, chronic insomnia, diabetes and other metabolic disorders is prohibited.
Health care specialist	Basic information, including a brief description of the drug (instructions for use); category of medicinal product leave; to be precise; be verified; sufficiently complete for the recipient to form his own opinion as to the therapeutic value; the class of supply of the medicinal product and the date of its preparation or last revision are indicated.
Advertising to the public	Give the impression that medical advice or surgery is unnecessary; indicate that the effect is guaranteed, without adverse reactions, or better or equivalent to the effect of another treatment or product; suggest that taking the product will improve health; suggest that abandoning the product may affect to health (except for vaccination campaigns); be directed exclusively or primarily at children; seek endorsements from people such as scientists, medical professionals or celebrities who may encourage consumption; suggest that the product is a food, cosmetic or other consumer product ; assume that the safety or effectiveness of the medicinal product is due to its naturalness; lead to false self-diagnosis due to the description of the medical history; refer to claims for compensation in inappropriate, alarming or misleading terms; use incorrect, alarming or misleading terms or depictions of changes in the human body caused by disease, injury or the effect of the product on the human body.

Member States are responsible for monitoring marketing activities in relation to professionals. MS have more detailed legislation than at the EU level. Member States should give courts or administrative authorities the power to issue orders to stop or ban advertising [34].

MS may require the inclusion in such advertising of information on the prices of various dosage forms of drugs, as well as on the conditions for reimbursement of costs for these products. All information contained in advertising must be true, up-to-date, verifiable and complete enough to enable health care professionals to form their own opinion on the therapeutic value of the medicinal product. MS should ensure the availability of adequate and effective methods of continuous monitoring of compliance with all regulatory requirements regarding the advertising of medicinal products. It may be based on a system of preliminary checks, but should always include statutory provisions under which regulatory authorities may take legal action against such advertising. According to the Directive, the main requirements for advertising to end consumers and to healthcare professionals (including all supporting documentation included in the advertisement) are presented in table 2.3 [36].

Despite the common structure in EU Directive 2001/83/EC, advertising rules are regulated by different texts and frameworks in each of the EU member states and Great Britain [36]. Each country has local peculiarities in the verification of advertising materials. Before starting local advertising operations in the EU and the UK, pharmaceutical companies must meet several local requirements to comply with local laws [32]. The European Union unifies 28 Member States as well as countries in the European Economic Area (EEA), providing a single market for the pharmaceutical industry. The EU's directives and regulations outline the requirements for the development, manufacture and marketing of medicinal products for human and veterinary use.

Each European country has different laws and regulations regarding drug advertising in Europe. Table 2.4 shows some of the main laws and regulations that pharmaceutical manufacturers must comply with.

Table 2.4

Laws and regulations of drug advertising in some EU countries

Laws and regulations	England	Germany	Italy	Switzerland
Laws and codes for advertising pharmaceuticals	EFPIA Code of Practice	Law on Advertising in the Field of Healthcare	Article 113 of Legislative Decree 219/2006	Federal Act on Medicinal Products and Medical Devices
Laws for internet advertising	Same as the above for advertising	Same as the above for advertising	Governed MoH guidelines of 17.02.2010	Same as the above for advertising
Laws for advertising on social media	Same as the above for advertising	Same as the above for advertising	Governed MoH guidelines of 06.02. 2017	Same as the above for advertising
Prior arrangements that companies must do	A final form is to be certified by a person on behalf of the company	Appoint an information officer	The MAH must have a scientific office that oversees the information released in the market	The MAH must designate a person who is responsible for advertising medicinal products
Penalties for failing to comply with advertising rules	Unlimited fine or two years of imprisonment	Intentional breach: 1-year imprisonment or fine Negligent breach: EUR 20,000 Negligent or intentional breach of explicitly listed regulations: EUR 50,000	Ranging from €2,600-€15,600 and €10,000-€60,000, when in the press or in radio-television programs	CHF 50,000
Need for Standard Operating Procedures for governing advertising activities	No legal requirement for SOPs	Provision of SOPs is advisable	No legal requirement for SOPs	No legal requirement for SOPs

Member States have the right to prohibit advertising on their territory for a wide range of medicinal products that are subject to reimbursement from the state budget. However, such restrictions do not apply to advertising aimed at healthcare professionals.

Conclusions to the II Chapter

From the above information, it can be concluded that in the EU countries, advertising of medicinal products for healthcare professionals is allowed. There are mandatory and advisory requirements for advertising materials in different countries, which may differ.

However, in most European countries they must comply with the Directive, which establishes general criteria. The unifying feature of the legislation of all EU states is the distinction between the advertising of medicinal products aimed at the end consumer and healthcare professionals.

It should also be noted that in the EU countries, when regulating the advertising of medicinal products, the general term "advertising aimed at persons authorized to prescribe drugs or supply them" is used, and the terms "information" and "advertisement" are more detailed compared to those in Ukrainian legislation and in different countries may include promotion, visits by medical representatives, and sampling [36].

CHAPTER 3. STUDY OF MODERN PROBLEMS OF DRUG ADVERTISING.

3.1 Law enforcement practice studying the risks in advertising medicines.

Advertising is the main tool for promoting goods on the market, the most effective mechanism for increasing sales of products and developing competition. Thus, the legislation in the field of advertising is primarily intended to regulate the process of advertising goods, ensuring its truthfulness and reliability.

All businesses that have a product or service to sell must advertise, and a competitive marketplace can lead to a range of dubious methods. Most of the time, businesses might exaggerate some aspect of their products and services, like calling them "The Best in the World," but some advertisements cross a line into unlawful territory. Claims that are outright misleading or false, especially those that could harm consumers or other businesses, are often prohibited by state consumer protection laws.

Laws against misleading advertisements differ widely from member state to member state within the EU. To respond to this issue in the internal market, the Commission adopted a directive, in force since October 1986, to establish minimum and objective criteria regarding truth in advertising. The Directive was amended in October 1997 to include comparative advertising. Under the Directive, misleading advertising is defined as any "advertising which in any way, including its presentation, deceives or is likely to deceive the persons to whom it is addressed or whom it reaches and which, by reason of its deceptive nature, is likely to affect their economic behavior or which for those reasons, injures or is likely to injure a competitor." Member States can authorize even more extensive protection under their national laws.

Manifestations of unfair competition in advertising are diverse. False advertising is defined as advertising that, due to inaccuracy, ambiguity, exaggeration, omission, violation of the requirements regarding time, place and method of distribution and other requirements provided for by EU law, introduces

or is likely to mislead consumers of advertising, cause harm to individuals and the state. The law specifies the characteristics of unfair advertising. For all that, unfair advertising does not include tricks and special effects, the purpose of which is to attract attention or cause laughter.

Comparative advertising, subject to certain conditions, is defined as "advertising which explicitly or by implication identifies a competitor or goods or services of a competitor." Member States can, and in some cases have, restricted misleading or comparative advertising.

The advertising of medicinal products for human use is regulated by Council Directive 2001/83/EC, as amended by Directive 2004/27/EC. The advertising of medicinal products is forbidden if market authorization has not yet been granted or if the product in question is a prescription drug. Mentioning therapeutic indications where self-medication is not suitable is not permitted, nor is the distribution of free samples to the general public. The text of the advertisement should be compatible with the characteristics listed on the product label and should encourage rational use of the product. The advertising of medicinal products destined for professionals should contain essential characteristics of the product as well as its classification. Inducements to prescribe or supply a medicinal product are prohibited, and the supply of free samples is restricted.

