

# ADMINISTRATIVE LIABILITY FOR OFFENSES RELATED TO MEDICINAL PRODUCTS' ELECTRONIC RETAIL TRADE

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**Abstract.** *The scientific research is focused on the specific features of administrative liability for offenses committed during the electronic retail trade of medicinal products. Ukrainian and European legislative acts regulating the circulation of medicinal products have been studied. The works of researchers who determined the specifics of administrative liability for offenses in the field of pharmaceutical activity have been also studied.*

*It is argued that administrative liability for offenses committed during the electronic retail trade of medicinal products can be defined as the application of organizational or financial restrictions by competent authorities in relation to legal entities and individuals for violation of pharmaceutical legislation, which encroach on the established proceedings of public pharmacy management. The authors have provided characteristics of certain types of administrative offenses that can be committed during the electronic retail trade of medicinal products. The authors have determined the powers of the authorities to bring pharmaceutical employees who have committed administrative offenses during the electronic retail trade of medicinal products to administrative liability.*

**Key words:** *administrative liability, medicinal products, electronic trade, retail trade.*

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## 1. Introduction

The legislative establishment of a new type of economic activity necessitates the study of all aspects of the implementation of this type of entrepreneurship. Legal principles of electronic retail trade of medicinal products have been established in Ukrainian legislation relatively recently. Pharmaceutical activity is oriented to provide citizens with necessary medicinal products of appropriate quality. Violations of the legislation on the circulation of medicinal products, which may occur during the implementation of this type of trade, are not sufficiently studied in the legal science. The given arguments substantiate the relevance of the chosen topic of scientific research.

## 2. Review of the literature

The problems of legal liability for the commission of offenses at the medicinal products market were the subject matter of scientific research by experts in the field of law and pharmacy. In particular, O. S. Khovpun studied specific features of pharmaceutical legal relations [1, p. 121–127] and peculiarities of administrative liability in the pharmaceutical field [2, p. 137–141]. The whole section in the monograph by N. V. Vovk and O. P. Svitlychnyi is focused on legal liability for offenses at the medicinal products market [3]. O. H. Strelchenko studied the specifics of administrative liability for norms violations in the field of circulation of medicinal products [4, p. 179–183]. The researcher O. H. Alekseeiev tried to determine the features of legal liability

in the pharmaceutical sector of health care [5, p. 167]. Peculiarities of administrative liability in the field of control over the circulation of medicinal products were studied by R. V. Myroniuk and O. A. Morhunov [6, p. 340–343]. The problems of combating the “black” online market of medicinal products were studied by N. O. Hutorova [7, p. 15–24]. The problems of proceedings in cases on administrative offenses in the health care sector were studied in the work of B. O. Lohvyenko [8]. The works of the mentioned scholars made it possible to determine the main features of administrative liability for offenses committed in the sphere of circulation of medicinal products.

Yu. Yu. Pustovit [9, p. 265–270] and M. O. Kravets [10, p. 75–78] focused their works to administrative liability of legal entities. The indicated articles made it possible to understand theoretical basis of sanctions that can be applied to pharmacy networks that have committed violations of the legislation on electronic retail trade of medicinal products.

## 3. Research purpose

The purpose of the article is to determine specific features of administrative liability for committing offenses during medicinal products' electronic retail trade.

## 4. Methodology

General scientific and special legal methods of cognition have been used while studying the prob-

lem. It is worth mentioning systemic, theoretical and legal, formal and dogmatic, comparative and legal methods of cognition among the special legal methods used in the research. In particular, the system method made it possible to study the system of Ukrainian legislation regulating the pharmaceutical activity. Theoretical and legal method was used to clarify the main concepts of Ukrainian law in the field of pharmacia. The norms of the legal institution of medicinal products' retail trade were researched by using the formal and dogmatic method.

