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Advertising of medicines in Ukraine: An ethical and legal view

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Abstract

The modern course of Ukraine towards economic and political and legal rapprochement with European states involves the adoption of uniform rules in the field of healthcare. The objective of this article is to examine the ethical and legal aspects of advertising medicines in the context of Ukraine's alignment with European states and the adoption of uniform healthcare rules. The article employs a dialectical method to explore the correlation between ethical and legal components in medicine advertising. By analyzing domestic normative and legislative acts, there was establish methodological features of medicine advertising from the perspectives of ethics and law. The research also considers the broader context of international and national regulation of advertising in the pharmaceutical sector. The analysis of ethical and ethical-legal criteria enshrined in domestic regulations clarifies the general direction of modern state and non-state regulation of medicine advertising in Ukraine. This finding helps to provide a deeper understanding of the principles guiding advertising activities in the pharmaceutical sector.

Overall, the article contributes to the ongoing ethical and legal research on advertising

Анотація

Сучасний курс України на економічне та політико-правове зближення з європейськими державами передбачає прийняття єдиних правил у сфері охорони здоров'я. Метою статті є розгляд етичних та правових аспектів реклами лікарських засобів у контексті наближення України до європейських держав та прийняття єдиних правил охорони здоров'я. У статті за допомогою діалектичного методу досліджено співвідношення етичної та правової складових у рекламі лікарських засобів. Аналізуючи вітчизняні нормативно-правові акти, встановлено методологічні особливості реклами лікарських засобів з позицій етики та права. Дослідження також розглядає ширший контекст міжнародного та національного регулювання реклами у фармацевтичному секторі. Аналіз етичних та етично-правових критеріїв, закріплених у вітчизняних нормативно-правових актах, уточнює загальний напрям сучасного державного та недержавного регулювання реклами лікарських засобів в Україні. Це відкриття допомагає глибше зрозуміти принципи, якими керується рекламна діяльність у фармацевтичному секторі.

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regulation in the field of medicine circulation. It provides a foundation for the development of international and national regulations governing medicine advertising, emphasizing the importance of ethical considerations alongside legal frameworks.

Keywords: morality, ethics, law, medicine, distribution, advertisement.

Introduction

Cooperation between Ukraine and the European Union in recent decades has produced processes of searching for the most optimal model for the development of the domestic healthcare sector and its proper regulation. The main normative regulators of public relations in the pharmaceutical market, including in the field of advertising of medicines, are law and morality (ethics). The understanding of ethics and law as social regulators depends primarily on the type of legal understanding that dominates in the legal consciousness of a particular researcher. The positivist tradition of legal understanding, which today dominates in the national regulatory framework for advertising of medicines, is not able to fully reveal the essence of the interaction between ethics and law, as well as all the patterns of their interpenetration and mutual influence.

The classical formal-logical approach, characteristic of the positivist type of legal understanding, is based on a two-level understanding of law: at the level of language - legal terms; at the level of logic - definitions (meanings) of legal terms. The specificity of the approach used in the research, based on the dialectical method, differs from the generally accepted philosophical and legal tradition of domestic legal science. The legal concept as a whole is understood in the unity of the term and definition, that is, in such a way that the latter are its components. Clarification at the conceptual level of the nature of the correlation of ethical and legal principles in the pharmaceutical field of healthcare at the present stage of its development in Ukraine will help accelerate the process of convergence of the national legal system with the legal system of the European Union.

The issues of the correlation between law and morality at the present stage of development of advertising of medicines remain insufficiently researched. A legal and ethical analysis of options for balancing public health with the dissemination of information, how to condemn

Загалом стаття є внеском у триваюче етико-правове дослідження регулювання реклами у сфері обігу лікарських засобів. Він забезпечує основу для розробки міжнародних і національних нормативних актів, що регулюють рекламу лікарських засобів, наголошуючи на важливості етичних міркувань поряд із правовою базою.

Ключові слова: мораль, етика, право, медицина, розповсюдження, реклама.

advertising actions without simply shifting the problem, and how significant changes in the healthcare system can affect this dynamic should also be at the center of interdisciplinary research (Schenker et. al., 2014). It should also be noted that in modern domestic and foreign scientific research of the methodological measurement of ethics and law, the potential of the dialectical method is almost not used. The conducted research begins to apply dialectics to solving ethical and legal problems in the pharmaceutical field of healthcare.

Materials and methods

In connection with the integration of Ukraine with the European Union, the transformation of the Ukrainian state is taking place. Rethinking values in such an important area for human life and society as healthcare requires updating the theoretical and methodological model for understanding the essential properties of social phenomena. The versatility and interdisciplinary status of the scientific problem of the correlation between the ethical and legal components of advertising of medicines requires a comprehensive application of scientific methods. Since the formal-logical method does not allow us to explore the conceptual content of such ethical and legal values as justice, honor, dignity, duty, conscience, responsibility, etc. the dialectical method was chosen as the main method of cognition in this research.

