

CAUSING HARM TO PHARMACEUTICAL ACTIVITY AS AN OBJECT OF CRIMINAL LAW PROTECTION

Olena Frolova

PhD, Professor at the Department of Law Enforcement and Anti-Corruption Activities at the Prince Volodymyr the Great Educational and Scientific Institute of Law, Higher Educational Institution "Interregional Academy of Personnel Management", Ukraine

orcid.org/0009-0007-5427-7581

Summary

The article is devoted to the issue of causing harm to pharmaceutical activity as an object of criminal law protection.

As the author notes, the current legislation regulating the procedure for pharmaceutical activity contains certain guidelines for determining harm to the specified social values or its individual fragments. In the opinion of the author, characterizing the formation of harm "within" pharmaceutical activity as an object of criminal law protection and its consideration in the composition of criminal offenses, it is necessary to determine the types of actions that affect pharmaceutical activity and lead to its violation – formation in it or in certain types of damage to its individual "components".

The author consistently proves that the aspects of influence on pharmaceutical activity, which give the committed act the properties of public danger, should be associated with various indicators of damage caused to pharmaceutical activity as an independent object of criminal law protection.

Key words: harm, criminal law protection, pharmaceutical activity, medicinal products, economic activity, criminal offence.

DOI <https://doi.org/10.23856/6220>

1. Introduction

The current legislation, which regulates the process of pharmaceutical activity, contains certain guidelines for determining damage to the specified social values or their individual fragments. Characterizing the formation of harm "inside" pharmaceutical activity as an object of criminal law protection and its consideration in the elements of criminal offences, it is necessary to deal with the next situation. First of all, it is necessary to determine the types of actions that affect the pharmaceutical activity and lead to its violation – the formation of certain types of damage in it or in its individual "components".

The purpose of the article is to determine the specifics of causing harm to pharmaceutical activity as an object of criminal law protection.

2. The impact on the "components" of pharmaceutical activity, capable of causing harm

The impact on the "components" of pharmaceutical activity, capable of causing harm, depends on:

a) the rights, freedoms and interests of subjects of legal relations that form the circulation of medicinal products and the circulation of products (goods) that are not medicinal products, as well as state regulation of pharmaceutical activity;

b) the rights, freedoms and interests of other persons who are not the specified subjects, but are important for ensuring the protection of individual and/or public health within the scope of pharmaceutical activity;

c) features of medicinal products, products (goods) that are not medicinal products, which are "dealt with" by persons who are or are not subjects of legal relations forming the circulation of medicinal products and the circulation of products (goods) that are not medicinal products means, as well as with which the "subjects" of influence in state regulation of pharmaceutical activity are connected;

d) connections between the specified persons, which acquire the meaning of legal relations in the field of circulation of medicinal products and circulation of products (goods) that are not medicinal products, as well as state regulation of pharmaceutical activity, and are implemented regarding their rights, freedoms and interests.

The reference point for damage to selected "components" of pharmaceutical activity as an object of criminal law protection should be considered to be their "damage", which entails their negative changes (*Berzin, 2009:122–154; Berzin, 2010:4–12*) or, in other words, the formation of negative changes in mandatory elements of pharmaceutical activity.

3. Aspects of the impact on pharmaceutical activity

Thus, the aspects of the impact on pharmaceutical activity, which give the committed act the properties of public danger, should be associated with various indicators of damage caused to pharmaceutical activity as an independent object of criminal law protection and have the meaning of two relatively independent manifestations of it:

a) in the form of direct damage resulting from a negative change in the mandatory elements of pharmaceutical activity and associated with the impossibility or complication of the performance of their functions (powers) by subjects of pharmaceutical activity – these functions directly relate to the realization of rights belonging to subjects, freedoms and interests;

b) in the form of indirect damage, which is a violation of the procedure for ensuring health care (individual and/or public).