## 5. Results

The researchers determine the specific features of legal liability of business entities that work at the medicinal products market. O. S. Khovpun notes that we should have all types of legal liability for offenses at the medicinal products market for the effective development and protection of legal relations arising in the pharmaceutical sphere [1, p. 125]. Indeed, persons guilty for violations of the legislation on medicinal products in accordance with the Art. 27 of the Law of Ukraine "On Medicinal Products" are subject to disciplinary, administrative, civil or criminal liability [11]. This norm is also applied to cases of the electronic retail trade of medicinal products.

N. V. Vovk and O. P. Svitlychnyi state that offenses in the pharmaceutical sector of the economy may be committed in the field of products standardization and certification, violation of licensing conditions and requirements in regard to the quality of medicinal products [3, p. 134]. Offenses of different nature can be committed in the same way during the production and sale of medicinal products.

O. H. Strelchenko defines an offense in the field of circulation of medicinal products as an illegal, culpable (intentional or negligent) action or omission that encroaches on the established management procedure in the sphere of circulation of medicinal products and which stipulates administrative liability under the law [4, p. 179]. Electronic retail trade of medicinal products belongs to the sphere of circulation of medicinal products. Therefore, any offense in the field of electronic retail trade of medicinal products can be defined as an illegal, culpable (intentional or negligent) action or omission that encroaches on the established management procedure in the field of electronic retail trade of medicinal products and which stipulates administrative liability under the law.

B. O. Lohvynenko defines set of elements of an administrative offense in the health care sector as a set of fundamental features that, in their totality, allow to qualify a specific illegal action as an administrative offense in the health care sector [8, p. 27]. The circulation of medicinal products belongs to the health care sector. Therefore, we can define set of elements of an administrative offense in the field of electronic retail trade of medicinal products as a set of fundamental features that together allow us to qualify a specific illegal act as an administrative

offense in the field of electronic retail trade of medicinal products.

O. H. Aleksieiev defines legal liability in the pharmaceutical sector of health care as the application of personal, organizational or financial restrictions by the competent state authorities to pharmaceutical employees who have committed violations of the law during the performance of their professional duties [5, p. 167]. Administrative liability is one of the varieties of legal liability. O. S. Khovpun while studying the problems of administrative liability in the field of circulation of medicinal products offers own definition of this term. The researcher claims that administrative liability in the pharmaceutical field can be defined as the imposition of administrative sanctions by the authorized entities on individuals and legal entities provided by law, which is a negative reaction of the state to administrative offenses that encroach on the established order of public management of pharmacia [2, p. 140]. The suggested definition fully corresponds to the essence of administrative liability, regardless of the economic sector, where an administrative offense was committed.

At the same time, electronic retail trade of medicinal products as a type of pharmaceutical activity is characterized by its own specific features. The Art. 19 of the Law of Ukraine "On Medicinal Products" establishes the terms for carrying out this type of economic activity. The legal requirements are to have a license for the specified type of pharmaceutical activity, to fill in the website with information, where there is electronic trade, to create one's own medicinal products delivery service and other requirements [11]. Norms regulating the electronic retail trade of medicinal products appeared in the Law of Ukraine "On Medicinal Products" in September 2020. In addition, special licensing conditions for the specified type of pharmaceutical activity were established in September 2021 in the Licensing Conditions for conducting economic activities on producing medicinal products, wholesale and retail trade of medicinal products, import of medicinal products (hereinafter – the Licensing Conditions). According to paragraph 13, clause 3 of the Licensing Conditions, electronic retail trade of medicinal products is defined as retail sale of medicinal products by using information and telecommunication systems in a remote manner, which includes acceptance, assembly, storage, delivery of orders for medicinal products and dispensing of medicinal products to consumers [12]. It is worth noting that the mentioned norms appeared in Ukrainian legislation as a result of adaptation to European standards and requirements. Since European legislation contains legal norms establishing the conditions for the sale at a distance of medicinal products. Sale at a distance of medicinal products to the public is allowed in accordance with the Articles 85b and 85c of the Directive No. 2001/83/EC of the European Parliament and of the Council "On the Community code relating to medicinal products for human use" dated from November 6, 2001.