A common form of false advertising involves deceptive or misleading product descriptions, particularly claims that a product has certain features or benefits that it does not, or that it is of a higher quality than it actually is.

Another common false advertising scheme involves hidden fees or surcharges, which can cause the final price paid by a consumer to be substantially higher than the advertised price. This might occur with telecommunications companies, when the service provider hides additional, unauthorized charges on consumers' bills.

False and misleading advertising of a medicinal product should be prohibited by law and subject to state control. We analyzed and assessed the promotion of medical products and advertising of medicines, taking into account the regulatory framework and other restrictions in some countries of the European Union (tbl.3.1).

Table 3.1

Regulation of false advertising in the life sciences sector

Country	Definition of False Advertising	Self-Regulatory Bodies	Public Authorities
Belgium	The applicable laws and regulations in Belgium do not define false or misleading advertising. Advertising practices could, however, be considered false or misleading if the advertisement causes confusion or deception which could negatively influence the consumer's decision to purchase a product or service. Belgian law also prohibits advertisements that are able, by their presentation or omission of information, to mislead the addressee of the advertisement.	Pharma.be is the Belgian self-regulatory body. Member companies of pharma.be can submit complaints to the body against another member company regarding any violations of the Code of Deontology.	The Federal Agency for Medicines and Health Products is responsible for the monitoring and enforcement of the applicable laws and regulations governing advertising of medicinal products in Belgium.
France	Advertising of medicines must not be misleading or involve a risk to public health. It must objectively present the medicine and promote its proper use. Comparative advertising of medicines to the general public is prohibited. More generally, advertising of medicines to the general public is strictly regulated and not all medicines can be the subject matter of an advertising campaign.	For medicines, CODEEM acts as a mediation body and its litigation department can order sanctions.	Depending on the product concerned, French Health Authority ANSM proceeds to a preliminary control resulting in an authorisation or to an a posteriori control. Where ANSM finds that the advertising breaches applicable provisions, it may reject the application and ask for modifications, suspension or withdrawal of the advertising.
Germany	In Germany, false or misleading advertising occurs when an advertisement is capable of causing a misconception by an average person in the target market. Claims are based on the Pharmaceutical Advertising Act in conjunction with the Act against Unfair Competition since both prohibit misleading advertising. Promises of efficacy are likewise prohibited. In pharmaceutical advertising the so-called principle of strict interpretation applies. Further, advertising for indications not listed in the marketing authorization is prohibited.	The German self-regulatory body is the FSA (the Voluntary self-regulatory body for the Pharmaceutical Industry), but advertising disputes are not usually mediated there.	The Federal Institute for Drugs and Medical Devices (BfArM) does not intervene; only in some – extremely rare – cases (advertising to consumers) have the local authorities initiated proceedings.

Table 3.1 continued

Italy	In general, the definition of false advertising set out by Italian law is fully in line with EU law (Directive 2006/114/EC concerning misleading and comparative advertising).	The Giurì at IAP can issue an order (which is not subject to appeal) to cease misleading advertising.	Misleading advertising can be brought to the attention of the Authority for Competition and Commerce (AGCM), which may also start proceedings on its own motion. AGCM is an independent administrative authority responsible for, among other things, monitoring advertising and may initiate administrative proceedings against comparative or misleading advertising in order to ensure a level playing field in the market.
Netherlands	In the Netherlands, false or misleading advertising occurs when information provided in advertising material is incorrect or misleading, for example, as regards the nature, composition, quality, characteristics (e.g. efficacy and safety) or possibilities for use (e.g. registered indication).	Most pharmaceutical advertising claims are litigated before the self-regulatory body: <ul style="list-style-type: none"> • 2 types of complaint proceedings: • Preliminary proceedings; and • Proceedings on the merits. • Preliminary proceedings are the most usual. • Initiated by a written complaint containing all arguments. • There will always be a hearing. 	The Dutch Healthcare Inspectorate (IGZ) is the relevant public authority. <ul style="list-style-type: none"> • The IGZ and the CGR have entered into a formal agreement that pharmaceutical advertising matters are, in principle, dealt with by CGR. • IGZ may still initiate enforcement actions, usually resulting in a substantial administrative penalty (> EUR 100,000).
England	Advertising is misleading if it does not comply with the general requirement that all claims must be true, not misleading (i.e. omit or exaggerate key information) and be capable of substantiation, or any of the detailed requirements set out in the relevant UK legislation or any applicable codes of practice.	In the UK, advertising complaints are usually handled by the relevant self-regulatory body: <ul style="list-style-type: none"> • advertising of prescription-only medicines to healthcare professionals: the PMCPA, which enforces the ABPI Code; • advertising of branded over-the-counter medicines: the PAGB; and • advertising of medical devices: ASA or ABHI. 	The Medicines and Healthcare products Regulatory Agency (MHRA), which deals with the advertising of medicines where the advertiser is not an ABPI or PAGB member.

Traditionally, drug advertising has been the focus of increased attention of various regulatory bodies from year to year. At the same time, given the social significance of the drug markets, the spread of the COVID-19 pandemic has become a catalyst for the active actions of these bodies in the field of monitoring compliance with the law on unfair competition in the advertising of medicines.

Often, in case of violation of the law on advertising misleading the consumer, it is not possible without imposing fines on drug manufacturers who, contrary to the recommendations, advertise drugs in violation of the Directive "On protection against unfair competition", which establishes a prohibition on the dissemination of incomplete, inaccurate or false information in advertising misleading.

Marketing of medicinal products and medical devices is highly competitive. Successful advertising often depends on making forceful statements in relation to a product's performance or in comparing a product with a competitor's product. As advertising is highly regulated, especially in the life sciences industry, these statements can cause legal problems and possibly invite legal sanction.

Companies are keen to challenge competitors' advertising which they believe to be inaccurate or misleading, as well as to robustly defend their own marketing claims in the event of a challenge from a competitor or a regulator.

One of the frequent violations of the law is the dissemination of inaccurate information about drug leadership.

When forming advertising statements that indicate the leadership qualities of the respective medicinal product and / or the business entity that manufactures and / or sells it, it is necessary:

- observe the most correct wording;
- be based on evidence;
- refrain from exaggeration;
- pay special attention to the time when the relevant research was carried out confirming the leadership of the product, and when the corresponding advertising is distributed.

Due to the importance of medicines to the public, the fight against misleading advertising claims is difficult. This study allowed us to conclude that the new rules in the EU countries facilitate the enforcement of cross-border judgments. In addition to the various options for taking action against misleading advertising in state courts and public authorities, the role of self-regulatory bodies is becoming increasingly important in many countries.

Preliminary control and review of promotional materials is a common practice in Europe. Thus, in France, any advertising of medicinal products requires permission from the Ministry of Public Health or its authorized bodies. Advertising of medicines in Italy and Denmark is subject to mandatory approval by ministries of health. Sanctions for violations of the law can range from government orders to stop advertising, to fines imposed by court decisions, and other forms, up to criminal liability.

3.2 Analysis of the norms of pharmaceutical legislation regarding the regulation of advertising activities on the pharmaceutical market.