"Disruption" of these legal relationships and changes in the rights, freedoms, or interests of business entities constitutes damage of a certain type, which is provided for in the Special Part of the Criminal Code (*Criminal Code of Ukraine*) as follows:

1) violation of the procedure for conducting clinical trials of medicinal products (Article 141 of the Criminal Code) is a fragment of damage to the legal relations of pharmaceutical activity in the form of a change in the creation, production and manufacture of medicinal products, their pharmaceutical development and research (testing). In the disposition of Article 141 of the Criminal Code, one of the subjects of this legal relationship is the "patient", in relation to whom clinical trials of medicinal products are conducted, and "his legal representative",

and their "written consent", providing by them, characterizes the relationship between these subjects. In addition, "death of the patient", which is determined in the disposition of Article 141 of the Criminal Code, acts as an additional alternative consequence that goes beyond the legal relationship of pharmaceutical activity, but is in connection with the specified fragment of damage to the legal relationship of pharmaceutical activity. At the same time, the violation of the procedure for conducting clinical trials of medicinal products also represents a fragment of damage to the state regulation of pharmaceutical activity, since they are related to the procedure for state registration of medicinal products, their quality control and supervision of their creation, production and manufacture, pharmaceutical development, research (testing) as parts of the circulation of medicinal products;

2) with fragments of damage caused to the legal relations of pharmaceutical activity and the rights, freedoms or interests of subjects of pharmaceutical activity, violations of the procedure for carrying out special medical and pharmaceutical "procedures" should be associated: experiments on humans (Article 142 of the Criminal Code), transplantation of anatomical materials (Article 143 of the Criminal Code) and forcibly or fraudulently extracting blood from a person for the purpose of using it as a donor (Article 144 of the Criminal Code). Violation of the legal relations of pharmaceutical activity, as well as the corresponding rights, freedoms or interests of its subjects, may be associated with the activities of persons who are not subjects of pharmaceutical activity, but carry out pharmaceutical "procedures", performing "an abortion by a person who does not have special medical education" (Part 1 of Article 134 of the Criminal Code), "illegal abortion" (Part 3 of Article 134 of the Criminal Code) and "illegal medical activity" (Article 138 of the Criminal Code);

3) disclosure of information on the conduct of a medical examination to detect infection with the human immunodeficiency virus or other incurable infectious disease (Article 132 of the Criminal Code) and disclosure of medical secrets (Article 145 of the Criminal Code) as a loss of the nature of secrecy that certain information in the field of pharmaceutical activity has, – characteristic of a change in the legal relationship of pharmaceutical activity, as well as the corresponding rights, freedoms or interests of its subjects;

4) since narcotic and psychotropic medicinal products are independent types of medicinal products, the Special Part of the Criminal Code stipulates manifestations of changes in the order of their circulation, which can be attributed to the legal relations of pharmaceutical activity, as well as the rights, freedoms or interests of its subjects. Part 1 of Article 305 of the Criminal Code provides for "smuggling of narcotic drugs, psychotropic substances ... that is their movement across the customs border of Ukraine ...", in Part 1 of Article 306 of the Criminal Code – "the use of funds obtained from the illegal circulation of ... poisonous or potent medicinal products for the purpose of continuing the illegal circulation of ... poisonous or potent medicinal products", in Part 1 of Art. 307 of the Criminal Code – "illegal production, manufacture, acquisition, storage, transportation or forwarding for the purpose of sale, as well as illegal sale of narcotic drugs, psychotropic substances", in Part 1 of Article 317 of the Criminal Code – "organization or maintenance of places for illegal ... production or manufacture of narcotic drugs, psychotropic substances." Since part of the concept of pharmaceutical activity is associated with economic activity, the mandatory component of which is the sale of medicinal products, the violation of the order of circulation of narcotic and psychotropic medicinal products must include such changes that are formed as a result of the sale of narcotic or psychotropic medicinal products or are related for the purpose of such implementation. The most typical legal construction that denotes such implementation is "for the purpose of sale" and "sale".