It is stipulated that a business entity wishing to carry out distance sales of medicinal products must notify the authorized agency of the EU Member State of its intention [13]. Therefore, the specified type of pharmaceutical activity is characterized by a number of features, which are that:

1) a medicinal product is ordered remotely, there is no personal contact between a pharmacist and a consumer;

2) the transportation conditions necessary to preserve the quality of a medicinal product must be observed;

3) the website where medicinal products are being sold must contain information about medicinal products provided by the law.

Taking into account the specifics of the electronic retail trade of medicinal products, we can define administrative liability for offenses related to the electronic retail trade of medicinal products, as the application of organizational or financial restrictions by the competent authorities to pharmaceutical employees for violating the law, which encroach on the established procedure for the circulation of medicinal products, N. V. Vovk and O. P. Svitlychnyi claim that the following torts can be applied within the limits of pharmaceutical relations: the Art. 164 of the Code of Ukraine on Administrative Offenses "Violations of the procedure for carrying out economic activity", the Art. 167 "Introduction into circulation or sale of products that do not meet the requirements of the standards", the Art. 170 "Failure to comply with standards during the transportation, storage and use of products", the Art. 188-10 of the Code of Ukraine on Administrative Offenses "Failure to comply with the legal requirements of officials of the central executive power agency, which implements the state policy in the field of quality control and safety of medicinal products" [3, p. 129]. The listed categories of administrative offenses are related to violations in the field of quality control of medicinal products. At the same time, pharmaceutical employees may commit other administrative offenses that were not indicated in this list during the performance of their professional duties. The specifics of the electronic retail trade of medicinal products determine the specific features of administrative offenses that may be committed during the implementation of this type of pharmaceutical activity. It is worth analyzing the following types of administrative offenses.

We would like to note that in Part 1 of the Art. 42-4 of the Code of Ukraine on Administrative Offenses establishes liability for the sale of medicinal products in pharmacies without a prescription in cases prohibited by law [14]. One should remember that the sale at a distance of prescribed medicinal products according to Part 5 of the Art. 19 of the Law of Ukraine "On Medicinal Products" is generally prohibited, except for the sale of medicinal products by electronic prescription, in the manner established by the Ministry of Health of Ukraine [11]. Therefore, in case of the

sale at a distance of a medicinal product without the necessary prescription, the pharmacist's action can be qualified under Part 1 of the Art. 42-4 of the Code of Ukraine on Administrative Offenses.

According to the Art. 244-8 and the Art. 255 of the Code of Ukraine on Administrative Offenses employees of the State Service of Ukraine on Medicines and Drugs Control have the right to draw up the minutes on administrative offenses and apply administrative fines under Part 1 of the Art. 42-4 [14]. Violations of legislation committed during the electronic retail trade of medicinal products may be detected during scheduled or unscheduled inspections of pharmacy networks by the State Service of Ukraine on Medicines and Drugs Control.

Besides, Part 2 of the Art. 42-4 of the Code of Ukraine on Administrative Offenses provides administrative liability for the sale at a distance of medicinal products to a minor who has not reached the age of 14 [14]. It is worth noting that pharmacy employees cannot determine the age of a consumer who remotely orders medicinal products on the website of the pharmacy network. As a rule, there is no personal communication between a pharmacist and a consumer.

R. V. Myroniuk draws attention to the significant public harm of this administrative offense. The researcher claims that minors fall into the crazy information space advertising various biological supplements and stimulants, have the opportunity to purchase drugs of dubious quality, the intake of which can even lead to fatal consequences [6, p. 342]. The researcher's arguments substantiate the ban on the sale at a distance of medicinal products to minors.

According to the Art. 255 of the Code of Ukraine on Administrative Offenses, both inspectors of the State Service of Ukraine on Medicines and Drugs Control and officers of the National Police have the right to draw up the minutes on administrative liability for the sale at a distance of medicinal products to minors. Judges of district, city district, city or intercity courts have the right to apply administrative penalties in case of committing this offense in accordance with Part 1 of the Art. 221 of the Code of Ukraine on Administrative Offenses [14]. The possibility of involving police officers to investigate this offense indicates its significant social harm.