The formal-legal method is used to analyze the norms of the current legislation of Ukraine that regulate relations arising in the process of production, distribution and consumption of advertising of medicines. With the help of the comparative legal method, modern approaches were established, which in international standards and national criteria determine both the ethical component in the advertising of medicines, and the ethical component in the legal regulation of this activity. The purpose of

understanding the essence of the interaction of ethics and law in such a specific area of information support for the stability of the pharmaceutical market as advertising of medicinal products determines the need to refer to the use of the dialectical method. In the process of ascent from the abstract to the concrete, a dialectical relationship was revealed in the staging of advertising activities. Analysis and synthesis were used to identify the stages of production, distribution and consumption of advertising of medicines. There is a dialectical interconnection between these two methods, as a result of which they cannot be considered as separate concepts, because they only co-exist, they are the nature of each other, two components, two moments of a single cognition, the end result of cognition of which is always represented by their dialectical unity. (Strelchenko, 2020).

The transition from legal positivism to a dialectical approach in the reflection and cognition of reality is justified by the change in the paradigm of world perception and worldview, which is taking place in Ukraine in connection with European integration processes. At the same time, an unthinking transfer of norms and rules from the healthcare system of the European Union to domestic legislation can lead to negative consequences in the life of a person and society. This is due to the inclusion of new concepts from the sphere of advertising of medicinal products in national legislative acts, as well as the use of already known terms but with a different semantic meaning. The compilation of social relations by legal norms through their abstractness has a general character, which does not allow for the understanding of the specific ethical and legal content of the corresponding terms used in the legislative acts of Ukraine. To overcome the terminological ethical-legal uncertainty in the national sphere of advertising of medicinal products, the dialectical method of scientific cognition is used in the research.

Results and Discussion

General provisions of ethics and law in the field of advertising

Back in 1821, the outstanding German philosopher G.W.F. Hegel, who first applied dialectics as a method to the knowledge of ethical problems in law, noted: "Law and moral foundations, the true world of law and morality can be embraced by thought, through thought this world acquires a meaningful form" (Hegel, 2000). The regulation of ethical principles

historically originates in the form of self-regulation as a response to the request of civil society. Further regulation takes place at the international level within the framework of treaty law and subsequently takes the form of state regulation by enshrining in national legislation. Philosophers suggest that, in historical retrospect, moral values were formed simultaneously with law and in competition with it. At a certain stage in the development of society, a kind of "division of labor" took place between law and morality. The subject of legal regulation remained mainly actions and relations that were proved as a result of a dispute, if necessary, were prevented or punished through measures of state coercion. The subject of moral assessments were the qualities of the individual, expressed in their behavior and actions.

The moral foundations of human existence are studied by ethics as a component of philosophy. Currently, morality is understood as a form of social consciousness and a type of social relations (moral relations), one of the ways to regulate human behavior in society through established prescriptions (Shemshuchenko, 2007). Moral norms are characterized by a certain uncertainty, the presence of some differences in the moral beliefs of people, depending on the level of their culture, age, material well-being, etc. Based on the fact that morality means the conformity of people's behavior with moral norms, it is difficult for ethics to find the main, general criterion for assessments that determines the content of moral principles and norms as the basis of moral behavior. Pharmaceutical ethics as part of social ethics is the science of the moral value of human actions. Professional deontology, within the framework of professional ethics, studies the moral and ethical culture of a professional, their behavior in the field of their activity, explores the problems of professional duty and the proper form of manifestation of social necessity specific to morality. Law is defined as a system of generally binding norms established or sanctioned by the state, the observance and execution of which is ensured both by persuasion and by the power of state coercion. Legal norms are specific in content, unambiguous, delineate rights and obligations, and have certain limits of validity (Shemshuchenko, 2007). With the help of morality, law seeks to resolve a social conflict on the basis of what is due as a moral ideal. Taking into account morality, the interests of certain groups of people are comprehended and reflected - collective, community, society; the ratio of private and public interest in favor of the public, taking into account public values, is

determined. Medical deontology is the doctrine of the principles and norms of behavior of medical personnel. General medical deontology is a set of rules for all medical professionals, regardless of their specialty. Specific types of medical deontology contain recommendations related to the characteristics of a particular medical specialty. The term "deontology" was proposed by the English lawyer and sociologist Jeremy Bentham in the 19th century in his work "Deontology, or the science of morality" to refer to the theory of ethics as a science of morality (Biryukova, Kharina, Nesterova, Malakhovskiy, 2021). Medical and legal deontology are considered the most developed, since the level of human being depends on the proper implementation of the professional activities by medical and legal workers.