According to the World Health Organization, self-medication as a cause of death ranks 5th after cancer and infectious diseases. Experts from Consumer Associations in a number of countries argue that intense advertising encourages patients to violate the prescriptions of doctors and choose the advertised drug. Over the past 5 years, sales of over-the-counter (OTC) drugs in developing countries such as Ukraine have been twice as high as prescription drugs, while in the EU countries there is a reverse trend.

In particular, in the United Kingdom without a prescription, you can buy no more than 20% of the total amount of drugs. The domestic market of medicines in 2019 reached a sales volume of 30.5 billion UAH for 1.27 billion packages. The total volume of pharmacy sales of OTC drugs in 2019 amounted to 13.5 billion UAH for 814.4 thousand packets, exceeding the previous year's figure by 12.1% in monetary terms and 0.4% in physical terms.

We have analyzed the requirements for advertising drugs of different categories and are reflected in the table 3.2.

Table 3.2

Requirements for advertising prescription and over-the-counter drugs

ADVERTISING OF OTC DRUGS	ADVERTISEMENT OF PRESCRIPTION GROUP MEDICINES
OTC drugs may be advertised to the general public, but must:	Advertising aimed at medical professionals (including all accompanying documentation related to the promotion) must:
<ul style="list-style-type: none"> • clearly indicate that the advertised product is a MP; • include the name of the drug and its generic name, if the drug contains only one active substance (MS have the option to deviate from this rule and allow references to the product name and INN); • include information necessary for the correct use of the product; • contain clarification on the need to carefully read the instructions for medical use on the leaflet or packaging. 	<ul style="list-style-type: none"> • to be exact; • be relevant; • be tested; • be complete enough to allow the recipient to form their own opinion about the therapeutic value, contain important information that corresponds to the summaries of the characteristics of the product; • indicate the classification of the medicinal product supplied and the date of its approval or last revision; • quotations and tables or illustrations from medical journals must be faithfully reproduced and original sources indicated.
Advertising of medicinal products to the public must not:	ADVERTISEMENT OF DRUGS, THE COST OF WHICH IS REIMBURSEMENT
<ul style="list-style-type: none"> • create the impression that medical consultation or surgery is not necessary, • that the effect of the drug is guaranteed, without side effects, or better or equivalent to the effects of another treatment or product (comparison), • be aimed exclusively or mainly at children, • use medical professionals, scientists or celebrities to advertise the consumption of the product, • use incorrect, alarming or misleading terms or images of changes in the human body caused by disease, injury or the effect of the product on the human body, etc. 	<ul style="list-style-type: none"> • Directive 2001/83/EC states that EU member states may prohibit advertising of reimbursable medicinal products. We are talking about non-prescription drugs that are included in the reimbursement system, which according to general rules can be advertised to the general public. • However, in some cases (for example, in countries such as Denmark, France and Portugal), the inclusion of an over-the-counter drug in the reimbursement system does not affect the possibility of its promotion.

The promotion of prescription drugs to the public (“direct to consumer advertising”) is currently used only in the United States and New Zealand. A systematic review of the clinical and economic consequences confirmed that this form of advertising influences patient demand and doctors' prescribing behavior, but evidence of health benefits or improvements in underuse was lacking.

Advertising for nonprescription medicines should be truthful and non-deceptive. Advertisers of nonprescription medicines should have adequate substantiation for all product claims before an advertisement is disseminated.

Advertising of a nonprescription medicine should urge consumers to read and follow label directions. A nonprescription medicine should not be advertised in a manner which is likely to lead to its use by young children without parental supervision. A nonprescription medicine should not be advertised on programs or in publications specifically directed toward young children.

Advertising of a nonprescription medicine should contain no reference to doctors, nurses, pharmacists, or hospitals unless such representations can be substantiated by independent evidence.

Advertising of non-prescription drugs is allowed in all media, with some exceptions. Thus, in certain EU countries, advertising of the drug of the OTC group is prohibited if there is a prescription drug with the same name in circulation. Permission or prohibition to advertise a medicinal product is generally issued upon receipt of a registration certificate.

According to the above-mentioned Directive, it is prohibited in the EU to carry out advertising campaigns aimed at the final consumer for drugs with a prescription status, as well as medicinal products containing substances that are classified by the UN conventions of 1961 and 1971 as narcotic or psychotropic drugs. It is worth noting that advertising of prescription drugs aimed at healthcare professionals is allowed, as it is a tool to inform about the drug.

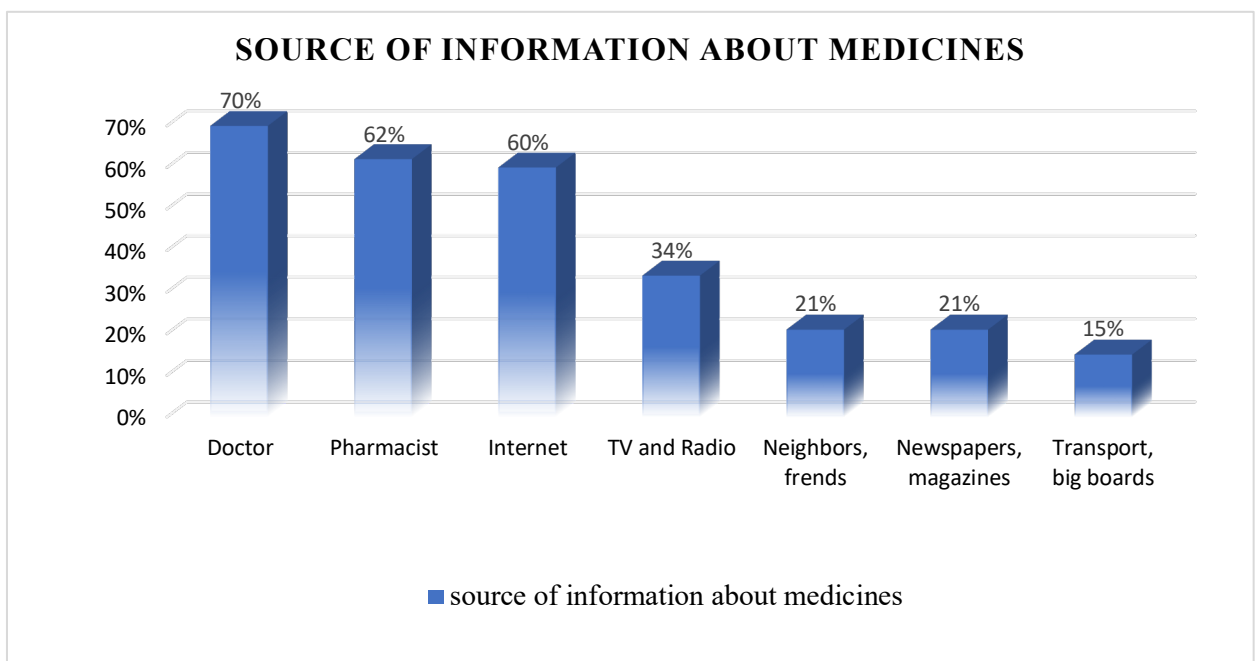
The ban on advertising of prescription drugs does not apply to advertising of vaccine campaigns carried out by the manufacturer and approved by the competent regulatory body.

EU member states have the opportunity to demand that the sales price or estimated price of the drug, the terms of reimbursement by social insurance authorities, etc. be included in the advertisement.