Therefore, the absence of the purpose of sale and direct sale in the mechanism of handling narcotic drugs and psychotropic substances in the disposition of a certain article or part of an article of the Criminal Code makes it impossible to recognize them as harm that occurs within the circulation of narcotic or psychotropic medicinal products (for example, Part 1 of Article 309 of the Criminal Code). In addition, precursors can be used in the pharmaceutical industry for the manufacture and production of narcotic drugs. In this case, the use of precursors is a component of the circulation of narcotic drugs (in particular, in terms of the creation, production and manufacture of narcotic drugs). However, other types of treatment of precursors, which are not related to their use, form a mechanism of their independent circulation, which is separated at the legislative level and is not included in the concept of pharmaceutical activity in the field of medicinal products and outside the field of medicinal products. After all, the intended purpose of precursors is their use in the process of manufacturing or production of medicinal products, but the order of their circulation is beyond the limits of their intended use;

5) the presence of a narcotic or psychotropic medicinal product in the human body when it is used as prescribed in the event that it is part of the circulation of narcotic medicinal products (Articles 314, 315, 316 of the Criminal Code), indicates damage to pharmaceutical activity when it is subjected to objects of circulation of narcotic or psychotropic medicinal products, as well as when state regulation of such circulation is violated;

6) the creation of forged documents that are used in the process of circulation of medicinal products, or in a broader sense – the change, distortion of the content of such documents, which affects this circulation (Article 318 of the Criminal Code), means damage to the order of circulation of medicinal products and state regulation of such circulation;

7) changes in the order of circulation of narcotic or psychotropic medicinal products (Articles 319, 320, 321 of the Criminal Code) indicate damage to such circulation, which is taken into account in the implementation of legal relations of pharmaceutical activity and its state regulation. It should be noted that in Part 1 of Art. 319 of the Criminal Code provides for liability for "illegal issuance of a prescription for the right to purchase narcotic drugs or psychotropic substances for selfish motives or in other personal interests". If we consider a prescription as a "written request from a doctor to a pharmacist", then a prescription illegally issued by a doctor "interferes" with the established order of circulation of narcotic and/or psychotropic drugs, changes this circulation. Therefore, at this stage of the research, it is important to note that there is no "opposite" type of criminal offense in the Special Part of the Criminal Code, which would involve responsibility for the pharmacist's use of a prescription that is known to be illegally issued by a doctor;

8) the production of falsified medicinal products and the circulation of falsified medicinal products (Article 321-1 of the Criminal Code) means damage to the legal relations of pharmaceutical activity in the form of a change in the order of circulation of medicinal products, as well as damage to the state regulation of pharmaceutical activity, which is related to the order of state registration medicinal products, their quality control and supervision of their circulation;

9) in Article 321-2 of the Criminal Code provides for "violation of the established order of preclinical study, clinical trials of medicinal products", "falsification of their results" and "violation of the established order of state registration of medicinal products". The first two violations indicate damage to the legal relations of pharmaceutical activity in the form of the creation, production and manufacture of medicinal products, pharmaceutical development, research (testing) of medicinal products, as well as damage to the state regulation of pharmaceutical activity related to the state registration of medicinal products, their quality control and supervision by their creation, production and manufacture. As for "violation of the established

order of state registration of medicinal products", it means damage caused to the order of state registration of medicinal products;

10) violation of the procedure for the performance of their professional duties by medical and pharmaceutical employees and other persons as subjects of legal relations of pharmaceutical activity (Articles 131, 137, 139, 140 of the Criminal Code) is associated with damage to legal relations of pharmaceutical activity, as well as appropriate rights, freedoms or interests of its subjects. Beyond this damage are additional consequences in the form of "infection of a person with the human immunodeficiency virus or other incurable infectious disease that is dangerous to human life" (Part 1 of Article 131 of the Criminal Code), as well as "infection of two or more persons" (Part 2, Article 131 of the Criminal Code), "significant harm to the victim's health" (Part 1, Article 137 of the Criminal Code), "death of a minor or other serious consequences" (Part 2, Article 137 of the Criminal Code), "serious consequences for the patient" (Part 1 of Article 139, Part 1 of Article 140 of the Criminal Code), "death of the patient or other serious consequences" (Part 2 of Article 139 of the Criminal Code) and "serious consequences for a minor" (Part 2 of Article 140 of the Criminal Code).