Consideration of the ethics of advertising as an object of informational legal relations was founded in 1938 by Francis Finkelhor (Hrytsyuta, 2012). Ethics in the field of law (legal ethics) is aimed at solving moral problems in the professional activities of subjects of legal relations with the help of ethical and legal norms. Ethical foundations are implemented in law at three levels:

- 1) axiological (legal values);
- 2) epistemological (legal understanding);
- 3) praxeological (law enforcement).

If it is impossible to resolve a certain social conflict with the help of law, the norms of morality are applied. In conditions of lowering the level of morality, for example, with the emergence of new values, ethical norms are fixed in the norms of law. Thus, the moral and legal forms of regulation of public life as a whole have a universal character. The interests of society and the state are the main principle and purpose of professional activity, in particular in the field of advertising. The main functions of social ethics in the field of advertising are informational and communicative, because under the intense and purposeful influence of advertising as a social phenomenon in society and in the individual, new values and attitudes are formed.

Ethical norms (norms of moral behavior) as ordinary acts, together with the fundamental principles, are enshrined in ethical codes - codified sets of basic principles and rules. As a rule, such regulatory documents are of a recommendatory nature, that is to say, not endowed with legal force. The provisions of codes of professional conduct do not provide for legal sanctions against violators of ethical

standards in the field of advertising. However, in case of violation of ethical prescriptions, regulated by law, certain legal consequences may arise.

The general orientation towards limiting the manifestations of dishonesty in the advertising of medicines by legal and moral norms is determined by the peculiarity of the consumer product by a person that is advertised. Thus, the potential danger of medicines to the health, and sometimes the life of the patient, entails the necessity and obligation of state monitoring and control in the field of advertising medicines in different countries of the world.

Correlation of ethical and legal aspects of advertising at the conceptual level

The ratio of law and ethics as the main social regulators in the pharmaceutical field of healthcare, on the one hand, is determined by their content (philosophical and legal), and on the other hand, by their interaction (mutual influence and interpenetration). The essence of law and morality is the main, relatively stable, qualitative basis of these categories, which determines their true nature and purpose in society (Yevhutyuch, 2017). In ethics and law, the following terms are widely used to denote universal human values: justice, honor, dignity, duty, conscience, responsibility, etc. However, at the conceptual level, the meanings of these terms in law and ethics do not coincide. Dialectics, on the other hand, makes it possible to trace the movement of thought from the differences between ethics and law to their contradictions, from their interaction to unity. Dialectics is the driving soul of any scientific development of thought, representing the only principle that introduces an immanent connection and necessity into the content of science... Dialectics is such a transition of one definition to another, in which it turns out that these definitions are one-sided and limited, that is, containing negation themselves (Hegel, 1973).

Morality is a form of social consciousness that reflects reality through moral norms, principles and rules of behavior. It reflects certain values that have developed in society, enshrined in the norms of human behavior and are contained in the concepts of good and evil, honor and dignity, conscience, justice and injustice. Morality regulates the behavior of people in all areas of life, while law is only socially significant behavior. Ethics and law are formal normative systems of public regulation of public relations. But unlike legal norms, all moral norms are based

on the rules of absolute deontic logic, that is, they are reduced to an order or prohibition addressed to a single individual. Moral norms are not identical to legal norms either in content, or in logical-theoretical (hypothesis, disposition, sanction), or in deontological structure. So, the main difference between them is the criteria for evaluating the actions, behavior of people and their relationships. Ethical concepts, due to their abstractness, are limitless and can be applied to natural phenomena and social life. However, moral concepts are concretized if they relate to legal relations between people. Legal relations between people are legal relationships; and moral – benevolence and compassion, friendship and guardianship, solidarity and mutual assistance, etc. Law is directed at social relations that can be formally defined for protection and reproduction (or prevention). The general goal of law and its implementation is the rule of law. The general goal of morality is the education of a moral and virtuous person.

The constant cause of contradictions between law and morality in any society is the formal certainty of law, which does not always make it possible to extend its action to situations that urgently require legal regulation, but not provided for by law, or, conversely, allows the application of law to life relationships and situations where morality considers such application unfair. Contradictions appear due to the fact that certain situations that are identical from the point of view of morality are not identical from the position of law. Or, on the contrary, some life circumstances that are similar from a legal point of view are considered different from a moral point of view.