A pharmaceutical company that uses an external service (medical representatives) in its work with health care professionals is obliged to ensure that they have adequate training and knowledge to convey complete and accurate information about the medicinal products they promote. At each visit, they should provide a brief description of the medicinal product's characteristics and, if permitted by national law, its price and reimbursement status. If a healthcare professional shares their experience with the product, this information must be passed on to the company's scientific department.

Using the Statistical data, we concluded that drug manufacturers focused their consumer advertising spending on 39 drugs between 2018 and 2020. We identified these 39 drugs because they represented the top 25 advertising spend for each of the 3 years accounted for about 66% of all expenses.

Advertising is the primary source of information about medicines for most consumers. At the same time, with respect to other sources from which information about the drug can be obtained, the result can be divided into several parts (fig.3.1).



SOURCES: EUROSTAT; NATIONAL E-COMMERCE ASSOCIATIONS; STATISTA

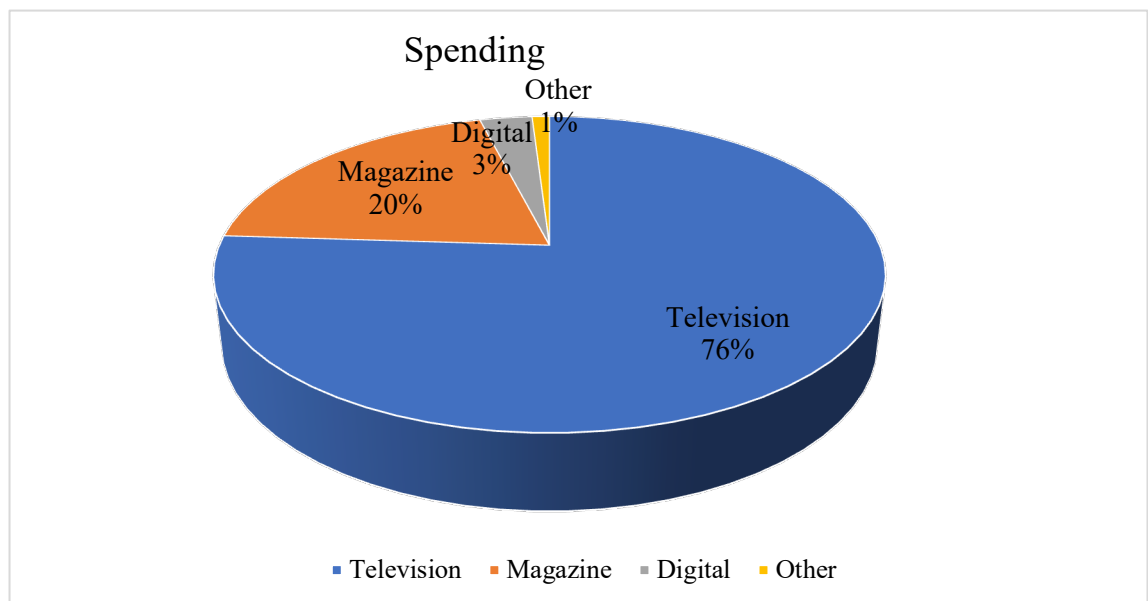
Fig.3.1 Primary source of information about medicines.

An analysis of data from organizations that control drug advertising in Europe showed how the sources of information about drugs for the consumer are ranked.

Advertising on television and radio takes 4th place (33%), after the following: 1) “from the doctor” (70 %); 2) “from a pharmacist in a pharmacy” (62 %) and 3) from the Internet (60 %). This suggests that despite the popularity of the Internet and television, large investments in advertising, nevertheless, the appointment of a doctor and the advice of a pharmacist are the main source of information about medicines. Drugs are one of the products most frequently advertised on television, and television advertising has become the largest component of consumer-targeted marketing expenses for pharmaceutical companies.

A large amount of information is received by the population from advertising from the media. The analysis of media advertising of medicines was informative.

Our analysis of spending across different types of media shows that television advertising for OTC drugs accounted for about 76 percent of total spending for the period 2018-2020, the largest share of manufacturers spending (fig.3.2).



SOURCES: EUROSTAT; NATIONAL E-COMMERCE ASSOCIATIONS; STATISTA

Fig.3.2 Direct-to-Consumer Advertising Spending by Media Type, 2019.

Although supporters of direct-to-consumer advertising contend that the practice provides an important educational resource to patients, research shows that advertising medicine to consumers prompts inappropriate prescriptions, increases adverse patient outcomes and boosts drug prices. The problem may loom even larger

as direct-to-consumer telehealth companies and pharmacies move into the online space. A recent investigation found a new danger with quick, online access to medicine: 25 percent of the websites investigated were leaking sensitive patient information to advertising platforms.

Although television advertising comprised the largest share of manufacturers' spending, we found that drug manufacturers purchased television advertisements for a relatively small portion of advertised drugs. Specifically, manufacturers advertised 113 drugs (or about 20 percent of the 553 advertised drugs) on television during the 2018 to 2020 period. Most often, consumers for self-treatment go to the pharmacy for the following groups of medicines: 55.0% - for sore throats; 48.0% - anti-inflammatory and analgesic; 45.0% - with a runny nose or nasal congestion; 37.0% - with dysfunctions of the gastrointestinal tract; 34.0% - when coughing; 34.0% - antiviral drugs; 32.0% - expectorant; 28.0% - in case of poisoning; 25.0% - vitamins and microelements and 22.0% - cardiological (fig. 3.3).