4. Damage to legal relations of pharmaceutical activity

The given legislative guidelines for determining damage to social values or its individual fragments are taken into account when determining the "impact" of legal relations of pharmaceutical activity, as well as the rights, freedoms and interests of its subjects. On the basis of the mentioned guidelines, the following typical types of such "impairment" can be identified, which are reflected in the Special Part of the Criminal Code:

1) violation of the rights, freedoms and interests of subjects of pharmaceutical activity, as well as violation of relations between subjects of pharmaceutical activity that ensure the circulation of medicinal products in its separate parts, in particular: creation, production or manufacture of medicinal products, their research (testing) (Articles 141, 321-2 of the Criminal Code), creation, production and manufacture of medicinal products, their sale (Articles 305, 306, 307, 309, 310, 313, 317, 320, 321 of the Criminal Code), acquisition of medicinal products and precursors used for the production of medicinal products (Articles 308, 312 of the Criminal Code), production, manufacture, acquisition, storage, transportation or forwarding of precursors used for the production of medicinal products (Article 311 of the Criminal Code), application medicinal product (Articles 314, 315, 316, 317, 323 of the Criminal Code), use of documents ensuring the circulation of medicinal products and other falsification of medicinal products (Articles 318, 319, 321-2 of the Criminal Code), production of falsified medicinal products and their circulation (art. 321-1 of the Criminal Code);

2) violation of the rights, freedoms and interests of subjects of pharmaceutical activity, as well as violation of relations between subjects of pharmaceutical activity, regardless of whether or not they ensure the circulation of medicinal products: violation of the procedure for conducting special medical and pharmaceutical "procedures" (Articles 134, 138, 142, 143, 144 of the Criminal Code); "handling" information related to pharmaceutical activity (Articles 132, 145 of the Criminal Code);

3) violation of such relations between subjects of pharmaceutical activity, that have the character of realization of professional duties by these subjects (Articles 131, 139, 140 of the Criminal Code);

4) rights, freedoms and interests of subjects of state regulation of pharmaceutical activity, relations between these subjects and other subjects of pharmaceutical activity, which extends to individual components of the circulation of medicinal products, as well as the order of state regulation of pharmaceutical activity as a whole, namely: within the limits of the state registration of medicinal products (Articles 142, 321-2 of the Criminal Code).

The specified most typical types of "injury" of the legal relations of pharmaceutical activity, as well as the rights, freedoms and interests of its subjects, form changes in pharmaceutical activity as an independent object of criminal law protection and are recognized as losses suffered by the relevant subjects of pharmaceutical activity (Frolova, O., Demchenko, I., Khmil, I., Oleksandr, M., Stratonov, V., & Vasylenko, V., 2024). According to its legal nature and taking into account the requirements of part 2 of Art. 22 of the Civil Code (*Civil Code of Ukraine*) these losses are **real losses**. In addition, if according to Part 2 of Art. 22 of the Civil Code to take into account the recognition as real losses of the costs that a person has made or must make to restore his/her violated right, then in pharmaceutical activity they should be considered: violation of the interests of the subjects of pharmaceutical activity, which are related to receiving income from the type performed by them pharmaceutical activity (since this activity has an economic nature); the result of failure or improper realize of professional duties by pharmaceutical employees, which is reflected in the pharmaceutical activity of its specific subjects and which they "experience" in the process of pharmaceutical activity (Berzin P., Demchenko I., Berzina A., 2023). Since part 2 of Art. 22 of the Civil Code, a type of loss is recognized as a lost profit, then its formation is also characteristic of the violated interests of subjects of pharmaceutical activity related to the receipt of income from a specific type of this activity carried out by them. Therefore, the mandatory guideline for the inclusion of income in expenses and its consideration in the content of the lost benefit is the provision of the regulatory legislation, which regulates the implementation of specific types of pharmaceutical activities by these subjects, related to: a) circulation of medicinal products, which by its nature is an economic activity that requires licensing and does not include state regulation of pharmaceutical activity; b) circulation of products (goods) that are not medicinal products – this circulation is an economic activity that requires state registration and licensing or only state registration.