The commonality of law and morality is manifested at the following levels: historical (genesis and development), teleological (ordering social relations with fair instructions), structural (norms, relationships, culture), categorical (universal scientific generalizations). Thus, the correlation between the concepts of ethics and law can be represented by a dialectical triad: ethics (thesis) – law (antithesis) – ethical law (synthesis). The unity of morality and law comes from the commonality of socio-economic institutions, culture, upbringing, people's commitment to the ideals of freedom, equality and justice. Complementing and correcting each other, law and morality should in no case duplicate each other; they cannot be identified, mixed, or replaced by one another or vice versa (Yurkovska et al., 2018). Rules of law are based on the principles of ethics and morality. Their purpose is to establish and maintain balance,

social stability and order, to achieve a social compromise associated with the creation of a standard, a model of behavior. Any activity for the circulation of medicines is implemented through a system of legal guidelines (legal norms) contained in regulatory legal acts of different legal force and determining the parameters of the proper behavior of the subjects of this activity (Strelchenko, 2019). Traditionally, monological (combination of norms in one legislative act) and polylogical (combination of norms in special legislative acts) regimes of legal regulation of advertising of medicines are distinguished. At the same time, in international law, we can identify a trend towards the unification of national laws in different states, and therefore unified rules for regulating advertising are being developed that operate regardless of borders (Pashkov et al., 2017).

International standards for the regulation of advertising of medicines

The International Chamber of Commerce (ICC) has been the main body of regulation in the field of international advertising since 1937, when the first ICC Code of Advertising Practices was published. Since then, the ICC self-regulatory sphere has expanded multiple times in order to assist companies in responsible promotion of their products on the market. In 2006, previously disparate codes were revised and merged into a single Consolidated Code of Advertising and Marketing Communications (ICC Constitution, 2018). Its latest update in 2018 follows the tradition of promoting high ethical standards for advertisers, advertising agencies and media worldwide. First of all, the code was conceived as an instrument of self-discipline of business entities. It uses the term "advertising" to mean any form of marketing communications carried out by the media, usually in exchange for payment or other valuable consideration. Legality, dignity, honesty and reliability, social and professional responsibility are the basic principles of all marketing communications, which must comply with the generally accepted principles of fair competition in business (Article 1). These ethical standards should be followed by all who are involved in advertising: advertisers, advertising producers, advertising agencies and the media. Article 17 of the Code states that marketing communications must not, unreasonably for educational or social reasons, contain a visual image or description of potentially dangerous activities or situations that demonstrate a disregard for safety or health measures, as defined by local national standards. In particular, the information provided with the

product must include comprehensive health and safety instructions where necessary. Appropriate warnings should be clearly articulated through the use of images, sound, text or their combinations. At the level of the principles regulating sales promotion, it is enshrined that all promotions must be fair to users, competitors and other market participants (Article A1).

The Ethical Criteria for Medicinal Drug Promotion (World Health Organization, 1988), approved by Resolution 41.17 of the 41st Assembly of the World Health Organization, should help to decide whether medicinal drug advertising practices are in line with generally accepted ethical standards. These criteria reflect the general principles of ethical standards, primarily the principles of honesty and fairness in the promotion of medicines on the market and do not constitute legal obligations. Promotion is the creation and maintenance of permanent links between the enterprise and the market in order to enhance sales of goods and form a positive image by informing, persuading and reminding of its activities (Olkhovskaya, 2019). The term "promotion on the market" is used in relation to all types of information and promotional activities carried out by manufacturing firms and supplying firms to stimulate the prescription, supply, purchase and/or use of medicines. All promotional materials containing any claims about medicines must be reliable, accurate, truthful, meaningful, balanced, up-to-date, evidence-based. They should not contain wording or unverified conclusions that are misleading. Any information that could lead to unjustified use of a medicine or unnecessary risk should also not be omitted. The word "safe" should only be applied to medicinal products that have been properly tested. Comparison of medicines should be based on real facts, be impartial and reasoned. Information and advertising material should be presented in a way that does not distort the essence of the promoted medicines.

In the European Union, integration and legal standards for the circulation of medicines are provided with the help of a single legal terminology, a unified definition of medicines, concepts and categories associated with their circulation (Pasechnyk, 2015). In the Member States of the European Union, medicinal products intended for marketing are subject to secondary EU law, in particular Directive 2001/83/EC (2001) of the European Parliament and of the Council on a Community Code relating to medicinal products for human use. Medicinal advertising must include any form of

targeted information, surveys or use of incentives to promote the prescribing, supply, sale or consumption of medicinal products. In particular, it applies to: the population; persons qualified to prescribe or dispense such medicines; visits by medical sales representatives to persons qualified to prescribe medicines; supply of samples; the use of incentives to encourage the prescription or dispensing of medicines in the form of a gift, offer or promise of any benefit or reward in cash or in kind, unless their real cost is minimal; financing of promotional activities involving persons qualified to prescribe or dispense medicines; financing of scientific conferences with the participation of persons qualified to prescribe or dispense medicines, in particular the payment of their travel and living expenses associated with such participation. Advertising of medicines does not apply to: labeling and accompanying leaflets tabs; correspondence, which may be accompanied by non-advertising material necessary to answer a specific question about a specific medicinal product; factual information announcements and reference material regarding, for example, repackaging, warnings about adverse reactions as part of general medicine warnings, sales catalogs and price lists, provided that they do not contain information about the product; information about human health or diseases, in the absence of references, even indirectly, to medicinal products (Article 86). Advertising of a medicinal product, firstly, must encourage the rational use of the medicinal product, presenting it objectively and without exaggerating its properties, and secondly, must not be misleading (Article 87). Member States must prohibit the advertising to the public of medicinal products which:

- a. are available on prescription only;
- b. contain substances defined by international convention, in particular the 1961 and 1971 United Nations Conventions, as psychotropic or narcotic substances.

They must prohibit direct distribution by the pharmaceutical industry of medicines to the public for promotional purposes. Member States have the right to prohibit in their territory the advertising to the public of medicinal products the cost of which may be reimbursed. To public it is allowed to advertise medicinal products which, due to their composition and purpose, are prescribed and developed for use without the intervention of a doctor for diagnostic purposes or for the prescription of treatment or observation, where appropriate, on the advice of a pharmacist (Article 88). The following special types of medicine advertising are distinguished:

- 1) advertising for an indefinite circle of people (population);
- 2) advertising addressed to healthcare professionals (doctors, junior medical workers, pharmacists) (Pashkov, Olefir, 2017).

The Code of Practice (Ethos) of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA, 2019) specifies that materials related to pharmaceutical products and their uses, whether they are promotional or no, that is sponsored by a company must clearly state who sponsored it. Promotion should not be disguised. According to the Information Consistency Standard, advertising must not conflict with approved local product information. The standard of accuracy and non-misleading requires that advertising information must be clear, legible, accurate, balanced, fair and complete enough to enable the recipient to form their own opinion about the therapeutic value of the relevant pharmaceutical product. Promotional information must be based on an updated assessment of all evidence and clearly reflect that evidence. It must not be misleading by distortion, exaggeration, undue emphasis, omission, or in any other way. Every effort should be made to avoid ambiguity. Absolute or comprehensive requirements should be used with caution and only with proper qualifications and justification. In general, descriptions such as "safe" and "no side effects" should be avoided, and appropriate qualifications should always be cited.

With the development of modern science and the pharmaceutical industry, the range of medicines is expanding on the world market. Total global pharmaceutical revenue, which stood at \$1.121 trillion in 2022, is expected to continue to grow at a rate of \$1.435 trillion until 2027 (Statista Health Market Outlook, 2023). Overall, the pharmaceuticals market is expected to grow by 5.39% on average between 2023 and 2027 (Statista). In turn, a wide range of pharmaceutical products requires operational awareness of medical and pharmaceutical workers about medicines. Pharmaceutical companies conduct their business depending on the strategy of promoting medicines among doctors in exchange for increasing the professional knowledge of the doctor. Everyone in this trade, besides of regulatory obligations, must be mindful of ethical beliefs (Kabir et al., 2021). Failure to comply with these conditions leads to the existence of unfair practices for the promotion of medicines by pharmaceutical companies among healthcare professionals. A separate link in the chain of

corrupt relations in the pharmaceutical sector is medicine marketing, which involves the establishment of unethical relations between pharmaceutical companies and medical workers (Bozhenko, 2022). In order to reduce the risks of violating the law in the field of unfair competition, paying significant fines and lengthy litigation, these companies implement compliance programs aimed at increasing the ability to act in compliance with both external (national laws or international treaties) and internal (codes of ethics and behavior) norms and rules. There are positive trends in the regulation of pharmaceutical promotion, such as rules requiring mandatory disclosure of information about the financing of medical professionals and patient groups, but more systemic fundamental changes are still needed. Most pharmaceutical companies have their own codes of ethics, which in some countries provide for the disclosure of payment information to third parties (Alves et al., 2019). However, often the information work of medical (pharmaceutical) or sales representatives of these companies is accompanied by the inclination of medical and pharmaceutical workers to recommend and prescribe products to patients in order to form a positive impression about them in the latter. Pharmaceutical companies can finance medical professionals to promote their products, which is one of the main types of corruption offenses in the healthcare sector (Bozhenko, 2022). However, in many countries around the world there are legal restrictions for healthcare professionals to perform activities related to the advertising of medicines. For example, in Ukraine the Law of Ukraine "Fundamentals of Ukrainian Legislation on Health Care" (Law No. 2801-XII, 1992) prohibits medical, pharmaceutical and rehabilitation specialists from advertising medicines during their professional activities (Article 78-1). It is significant that the legislator has not introduced a complete ban on communication between company representatives and medical workers. Naturally, without professional communication of the medical and pharmaceutical communities, the development of medical science and, accordingly, improving the quality of treatment in the interests of patients is impossible (Aleksieiev & Anishchenko, 2019).