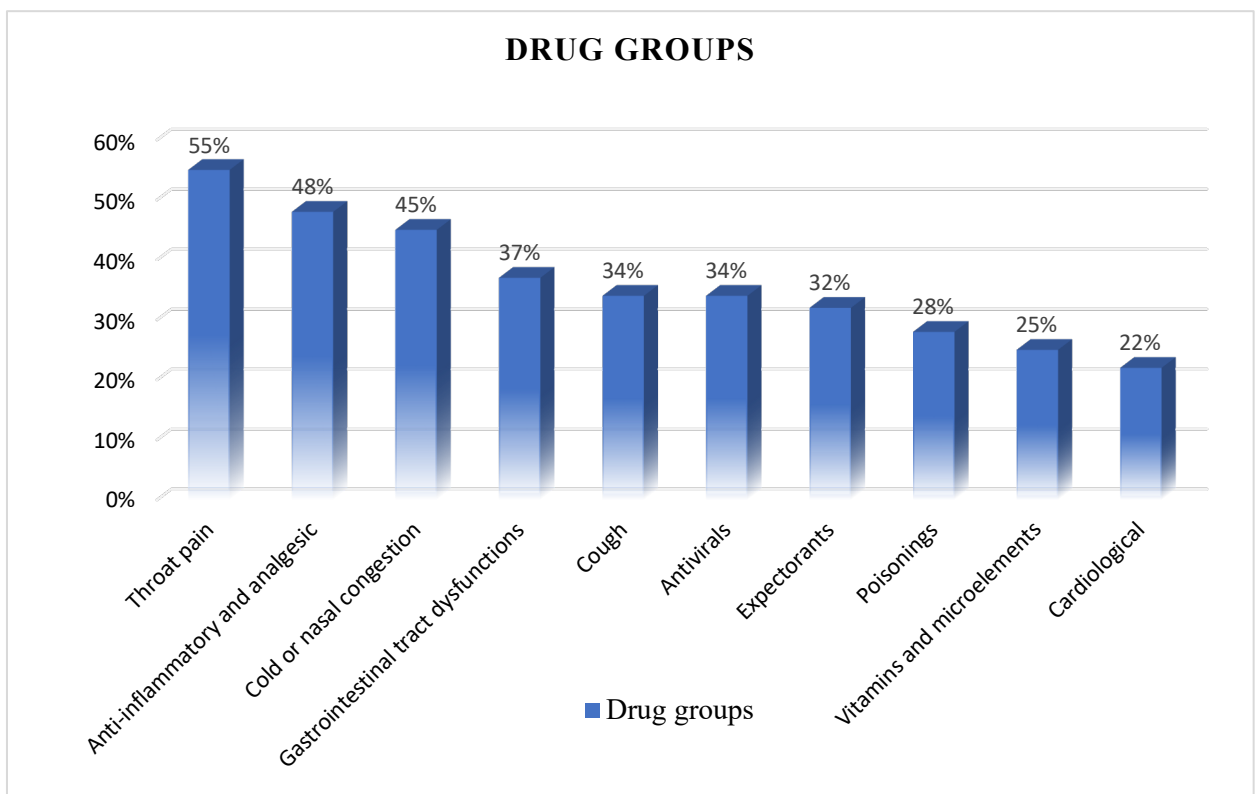


Fig. 3.3 Top 10 groups of drugs that are most often advertised for self-medication.

The results of the analysis of modern foreign experience from the studied problem showed that advertising of drugs is a subject of special attention from the

state. Government health promotion campaigns help people to think more about their health and become more aware of their symptoms and condition. Nonprescription medicines' advertising reinforces this by showing the availability of medicines that can help. Regulations should recognize the role and limitation of advertising. Basic standards will ensure that the information conveyed is truthful and not misleading to consumers. Health departments, regulators and manufacturers should work together to ensure that consumers have the information they need about the benefits and risks of the medicine. Despite the general framework contained in EU Directive 2001/83/EC, advertising regulation is governed by different texts and structures across the EU and in the UK. Each country has local specifics regarding the responsible person and their roles and responsibilities, for example when checking promotional materials. Pharmaceutical companies must fulfill many local requirements in order to comply with local regulations before they can start advertising locally in the EU and the UK.

It is necessary to strengthen control over the observance by subjects of economic activity of the legislation on advertising, after all, medicines, in contrast to other products, are a special product of consumption. Their misuse is associated with significant risks to health, and sometimes to human life. These risks are greatly increased if patients, under the influence of «aggressive» advertising, resort to self-treatment. The existing mechanism of legal regulation of drug advertising requires some improvement. The restriction of advertising of OTC drugs, reviewing its objectivity and conscientiousness is a significant step towards solving the problem of irresponsible self-treatment and self-prescribing of drugs.

A large segment of drug advertising is located in pharmacies, so a great responsibility lies with this organization itself and a particular employee.

Pharmacists should be aware that there are many laws that relate to advertising and pharmacy. The pharmacy owner and any other 'responsible person' who is named on the pharmacy license must be responsible for the form and content of any promotion or advertisement whether placed by them personally, or by another staff member or by another organisation on behalf of the pharmacy. We have identified

the main recommendations for the pharmacist in accordance with the current legislation (tabl.3.3).

Table 3.3

Advertising of therapeutic goods and health services by pharmacies

Title	Content
Advertising therapeutic goods	<p>Advertise, in relation to therapeutic goods, includes making any statement, pictorial representation or design that is intended, whether directly or indirectly, to promote the use or supply of the goods, including where the statement, pictorial representation or design:</p> <ul style="list-style-type: none"> • is on the label of the goods; or • is on the package in which the goods are contained; or • is on any material included with the package in which the goods are contained.
'Short-form' advertisement	<p>Short form' advertisements include:</p> <p>Radio advertisements that are 15 seconds or less in duration.</p> <p>Text only advertisements that consist of 300 characters or less, and where there is no capacity to include a picture, logo or other imagery as part of the advertisement.</p> <p>Advertisements in social media are not considered 'short form advertisements' because they either have capacity to include all the applicable mandatory statements in the advertisement itself or they can include links to all the applicable mandatory statements.</p>
Therapeutic goods cannot be advertised	<p>Some therapeutic goods cannot be advertised. Do not advertise prescription medicines. Only advertise pharmacist only non-prescription medicines.</p>
Advertising health services	<p>Be factual and promote your health service on its merits.</p> <p>Do not create any unreasonable expectation or attempt to induce consumers to use the service unnecessarily.</p> <p>Be honest in relation to your business practices.</p>
What must advertisements of therapeutic goods avoid	<p>Make no claims that contradict information on the label or otherwise supplied with the product. Do not make performance claims that are unrealistic, do not encourage inappropriate use.</p> <p>Do not claim that taking this or that analgesic is safe.</p> <p>Avoid suggesting that vitamins and minerals replace good nutrition.</p> <p>Sunscreen advertisements must not present sunscreen as the only necessary protection against the sun.</p> <p>Claims about weight loss products must not imply that they are substitutes for a controlled diet and physical activity.</p> <p>Advertisements must not contradict a current public health campaign.</p>
Consumer rights protection	<p>The principles of Consumer Law apply to all advertising and sales techniques for any kind of product regardless of whether they are therapeutic goods and regulated health services or ordinary consumer goods. The most basic principles are:</p> <ul style="list-style-type: none"> • do not engage in conduct that is likely to mislead or deceive. • do not make false or misleading claims or statements.

Where the promotion or advertising material is developed by an organisation on behalf of its members, it is anticipated the practice standards pharmacist or similar takes responsibility to ensure these guidelines are followed.

Conclusions to the III Chapter

Based on the analysis of the information, it can be concluded that advertising of medicines for healthcare professionals is allowed in the EU countries. Mandatory and advisory requirements are imposed on advertising materials in different countries, which may differ. However, in most European countries they must comply with the provisions of the Directive establishing common criteria.

Legal regulation of drug advertising in the countries of the European Union is generally uniform. This is due to the adopted EU Directive, it is she who describes all the requirements for the regulation of advertising of pharmaceutical products. In accordance with this document, advertising of prescription drugs and psychotropic drugs is prohibited in the EU countries.

The most stringent conditions apply in Belgium, where there are restrictions on advertising not only for the general audience, but also for specialists, distribution of advertising samples even to healthcare workers is prohibited.

In Germany, there is an additional law regulating advertising activities - "On Advertising of Medicines". In particular, it prohibits the inclusion in the advertising text of information representing the advice of scientists or opinion leaders. In England, drug advertising is regulated by several documents, in particular, some rules are presented in the guide "Advertising and promoting medicines in Britain", also known as the "Blue Guide".

In most EU countries, systems of self-regulation and self-restriction of advertising are well developed, so control and detection of unfair drug advertising is carried out by public organizations, such as, for example, INTEGRITAS in Germany. These public organizations have the right to initiate legal proceedings against violators of advertising laws and use such methods as public censure (publications in the press, etc.), as well as pre-review advertising materials.