The liability of pharmacists for violating the restrictions existing for pharmaceutical employees during their professional activities is established in Part 1 of the Art. 44-2 of the Code of Ukraine on Administrative Offenses [14]. The list of legal restrictions is established in the Art. 78-1 of the Basics of legislation on health care of Ukraine. In particular, it is stipulated that pharmaceutical employees do not have the right during the sale of a medicinal product to provide inaccurate information about the availability of medicinal products with the same active substance, form of release and dosage in this pharmacy, in particular to hide information about the availability of

such medicinal products at a lower price [15]. It may seem that there is no communication between a consumer and a pharmacist during the sale at a distance of medicinal products. But paragraph 4, Part 4 of the Art. 19 of the Law of Ukraine "On Medicinal Products" stipulates that a website for the sale at a distance of medicinal products must contain an option to provide a pharmacist's consultation (if needed) while ordering a medicinal product [11]. Therefore, consultation on the website while purchasing a medicinal product is quite possible. A pharmacist may violate professional requirements to inform a consumer about the availability of medicinal products at a lower price in the process of communication. It can be concluded that an administrative offense under the Art. 44-2 of the Code of Ukraine on Administrative Offenses may be committed during the electronic retail trade of medicinal products.

Officials of the State Service of Ukraine on Medicines and Drugs Control have the right in accordance with the Art. 244-8 and the Art. 255 of the Code of Ukraine on Administrative Offenses to draw up the minutes on administrative offenses and apply measures of administrative liability in case of violation of professional restrictions by pharmacists during medicinal products' electronic retail trade [14]. Therefore, buyers have the right to appeal to the State Service of Ukraine on Medicines and Drugs Control with complaints about the work of pharmacy employees during medicinal products' electronic retail trade.

The next administrative offense that can be committed during the electronic retail trade of medicinal products is the implementation of this type of business without obtaining a license. Liability for such actions is established in Part 1 of the Art. 164 of the Code of Ukraine on Administrative Offenses [14]. It can be assumed that a pharmacy that has a license for the retail sale of medicinal products will try to conduct e-retail without a license to avoid unnecessary expenses. In this case, the head of the pharmacy may be held administratively liable under Part 1 of the Art. 164 of the Code of Ukraine on Administrative Offenses.

Part 3 of the Art. 164 of the Code of Ukraine on Administrative Offenses also provides for administrative liability for the provision of inaccurate information by a business entity to the licensing agency regarding the compliance of the financial and technical base with the requirements of the law [14]. It should be noted that paragraph 4, sub-clause 1, clause 7 of the Licensing Conditions provides the submission of information about the financial and technical base of the pharmacy for obtaining a license for electronic retail trade of medicinal products [12]. Thus, when obtaining a license for the studied type of pharmaceutical activity, an offense may be committed, which is provided under Part 3 of the Art. 164 of the Code of Ukraine on Administrative Offenses.

We note that according to the Art. 255 of the Code of Ukraine on Administrative Offenses inspectors of

the State Service of Ukraine on Medicines and Drugs Control, i.e., the licensing authority, have the right to draw up the minutes on administrative offenses provided by the Art. 164 of the Code of Ukraine on Administrative Offenses. Decision-making in such cases, in accordance with the Art. 221 of the Code of Ukraine on Administrative Offenses belongs to the competence of judges of district, city district, city or intercity courts [14]. Inspectors of the State Service of Ukraine on Medicines and Drugs Control may detect a corresponding misdemeanor while examining documents for obtaining a license. Officials of the State Service of Ukraine on Medicines and Drugs Control may also detect cases of electronic retail trade of medicinal products without obtaining a license in the process of scheduled or unscheduled inspection of the pharmacy network.