National moral, ethical and legal criteria for advertising medicinal products

In Ukraine, at the constitutional level, a person, their life and health, honor and dignity, inviolability and security are recognized as the highest social value. Ensuring the economic and

information security of Ukraine is the most important function of the state, the cause of the entire Ukrainian people.

The preamble of the founding Law of Ukraine "Fundamentals of Ukrainian Legislation on Health Care" (Law No. 2801-XII, 1992) states that every person has a natural, inalienable and inviolable right to health care. Responsibility to present and future generations for the level of health and the preservation of the gene pool of the people of Ukraine, the introduction of a healthy lifestyle is assigned to society and the state. It is the state's responsibility to ensure compliance with the requirements of the law on the restriction of advertising of medicines (Article 19). At the same time, state regulation of advertising activities through law is directed, first of all, to the prevention and termination of unfair advertising. Promotional ethics and advertising are one of the key legislative and regulatory vectors that determine the most active fundamental factors of influence on the legal basis for the circulation of medicines (Solovyov, 2018). Thus, medical, pharmaceutical and rehabilitation specialists during their professional activities do not have the right to advertise medicines, including prescribing medicines on forms containing advertising information, and indicating manufacturers of medicines (trademarks) (Article 78-1). At the same time, their professional duty is the requirement to comply with professional ethics (Article 78). In general, about the advertising of goods harmful to human health, Article 32 of the said Law contains a reference prescription to the Law of Ukraine "On Advertising" (Law of Ukraine No. 270/96-VR, 1996).

The Law of Ukraine "On Advertising" (Law of Ukraine No. 270/96-VR, 1996) defines advertising as information about a person or product, distributed in any form and by any means, and intended to form or maintain awareness of advertising consumers and their interest in such a person or product (Article 1). This Law does not apply to announcements of individuals not related to entrepreneurial activities (Article 2). At the same time, such concepts as "social advertising", "sponsorship" used in the Law indicate that the purpose of advertising activities is not necessarily to make a profit. It is this Law that defines the features of advertising medicines as a socially significant category of goods, which directly affects the health of consumers and requires increased control by the state. Thus, it is allowed to advertise medicines that are duly authorized by the central executive body implementing the

state policy in the field of healthcare for use in Ukraine and dispensed without a doctor's prescription and not included by the central executive body in the field of healthcare to the list of medicines prohibited from advertising. Advertising activity is also limited to the establishment of legal and ethical principles and norms in order to exercise the right to complete, reliable information about the medicinal product and to prevent harm to both public and state interests and consumer rights. Thus, the basic principles of advertising are determined by: legality, accuracy, reliability, the use of forms and means that do not cause harm to the consumer of advertising. It is indicated that advertising should not undermine public confidence in advertising and must comply with the principles of fair competition; must not contain information or images that violate ethical, humanistic, moral standards, neglecting the rules of decency (Article 7). It is prohibited to advertise medicines, the use and dispensing of which is allowed only by prescription, as well as medicines included in the list of medicines prohibited from advertising. It is determined that the advertisement must contain: objective information about the medicinal product and be carried out in such a way that it is clear that the given message is an advertisement, and the advertised product is a medicinal product; the requirement to consult a doctor before using the medicinal product; recommendation on mandatory familiarization with the instructions for the medicinal product; warning text that contains: "Self-treatment may be harmful to your health." It is forbidden to post: information that may give the impression that when using the medicinal product, consultation with a specialist is not necessary; that the therapeutic effect of the use of the medicine is guaranteed; images of changes in the human body or its parts as a result of illness, injury; recommendations or references to the recommendations of medical professionals, scientists, medical institutions and organizations on advertised goods or services; special expressions of gratitude, letters, excerpts from them with recommendations, stories about the use and results of the advertised goods or services from individuals; images and mentions of the names of popular people, heroes of film, television and animation films, authoritative organizations; information that may mislead the consumer about the composition, origin, effectiveness, patent protection of the advertised product, etc. At the same time, it is allowed to distribute advertising of medicines placed in specialized publications intended for medical institutions and doctors, as well as distributed at seminars, conferences, symposiums on medical

topics. Participation of doctors and other professional medical workers, as well as persons whose appearance imitates the appearance of doctors, is prohibited in the advertising of medicines. The Law contains the term "ethics" and the term combination: "ethical norms", "ethical and moral and legal aspects", "ethical and humane considerations", but they are not directly associated with advertising. The terms "advertisement" and "advertising" are covered by the term "media provision" (Article 26). The terms "promotion of the relevant product on the market" (Article 1) and "advertising activities" (Article 22) are also used.