GENERAL CONCLUSIONS

1. According to the scientific literature, we analyzed the current legislation of the EU countries. It has been established that the national legislation of the EU countries that have ratified the Directive must comply with the provisions set forth in it. However, each of them can approve additional rules, for example, regarding the advertising of medicinal products. A common feature of the legislation of all these states is the distinction between the advertising of medicinal products aimed at the end consumer and health care professionals.
2. The analysis of regulatory legal acts showed that in the EU countries, when regulating the advertising of medicinal products, the general term "advertising aimed at persons authorized to prescribe or dispense medicinal products" is used, while the terms "information" and "advertising" are more detailed compared to the legislation other countries in the world, may include promotions, visits by medical representatives and sampling.
3. An analysis of regulatory documents on the advertising of over-the-counter medicinal products was carried out. It has been established that neither the Law on Advertising nor any other EU legislation provides for special rules for the advertising of medicines and medical products on the Internet/in social media posts. At the same time, any advertising of pharmaceuticals and medical products, including those placed on the Internet and on social media platforms, must meet the general requirements for advertising medicinal products and medical products.
4. The normative act regulating the circulation of medicines in the EU is Directive 2001/83 / EC of the European Parliament and of the Council of the EU of 06.11.2001 "On the Code of Community Laws concerning Medicines for Human Use", as amended. This document approved a set of rules that regulate the production, classification of drugs, their labeling, advertising, launching on the market, wholesale and retail trade, pharmacological supervision, etc.

5. The directive prohibits advertising of prescription drugs to the end consumer, as well as drugs for the treatment of tuberculosis, sexually transmitted diseases, other dangerous infectious diseases, malignant neoplasms, chronic insomnia, diabetes mellitus and other metabolic disorders. Member States shall have the right to prohibit advertising on their territory to the public of medicines the cost of which is reimbursed from the state budget. However, such restrictions do not apply to advertising directed at medical professionals.
6. The EU law provisions, as implemented in national laws, are enforced nationally through varying mechanisms; in some Member States it is possible for companies to bring direct actions against competitors, whereas other countries require actions to be brought only by regulatory authorities.
7. In the EU countries, drug advertising is regulated clearly and unambiguously. It is strictly forbidden to conduct advertising campaigns for prescription drugs for the final consumer. Advertising of prescription drugs aimed at healthcare professionals is permitted as it is a communication tool. Advertising restrictions for OTC drugs mainly apply to the group of reimbursed drugs. In some cases, the inclusion of a drug in the reimbursement system does not affect the ability to be advertised.
8. In the USA, it is observed that advertising of all medicines is allowed, but it is subject to strict control by the competent authorities. At the same time, the content must strictly comply with the established criteria, and before launching advertising campaigns, it must go through the approval process.
9. In some other countries, the criteria for allowing/banning advertising are not related to drug status, but to the therapeutic class.
10. The European healthcare advertising market is divided: by type; form of interaction; technologies; approach and direct advertising to consumers, format; application advertising; biopharmaceuticals; vaccines; over-the-counter medicines; prescription drugs; medical devices and equipment; biotechnology companies; fitness and Dietary products and services, Hygiene products.

REFERENCES

1. Association of the European Self-Care Industry/<https://aesgp.eu/who-we-are>.
2. American Medical Association (AMA). AMA calls for ban on DTC ads of prescription drugs and medical devices. Available at: <https://www.ama-assn.org/press-center/press-releases/ama-calls-ban-dtc-ads-prescription-drugs-and-medical-devices>.
3. Anderson, S. (2016). Travelers, patent medicines, and pharmacopeias: American pharmacy and British India, 1857 to 1931. *Pharmacy in History*, 58(3-4), 63-82.
4. Advertisement English meaning - Cambridge Dictionary <https://dictionary.cambridge.org>
5. Brownfield E, Bernhardt J, Phan J, Williams M, Parker R. Direct-to-consumer drug advertisements on network television: an exploration of quantity, frequency, and placement. *J Health Commun.*2018;9:491–497.
6. Cochrane Effective Practice, Organisation of Care (EPOC). Suggested risk of bias criteria for EPOC reviews. EPOC Resources for Review Authors. Oslo: Norwegian Knowledge Centre for the Health Services, 2015.
7. Code of Practice of the European Federation of Pharmaceutical Industry Associations of England <https://www.pmcpa.org.uk/the-code/2021-interactive-abpi-code-of-practice/>
8. Content Analysis of Television Advertising for Drugs That Switch from Prescription to Over-the-Counter: Balancing Information and Appeals. Available from: <https://www.researchgate.net/publication/254087918>.
9. Consumer Code – Code de la consommation: https://www.legifrance.gouv.fr/codes/texte_lc/LEGITEXT000006069565/
10. Coleman B. Producing an information leaflet to help patients access high quality drug information on the Internet: a local study. *Health Information & Libraries Journal* 2013;20:160-171.

11. Commission of the European Communities. Communication from the Commission to the European Parliament and the Council concerning the Report on current practice with regard to provision of information to patients on medicines products, 2008b. Available at: http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2007/2007_12/information_to_patientscom_2007_862_en.pdf (27 November 2009)

12. Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council.

13. Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising.

14. 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: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02001L0083-20190726>

15. Drugs and the Internet: A Deadly Combination, DRUG ENFORCEMENT AGENCY, <http://www.justice.gov/dea/prevention/francine-interview.shtml>.

16. Donohue, J. (2006). A history of drug advertising: The evolving roles of consumers and consumer protection. *The Milbank Quarterly*, 84(4), 659-699.

17. European Parliament and Council. Directive 2004/27/EC of the European Parliament and the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use. *EU Official Journal* 2004; Vol. 86, issue 2.

18. European Commission, State of health in the EU: companion report 2019 (ISBN 978-92-76-10194-9).

19. European Commission. Proposal for a Directive of the European Parliament and of the Council amending, as regards information to the general public

on medicinal products subject to medical prescription, Directive 2001/83/EC on the Community code relating to medicinal products for human use. European Commission December 2008.

20. European Commission. The state of men's health in Europe. Directorate-General for Health and Consumers 2011; Vol. Report.

21. European Parliament. Disease mongering (Pseudo-disease promotion). DG Internal Policies 2012; Vol. IP/A/ENVI/NT/2012-20. PE 492.462.

22. Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) of 15 December 2000 (Status as of 1 January 2022) <https://fedlex.data.admin.ch/filestore/fedlex.data.admin.ch/eli/cc/2001/422/20220101/en/pdf-a/fedlex-data-admin-ch-eli-cc-2001-422-20220101-en-pdf-a.pdf>

23. Fugh-Berman A, Melnick D. Off-label promotion, on-target sales. *PLoS Medicine* 2008;5(10):e210.

24. Jacob NT. Drug promotion practices: A review. *Br J Clin Pharmacol.* 2018 Aug;84(8):1659-1667.

25. Law on Advertising in the Health Sector (Heilmittelwerbegesetz, or HWG).

26. Loza Garcia M, Cordero Puentes L, Fernandez-Llimos F, Garcia Corral P et al. Drug information sources used by community pharmacists in Galicia. *Pharm Care Esp* 2020; 2: 108 – 22.

27. Legislative Decree no. 219/2006 “Code of Medicines”. https://www.uaipit.com/uploads/legislacion/files/itit_45091.pdf

28. Limbu Y., Prescription drug advertising: pros, cons and avenues for future research, New Mexico State University, Department of Marketing 436 – 447 <http://www.researchgate.net/file.PostFile>.