N. O. Hutorova draws attention to the fact that such acts as carrying out business activities without a license were decriminalized in 2011. Such amendments in the legislation made it impossible to carry out investigative actions and secret investigative (search) actions in case of illegal sale of medicinal products via the Internet [7, p. 21]. Such a problem really exists. Law enforcement agencies must combat electronic trade in falsified or unregistered medicinal products.

Electronic trade in low-quality medicinal products can be qualified under the Art. 167 of the Code of Ukraine on Administrative Offenses, because this norm establishes liability for the sale of products that do not meet the requirements of safety and quality standards [14]. One should remember that according to Part 9 of the Art. 19 of the Law of Ukraine "On Medicinal Products", a business entity having a license to carry out business activities in the retail trade of medicinal products is responsible to a consumer for maintaining the quality of a medicinal product [11]. Therefore, any sale at a distance of low-quality medicinal products may become the basis for administrative liability of a pharmaceutical employee. At the same time, the quality of a medicinal product, which is the object of the consumer's suspicions, can be verified in the laboratories of the State Service of Ukraine on Medicines and Drugs Control in accordance with the Art. 17 of the Law of Ukraine "On the Basic Principles of State Supervision (Control) in the Sphere of Economic Activity".

In case of failure to comply with the transportation conditions of medicinal products, which caused a decrease in the quality of the product, the guilty persons may be held administratively liable under the Art. 170 of the Code of Ukraine on Administrative Offenses [14]. One of the conditions for the electronic retail trade of medicinal products according to paragraph 4, Part 4 of the Art. 19 of the Law of Ukraine "On Medicinal Products" is the availability of the pharmacy network's own delivery service, equipment and facilities that ensure the compliance with the manufacturer's storage conditions for medicinal prod-

ucts during their delivery. The delivery of medicinal products can be also carried out by postal operators, but only if they have special equipment to preserve a medicinal product during the delivery [11]. Violation of the storage conditions of a medicinal product may be the reason for its spoilage and grounds for administrative liability of an official of a pharmaceutical organization or a postal operator.

According to the Articles 244-8 and 255 of the Code of Ukraine on Administrative Offenses, officials of the State Service of Ukraine on Medicines and Drugs Control have the right to draw up the minutes on administrative offenses and apply administrative penalties to offenders for committing the above offenses [14]. The indicated violations may be detected during scheduled or unscheduled inspections of the State Service of Ukraine on Medicines and Drugs Control. Information about possible violations of legislation within the activities of a pharmaceutical organization can also be obtained from complaints of citizens who have purchased low-quality medicinal products. In most cases state inspectors for quality control of medicinal products also have the right to consider cases of committing such offenses.

It should be noted that the employees of the State Service of Ukraine on Medicines and Drugs Control according to Part 1 of the Art. 8 of the Law of Ukraine "On the Basic Principles of State Supervision (Control) in the Sphere of Economic Activity", based on the results of the inspection of pharmaceutical organizations, have the right to issue binding orders to eliminate violations and deficiencies [16]. In case of failure to comply with the legal requirements of the state supervisory agency, the culprits may be held administratively liable under the Art. 188-10 of the Code of Ukraine on Administrative Offenses. Moreover, the right to draw up the minutes on an administrative offense and to apply administrative penalties belongs precisely to the inspectors of the State Service of Ukraine on Medicines and Drugs Control in accordance with the Art. 244-8 of the Code of Ukraine on Administrative Offenses [14]. Therefore, managers of pharmacy networks should pay close attention to the implementation of the prescriptions of the State Service of Ukraine on Medicines and Drugs Control issued as a result of such inspections.

Restrictive measures may be applied to pharmacy networks as a result of the violation of legislation on the electronic retail trade of medicinal products. Yu. Yu. Pustovit notes that many legislative acts provide the possibility of applying fines to legal entities that have violated the law. In particular, the legislation on licensing provides the possibility of canceling a license. The application of the listed measures is covered by the concept of legal liability of legal entities [9, p. 269]. It is worth noting that the legislation on the protection of consumer rights and on the protection of economic competition provides various fines for violations of the law. At the same time, there

are no special regulations on penalties for manufacturers of medicinal products or pharmacy networks in the national legislation on the circulation of medicinal products.