The Law of Ukraine "On Medicinal Products" (Law No. 123/96-BP, 1996) determines that the features of advertising medicines are determined by the Law of Ukraine "On Advertising" (Law of Ukraine No. 270/96-VR, 1996), that is, not the Law of Ukraine "Fundamentals of Ukrainian Legislation on Health Care" (Law No. 2801-XII, 1992). The same Law permits the advertising of medicines dispensed without a doctor's prescription and not included in the list of medicines prohibited from advertising. It is established that the advertising of medicines, the use and dispensing of which is allowed only by prescription, as well as those included in the list of medicines prohibited from advertising, is prohibited. The current Law of Ukraine "On Medicinal Products" (Law No. 2469, 2022), which has not yet entered into force, states that the requirements for advertising medicines are established by the Law of Ukraine "On Advertising" (Law of Ukraine No. 270/96-VR, 1996), taking into account the specifics defined by this Law (Article 87). This Law, adopted taking into account the provisions of the Directive of the European Parliament and Council 2001/83/EC (2001), enshrines a number of new terms for national legislation in the field of medicine circulation: "ethical and scientific requirements", "ethical principles", "principles of medical ethics". Section VIII of Directive 2001/83/EC (2001) of the European Parliament and of the Council uses the terms "advertising of medicinal products", "advertisement of medicinal products" (Articles 16g, 92) and the term "marketing" (Article 98). And in this Law, the term combinations are used: "advertising and promotion of medicines", "advertisement and promotion of medicines", "distribution of medicines", "promotional events", "promotional materials", "promotional statements" (Article 87). Thus, promotion of a medicinal product is defined as information about a medicinal product, disseminated in any form and by any means, intended to form or maintain awareness

of medical and pharmaceutical workers, rehabilitation specialists about such a medicinal product and aimed at promoting the prescription, dispensing, sale or use of a medicinal product (Article 2). It should be noted that the term "promotion" is not new to Ukrainian legislation. Thus, due to the fact that, as of 2013, pharmaceutical companies, in addition to direct advertising of medicines, actively used the means and methods of promoting medicines that are not regulated by national regulations, by Order of the Ministry of Health of Ukraine dated October 09, 2013 No. 870, it was approved and introduced guideline "Medicines. Proper Promotion Practice. Standardization of MHU 42-1.2:2013" was put into effect. The specified national standard, taking into account the provisions of Section VIII of the Directive of the European Parliament and of the Council 2001/83/EC (2001), proposed a new system of hierarchy of concepts in the field of medicine promotion and introduced some new terms. Advertising and promotion of medicines were devoted to separate sections of the guide. The concept of "medicine promotion" was defined as a set of activities or any ongoing, supported activity, including through the media, the Internet, organized or sponsored by a pharmaceutical company in order to promote medicines, increase the volume of recommendations, supply or use of medicines. At the same time, the promotion of medicinal products also included such activities as: advertising of medicinal products, the advertising of which is permitted in accordance with the requirements of the current legislation of Ukraine; providing information about any medicines; sponsorship. The concept of "promotional material" was understood as any informational carrier created for the purpose of promoting a medicinal product both among healthcare professionals and among any other persons. Also, the term "promotion" is used in the Action Plan aimed at obtaining support for granting Ukraine the status of a candidate member of the European Union, approved by the Decree of the Cabinet of Ministers of Ukraine on June 17, 2022 No. 480-r. and in the Communication Strategy for the European Integration of Ukraine for the period up to 2026, approved by the Decree of the Cabinet of Ministers of Ukraine dated December 9, 2022 No. 1155-p. The terms "promotion" and "marketing" are used as synonyms in the Action Plan for the implementation of the Human Development Strategy for 2021-2023, approved by the Decree of the Cabinet of Ministers of Ukraine dated December 9, 2021 No. 1617-p. The term "promotion and advertising of medicines" is used in the Decision of the

National Security and Defense Council of Ukraine "On the state of the national healthcare system and urgent measures to provide citizens of Ukraine with medical care" dated July 30, 2021, put into effect by Decree of the President of Ukraine dated August 18, 2021 No. 369/2021. In the IFPMA Code of Practice (Ethos) (2019), the term "promotion" means any activity conducted, organized or sponsored by a member company and directed at healthcare professionals for the purpose of promoting the prescriptions, recommendations, supply, use or consumption of their pharmaceutical products through all communication methods, including the Internet.