29. MHRA BlueGuide, November 2020, Advertising and Promotion of Medicines in the UK, Third Edition Third revision: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/956846/BG_2020_Brexit_Final_version.pdf

30. Mintzes, B. (2012). Advertising of Prescription-Only Medicines to the Public: Does Evidence of Benefit Counterbalance Harm? *Annual Review of Public Health*, 33(1), 259-277.
31. Navon, D. (2017). Truth in advertising: Rationalizing ads and knowing consumers in the early twentieth-century United States. *Theory and Society*, 46(2), 143-176.
32. Nicklaus P. Lang, European Interactive Digital Advertising Alliance Launches, *Journal of Clinical Periodontology*, (2019) http://www.easa-alliance.org/News/News/page.aspx/46?xf_itemId=157&xf_selectionDatapartI9.
33. Pashkov V. M. and others. Legal features of drug advertising/ *Article/ Wiadomości lekarskie*, 70, 1, 133-138· January 2017.
34. Pharmaceutical advertising regulations in Europe: Responsible Persons All.pdf// March 16th, 2021.
35. Regulation (EC) No. 2006/2004 of the European Parliament and of the Council of October 27, 2004 <https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:02004R2006-20200117>
36. Resolution of the World Health Organization (WHO), adopted by the 41st WHO Assembly on May 13, 1988. https://apps.who.int/iris/bitstream/handle/10665/164197/WHA41_1988-REC-1_eng.pdf?sequence=1
37. Royal Decree 1416/1994, 29 July 1994 on regulation for advertising for human medicines: https://www.aemps.gob.es/legislacion/espana/otrosTemas/docs/publicidad/rcl_1994_2219.pdf
38. Ruppner H. Das Informationsverhalten über Arzneimittel von Ärzten und Apothekern. Use of drug information by physicians and pharmacists. Institut für Klinische Pharmakologie. Bern, 2016.
39. IFPMA code of practice, 2019:https://www.ifpma.org/wp-content/uploads/2018/09/IFPMA_Code_of_Practice_2019.pdf

40. PAGB Consumer Code for Medicines, 2019: <https://www.pagb.co.uk/content/uploads/2018/12/PAGB-Consumer-Code-Jan-2019.pdf>
41. The MHRA Blue Guide, Advertising and Promotion of Medicines in the UK, is available on the MHRA website at <https://www.gov.uk/government/publications/blue-guide-advertising-and-promoting-medicines>.
42. The European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice does not apply to activities relating solely to non-prescription medicines.
43. The European Convention on Human Rights and its Five Protocols, Council of Europe <http://www.hri.org/docs/ECHR50.html>.
44. Griffin, O. H. (2014). The role of the United States Supreme Court in shaping federal drug policy. *American Journal of Criminal Justice*, 39(3), 660-679.
45. Global Insight, «The Comprehensive Economic Impact of Advertising Spending in the United States», [http:// www.naa.org/Resources/Articles/Public-Policy-The-Comprehensive-Economic-Impact-of-Advertising-Expenditures-in-the-United-States/Public-Policy](http://www.naa.org/Resources/Articles/Public-Policy-The-Comprehensive-Economic-Impact-of-Advertising-Expenditures-in-the-United-States/Public-Policy).
46. Greenway, T., & Ross, J. (2017). US drug marketing: how does promotion correspond with health value? *BMJ*, 357, j1855.
47. World Health Organization. (1988). Ethical criteria for medicinal drug promotion. WHO. <https://apps.who.int/iris/handle/10665/38125>
48. WHO Global Health Observatory Data Repository – Geneva, World Health Organization, 2013. [Electronic resource]. – Access to the resource: <http://apps.who.int/gho/data/view>.

National University of Pharmacy

Faculty for foreign citizens' education
Department of social pharmacy

Level of higher education master's

Specialty 226 Pharmacy, industrial pharmacy
Educational program Pharmacy

APPROVED
The Head of Department
of Social Pharmacy

Alina VOLKOVA
“28” of September 2022

ASSIGNMENT
FOR QUALIFICATION WORK
OF AN APPLICANT FOR HIGHER EDUCATION

Nidal LAKLAAI

1. Topic of qualification work: «Analysis of legal features of the drug advertising», supervisor of qualification work:
Lyubov TERESHCHENKO, PhD, assoc. prof.,

approved by order of NUPh from “06” of February 2023 № 35

2. Deadline for submission of qualification work by the applicant for higher education: April 2023.

3. Outgoing data for qualification work: authors' publications; media publications; official health sites; State Statistics Service of the world; sites of WHO, IFD, Internet, etc.

4. Contents of the settlement and explanatory note (list of questions that need to be developed): to identify and analyze problematic aspects of the regulation of drug advertising in the world, to investigate modern approaches to drug promotion in EU countries; study of new approaches in advertising regulation in EU countries.

5. List of graphic material (with exact indication of the required drawings):
Tables – 10, schemes – 11.

6. Consultants of chapters of qualification work

Chapters	Name, SURNAME, position of consultant	Signature, date	
		assignment was issued	assignment was received
1	Lyubov TERESHCHENKO, associate professor of higher education institution of department of social pharmacy	30.09.22	30.09.22
2	Lyubov TERESHCHENKO, associate professor of higher education institution of department of social pharmacy	15.11.22	15.11.22
3	Lyubov TERESHCHENKO, associate professor of higher education institution of department social of pharmacy	23.12.23	23.12.23

7. Date of issue of the assignment: «_ 28_ » of September 2022.

CALENDAR PLAN

№ з/п	Name of stages of qualification work	Deadline for the stages of qualification work	Notes
1	To study of historical aspects of the global experience of advertising research	<i>October 2022</i>	done
2	A systematic review of the legal regulation of drug advertising in the world	<i>November-December 2022</i>	done
3	To investigation of the legal framework for the regulation of advertising: world experience	<i>January-February 2023</i>	done
4	Registration of a qualification work according to the general requirements	<i>March 2023</i>	done
5	Preparation of the report and multimedia presentation in official protection of a master's thesis	<i>April 2023</i>	done

An applicant of higher education _____

Nidal LAKLAAI

Supervisor of qualification work _____

Lyubov TERESHCHENKO

ВИТЯГ З НАКАЗУ № 35
По Національному фармацевтичному університету
від 06 лютого 2023 року

нижченаведеним студентам 5-го курсу 2022-2023 навчального року, навчання за освітнім ступенем «магістр», галузь знань 22 охорона здоров'я, спеціальності 226 – фармація, промислова фармація, освітня програма – фармація, денна форма здобуття освіти (термін навчання 4 роки 10 місяців та 3 роки 10 місяців), які навчаються за контрактом, затвердити теми кваліфікаційних робіт:

Прізвище студента	Тема кваліфікаційної роботи	Посада, прізвище та ініціали керівника	Рецензент кваліфікаційної роботи
• по кафедрі соціальної фармації			
Лаклаай Нідал	Аналіз правових особливостей реклами лікарських засобів	Analysis of legal features of the drug advertising доцент Терещенко Л. В.	професор Панфілова Г.Л.

Підстава: подання декана кафедри ректора

Ректор

Вірно. Секретар



ВИСНОВОК

**Комісії з академічної доброчесності про проведену експертизу
щодо академічного плагіату у кваліфікаційній роботі
здобувача вищої освіти**

№ 112593 від « 26 » квітня 2023 р.