M. O. Kravets notes that the basis for legal liability of legal entities is illegal acts of officials and other employees of enterprises, institutions, and organizations. The guilt of a specific employee in violating the law while performing his / her labor duties is established during the investigation. But there are no special rules of proceedings in cases of violations of legislation by legal entities [10, p. 77]. It should be noted that the procedure and grounds for bringing legal entities to administrative liability are not consolidated at the legislative level. There is no clear understanding of whether the suspension or cancellation of a license can be considered as one of the measures of administrative liability of legal entities, or whether it is a type of economic sanctions.

It is worth paying attention to the fact that the Art. 16 of the Law of Ukraine "On Licensing the Types of Economic Activity" provides grounds for suspension and cancellation of licenses. In particular, the reason for suspending the validity of the license may be the drawing up of an act of non-fulfillment of the ruling on the elimination of violations of the licensing conditions for conducting the type of economic activity. If the violations of the law were not eliminated during the suspension of the license, it may be canceled [17]. The specified decisions on the suspension or cancellation of the license can be made in relation to pharmacy networks that carry out electronic retail trade of medicinal products. The State Service of Ukraine on Medicines and Drugs Control may detect violations of pharmaceutical legislation during scheduled or unscheduled inspections of pharmacies and may issue rulings to eliminate them. Failure to comply with the requirements of the State Service of Ukraine on Medicines and Drugs Control to eliminate violations of the licensing conditions of electronic retail trade of medicinal products may be a reason for suspension, and only then for cancellation of the license. It is this measure of administrative liability of legal entities that can be applied to pharmaceutical organizations for violations of the legislation.

## 6. Conclusions

Administrative liability for offenses related to medicinal products' electronic retail trade can be defined as the application of organizational or financial restrictions by the competent authorities to pharmaceutical employees for violations of legislation that encroach on the established proceedings of circulation of medicinal products.

Such administrative offenses may be committed during the electronic retail trade of medicinal products as:

- sale at a distance of medicinal products to a minor who has not reached the age of 14 (Part 3 and

Part 4 of the Art. 42-4 of the Code of Ukraine on Administrative Offenses);

- violation of professional requirements by a pharmacist in regard to informing the consumer about the availability of medicinal products at a lower price (the Art. 44-2 of the Code of Ukraine on Administrative Offenses);

- implementation of electronic sale at a distance of medicinal products without a license (Part 1 of the Art. 164 of the Code of Ukraine on Administrative Offenses);

- submission of false information in documents for obtaining a license for electronic retail sale of medicinal products (Part 3 of the Art. 164 of the Code of Ukraine on Administrative Offenses);

- electronic trade in low-quality medicinal products can be qualified under the Art. 167 of the Code of Ukraine on Administrative Offenses;

- failure to comply with the transportation conditions of a medicinal product, which caused a decrease in its quality (the Art. 170 of the Code of Ukraine on Administrative Offenses).

The powers to draw up the minutes on administrative liability in all of the listed cases belongs to the officials of the State Service of Ukraine on Medicines and Drugs Control, and in case of the sale at a distance of medicinal products to a minor, to the police as well. Consideration and rendering of decisions on bringing to administrative liability in case of committing administrative offense under the Art. 164 of the Code of Ukraine on Administrative Offenses belongs to the jurisdiction of district, city district, city or intercity courts in accordance with the Art. 221 of the Code of Ukraine on Administrative Offenses. In cases of committing other besides the listed offenses, the right to apply administrative sanctions belongs to the inspectors of the State Service of Ukraine on Medicines and Drugs Control. Licenses of pharmacy networks that have committed offenses during medicinal products' electronic retail trade may be suspended or revoked, but the application of such sanctions to legal entities goes beyond administrative liability.

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