The term "distribution" (wholesale of medicines) in the Law is defined as the activity of business entities (except for individuals - entrepreneurs) to purchase medicines from business entities that have the appropriate license (manufacturers, importers or distributors), storage, transportation, supply, import, export and sale of medicines from pharmacy warehouses (bases) to other subjects of wholesale or retail trade in medicines that have received appropriate licenses for this, to medicine manufacturers, directly to medical institutions or legal entities, structural units of which are medical and preventive healthcare institutions. It should be noted that the regulatory and legal definition of the term "distribution of medicinal products" is given in the Resolution of the Cabinet of Ministers of Ukraine dated November 30, 2016 No. 929 "On Approval of the License Conditions for the Implementation of Economic Activities in the Production of Medicines, Wholesale and Retail Trade in Medicines, Import of Medicines (excluding active pharmaceutical ingredients)". Distribution (wholesale distribution) of medicines is defined as any activity related to the receipt, storage, supply, transportation and import/export of medicines, with the exception of their sales directly to citizens for personal consumption. This activity is carried out jointly with manufacturers or their representatives, importers, other enterprises engaged in wholesale and/or retail trade in medicinal products, and medical and preventive healthcare institutions. We should note that a medicine as a product of pharmaceutical activity in the process of circulation, from manufacturer to consumer, may contain a variety of intellectual property objects and be protected through the system of copyright, industrial property rights (Kodinet et al., 2022).

At the level of self-regulation in Ukraine, there is the Code of Ethics of Pharmaceutical Workers of Ukraine (2010), approved by the VII National

Congress of Pharmacists of Ukraine. It defines the fundamental ethical principles based on universal human values and the norms of professional behavior and moral responsibility of pharmaceutical workers in the process of their professional activities, based on the foundations of pharmaceutical ethics and deontology. The Code is based on international ethical standards, and its legislative base is determined by the Constitution of Ukraine, the Civil Code of Ukraine, the Laws of Ukraine "Fundamentals of Ukrainian Legislation on Health Care", "On Medicinal Products", "On Protection of Consumer Rights" (Law of Ukraine No. 30), "On Advertising" and other regulatory legal acts of Ukraine. In particular, it provides for the obligation of a pharmaceutical worker to comply with the norms of the legislation of Ukraine on the advertising of medicines. Therefore, the Code of Ethics for Pharmaceutical Workers of Ukraine is a recommendatory act, however, it demonstrates a combination of ethical and legal prescriptions and is based on the provisions of the current legislation of Ukraine and international standards in the field of public health and pharmaceuticals (Terzi et al., 2019). The code uses: the term "self-promotion" and the term "unethical advertising". The terms "marketing" and "distribution" of medicinal products are used as synonyms in relation to the principles of advertising. The Code also uses the terms "promotion of medicines", "distribution of medicines", "marketing of medicines", "advertisement of medicines". However, their definitions are not given.

Therefore, the terms and term combinations for the designation of concepts related to the advertising of medicines used both in the national code of ethics and in acts of legislation of Ukraine can be classified into the following terminological groups. The first (single-valued) group: 1) advertisement, advertisement of a medicinal product; 2) advertising, advertising activities, advertising of medicines; 3) promotion, promotion of medicinal products, promotional events, promotional materials, promotional statements; 4) marketing, marketing of medicines; 5) distribution of medicines. The second (synonymous) group: 1) promotion and marketing; 2) marketing and distribution. The third (equivalent) group: 1) advertisement and promotion of medicinal products, promotion and advertising of medicines, advertising and promotion of medicinal products.

Conclusions

The research shows that the regulation of ethical foundations of public relations through morality and law historically originated in non-state, and subsequently in state forms. Law and morality, as social normative regulators, are aimed at establishing and maintaining order in society and form the standards of people's behavior. Moral norms are generalized rules of behavior through ideas and principles that form the social qualities of the individual, regulate their internal awareness of their behavior. The norms of law as specific rules of conduct determine, support and regulate the external form of the latter.

At the level of international and national regulations that define ethical and legal standards and criteria in the field of advertising of medicines, using the dialectical method, correlations and mutual transitions of the definitions of ethical and legal concepts are revealed, the unity of moral and legal systems is traced.

The conducted research proves that the implementation of the provisions of international legislation, primarily of the European Union in the field of advertising of medicines, into Ukrainian legislation has a generally positive effect, manifested in the elimination of gaps that exist in domestic legislative acts. The current state of the problems of bringing Ukraine closer to the European standards for regulating the advertising of medicines at the conceptual level has been researched. It is determined that the legislation of Ukraine contains a number of thematic concepts that either coincide or are close in terms of definitions to the concepts contained in the relevant EU legislation.

It has been established that a conceptual inconsistency in the ethical-legal terminology used in domestic regulatory acts governing relations advertising of medicinal products at both state and non-state levels still remains. This requires the continuation of scientific research on the regulation of advertising of medicinal products in Ukraine in order to further unify domestic terminology with the terminology of European Union legislation.

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