Проаналізувавши випускню кваліфікаційну роботу за магістерським рівнем здобувача вищої освіти денної форми навчання Лаклаай Нідал, 5 курсу, _____ групи, спеціальності 226 Фармація, промислова фармація, на тему: «Аналіз правових особливостей реклами лікарських засобів / Analysis of legal features of the drug advertising», Комісія з академічної доброчесності дійшла висновку, що робота, представлена до Екзаменаційної комісії для захисту, виконана самостійно і не містить елементів академічного плагіату (копіляції).

**Голова комісії,
професор**



Інна ВЛАДИМИРОВА

2%

25%

REVIEW

of scientific supervisor for the qualification work of the master's level of higher education of the specialty 226 Pharmacy, industrial pharmacy

Nidal LAKLAAI

on the topic: « Analysis of legal features of the drug advertising»

Relevance of the topic. Advertising of medicinal products is recognized as one of the most effective mechanisms for the promotion of medicinal products. The significant spread of drug advertising is facilitated by society's attitude to advertising as a reliable source of information about drugs, mistrust of doctors and the health care system, and, as a result, the prevalence of self-medication. But improper use of drugs is often associated with significant risks to health, and sometimes to human life. Patients mostly do not have the necessary medical and pharmaceutical knowledge to correctly evaluate reliable and objective information about drugs on their own, not to mention various forms of abuse in the implementation of advertising activities.

Practical value of conclusions, recommendations and their validity. The qualification work clearly defines the purpose of the research, tasks and objects, according to which the results of the analysis of analytical data, the provisions of the regulatory acts regulating the regulation of drug advertising are presented. The conclusions and recommendations obtained in the research process are well-founded and constitute the personal contribution of the recipient to the scientific development of the issue of the effectiveness of drug promotion.

Assessment of work. The work is done and designed properly and deserves a positive assessment.

General conclusion and recommendations on admission to defend. During the performance of the work, the procurer Nidal LAKLAAI demonstrated the ability to work with literature, summarize the obtained results, draw conclusions based on the conducted research. Thus, the qualifying work meets all requirements for qualifying works and can be submitted for defense.

Scientific supervisor _____ Lyubov TERESHCHENKO

«06» of April 2023

REVIEW

for qualification work of the master's level of higher education, specialty

226 Pharmacy, industrial pharmacy

Nidal LAKLAAI

on the topic: « Analysis of legal features of the drug advertising »

Relevance of the topic. Advertising of medicinal products has a significant impact on society, so issues related to advertising of medicinal products in the state are quite relevant at today's stage of development of the pharmaceutical sector. In order to protect the interests of consumers and economic competition, the state ensures compliance with the requirements of legislation in the field of advertising medicinal products. The legislation on advertising in general and on the advertising of medicinal products, in particular, is written in sufficient detail. However, more interesting are the problematic issues of the practice of applying the relevant provisions of the law in the organization of pharmacy work.

Theoretical level of work. In the qualifying work, the peculiarities of the legal regulation of drug advertising were investigated, the legislative framework regulating pharmaceutical activity in the EU countries was analyzed; an analysis of EU legislation in the field of drug promotion was carried out.

Author's suggestions on the research topic. Higher education student Nidal LAKLAAI identified a number of differences in European legislation on the legal regulation of drug advertising, which will contribute to the convergence of national standards of different countries.

Practical value of conclusions, recommendations and their validity. The conclusions and recommendations of the researcher are well-founded, obtained by him independently and can be taken into account by other researchers in the foreseeable future.

Disadvantages of work. The results of the work are mainly theoretical in nature. This remark fundamentally does not change the evaluation of the work.

General conclusion and assessment of the work. On the basis of the clearly formulated tasks, the complex of research methods used, and the evaluation of the results of the conducted research, Nidal LAKLAAI managed to achieve the goal set in the qualification work. Thus, the qualification work meets the requirements and can be recommended to of protection at the Examination Commission of the NUPh.

Reviewer

Hanna PANFILOVA

ВИТЯГ

з протоколу засідання кафедри соціальної фармації № 12 від «20» квітня 2023 року

ПРИСУТНІ: зав. каф. доц. Волкова А. В., доц. Кубарева І.В., доц. Овакімян О.С., доц. Болдарь Г.Є., доц. Корж Ю.В., доц. Терещенко Л.В., доц. Гавриш Н.Б., доц. Калайчева С.Г., ас. Пилюга Л.В., ас. Сєврюков О.В., ас. Сурікова І.О., ас. Тарасенко Д.Ю., ас. Ноздріна А.А.

ПОРЯДОК ДЕННИЙ: Про представлення до захисту в Екзаменаційній комісії кваліфікаційних робіт.

СЛУХАЛИ: завідувачку кафедри доц. Волкову А. В. з рекомендацією представити до захисту в Екзаменаційній комісії кваліфікаційну роботу здобувача вищої освіти спеціальності 226 Фармація, промислова фармація Лаклаай Нідал, на тему: «Аналіз правових особливостей реклами лікарських засобів»

Науковий керівник: к. фарм. н., доцент кафедри СФ Терещенко Л.В.

Рецензент: д. фарм. н., професор кафедри ОЕФ Панфілова Г.Л.

ВИСТУПИЛИ: доц. Кубарева І.В., доц. Овакімян О.С., доц. Корж Ю.В., висловили рекомендації до кваліфікаційної роботи Лаклаай Нідал

УХВАЛИЛИ: Рекомендувати до захисту в Екзаменаційній комісії кваліфікаційну роботу здобувача вищої освіти Лаклаай Нідал, на тему: «Аналіз правових особливостей реклами лікарських засобів»

Завідувачка каф. СФ, доцент _____

Аліна ВОЛКОВА

Секретар, асистент _____

Альміра НОЗДРІНА

НАЦІОНАЛЬНИЙ ФАРМАЦЕВТИЧНИЙ УНІВЕРСИТЕТ

**ПОДАННЯ
ГОЛОВІ ЕКЗАМЕНАЦІЙНОЇ КОМІСІЇ
ЩОДО ЗАХИСТУ КВАЛІФІКАЦІЙНОЇ РОБОТИ**

Направляється здобувач вищої освіти Нідал ЛАКЛААЙ до захисту кваліфікаційної роботи за галуззю знань 22 Охорона здоров'я спеціальністю 226 Фармація, промислова фармація освітньою програмою Фармація на тему: «Analysis of legal features of the drug advertising».

Кваліфікаційна робота і рецензія додаються.

Декан факультету _____ / Світлана КАЛАЙЧЕВА /

Висновок керівника кваліфікаційної роботи

Здобувач вищої освіти Нідал ЛАКЛААЙ під час виконання кваліфікаційної роботи вивчив і проаналізував значний обсяг літератури та нормативно правових актів по темі. Проведений аналіз підтверджує актуальність досліджень і висуває необхідність їх проведення.

Керівник кваліфікаційної роботи _____ Любов ТЕРЕЩЕНКО

«06» квітня 2023 р.

Висновок кафедри про кваліфікаційну роботу

Кваліфікаційну роботу розглянуто. Здобувач вищої освіти Нідал ЛАКЛААЙ допускається до захисту даної кваліфікаційної роботи в Екзаменаційній комісії.

Завідувачка кафедри
соціальної фармації _____ Аліна ВОЛКОВА

«20» квітня 2023 р.

Qualification work was defended

of Examination commission on

« ____ » _____ 2023

With the grade _____

Head of the State Examination commission,

DPharmSc, Professor

_____ / Oleh SHPYCHAK /