It is also important to note that the above-mentioned fragments of harm in pharmaceutical activity can be considered a normatively defined "indicator" of social danger of the corresponding types of violations of pharmaceutical activity only in the presence of a violation of individual and/or public health protection (such a violation of health protection can be expressed both in causing real harm to the health care system and in creating the danger of causing such harm). In this case, "violation of the protection of individual and/or public health" is the indicator of the public danger of violations of pharmaceutical activity, which corresponds to the concept of "substantial damage" provided for in Part 2 of Article 11 of the Criminal Code to characterize the public danger of the act.

5. Conclusions

The criteria for identifying the types of pharmaceutical activity in the field of medicinal products that are capable of being harmed are the sale of medicinal products by a person, which is: a) an economic activity that requires licensing and b) related to state regulation of pharmaceutical activity in the field of medicinal products, but by its nature is not an economic activity and does not require licensing.

The most typical types of "injury" of pharmaceutical activity, which are reflected in the current regulations of the Special Part of the Criminal Code, should be associated with: 1) violation of the rights, freedoms and interests of subjects of pharmaceutical activity, as well as violation of relations between subjects of pharmaceutical activity, which ensure the circulation of medicinal products in its individual parts; 2) violation of the rights, freedoms and interests of subjects of pharmaceutical activity, as well as violation of relations between subjects of pharmaceutical activity, regardless of whether or not they ensure the circulation of medicinal products; 3) violation of such relations between subjects of pharmaceutical activity, that have the character of realization of professional duties by these subjects; 4) violation of the rights, freedoms and interests of the subjects of state regulation of pharmaceutical activity, the relations between these subjects and other subjects of pharmaceutical activity, which extends to individual components of the circulation of medicinal products, as well as the order of state regulation of pharmaceutical activity as a whole.

References

1. Berzin P. (2009). *Zlochynni naslidky: ponyattya, osnovni riznovydy, kryminal'no-pravove znachennya: monohrafiya. [Criminal consequences: concepts, main varieties, criminal law significance: monograph.]* K.: Dakor. [in Ukrainian].
2. Berzin P. (2010). *Zlochynni naslidky v mekhanizmi kryminal'no-pravovoho rehulyuvannya: avtoreferat dys. na zdobuttya nauk. stupenya d-ra yuryd. nauk; spetsial'nist' 12.00.08 – kryminal'ne pravo ta kryminolohiya; kryminal'no-vykonavche pravo [Criminal consequences in the mechanism of criminal law regulation: abstract of the dissertation. For obtaining sciences degree of doctor of law sciences; specialty 12.00.08 – criminal law and criminology; criminal executive law].* Kyiv: Kyiv natsional'nyy universytet imeni Tarasa Shevchenka. K. [in Ukrainian].
3. *Kryminal'nyy kodeks Ukrayiny: Kodeks Ukrayiny vid 05.04.2005 r. № 2341-III. [Criminal Code of Ukraine].* Retrieved from <https://zakon.rada.gov.ua/laws/show/2341-14#Text> [in Ukrainian].
4. Frolova, O., Demchenko, I., Khmil, I., Oleksandr, M., Stratonov, V., & Vasylenko, V. (2024). *The Subject of Criminal Offenses Encroaching on Pharmaceutical Activity in Ukrainian Criminal Law. Lex Humana (ISSN 2175-0947), 16(1), 461–473.* Retrieved from <https://seer.ucp.br/seer/index.php/LexHumana/article/view/2935> [in English].
5. *Tsyvil'nyy kodeks Ukrayiny : Kodeks Ukrayiny vid 16.01.2003 r. № 435-IV. [Civil Code of Ukraine].* Retrieved from <https://zakon.rada.gov.ua/laws/show/435-15#Text> [in Ukrainian].
6. Berzin P, Demchenko I, Berzina A. *The problems of criminal liability of pharmaceutical employees in the context of certain forms of collaborative activities. Wiad Lek. 2023;7:1681–1684. doi: 10.36740/WLek202307125* [in English].