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Atypical Types of Criminal Offences Encroaching on Pharmaceutical Activity in Acts of Foreign Criminal Legislation

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Abstract **Purpose:** To determine the atypical types of criminal offences encroaching on pharmaceutical activity in acts of foreign criminal legislation. **Methods:** This article is based on systemic analysis and comparative legal methods. **Results and Discussion:** We chose the way of systematization of atypical types of criminal offences that encroach on pharmaceutical activity in acts of foreign criminal legislation. Criteria for the systematization of atypical types of criminal offences encroaching on pharmaceutical activity are proposed. **Implications of the Research:** We have identified the impact of the construction of legal norms of atypical types of criminal offences encroaching on pharmaceutical activity in acts of foreign criminal legislation. Identification of atypical types of criminal offenses and their systematization were useful for finding out "damage" of certain fragments of pharmaceutical activity (its mechanism). **Originality/value:** We were asked the question of identifying the impact of the construction of legal norms of atypical types of criminal offences encroaching on pharmaceutical activity in acts of foreign criminal legislation. The norms of criminal legislation of EU (Germany), USA (the State of New York, the State of California), Brazil, Switzerland, Turkey, Estonia, Georgia, Ukraine, Kazakhstan, Tajikistan, Uzbekistan were used. It was found that their "atypicality" does not mean errors of legal technique in acts of foreign criminal legislation, but is carried out on the basis of normative (blanket) legislation in the field of pharmaceutical activity.

Index Terms pharmaceutical activity, criminal offences, medicinal products, foreign criminal legislation, medical devices

I. Introduction

Pharmaceutical activity is a mandatory component of the health care system in the state. Ensuring health care is impossible without regulating the pharmaceutical sector, which essentially provides one of the "spheres" of health care. Normative regulation of pharmaceutical activity directly affects the legal protection of the health care system.

It is proposed to define atypical types of criminal offences that encroach on pharmaceutical activity in the acts of foreign criminal legislation on the basis of systematization (not classification) of the relevant legislative norms of those states that primarily ensure the largest volume of circulation of medicinal products and circulation of medical devices. It is also suggested to turn to the experience of those states that have built a more "optimal" mechanism for regulating pharmaceutical activity for criminal law enforcement.

A. Theoretical Framework

In the broadest socio-legal sense, pharmaceutical activity is associated with the field of scientific and practical activity in health care, with its subject: medicinal products, biologically active supplements, medical devices, baby food, perfumery and cosmetic products, individual diagnostic devices, items for patient care, sanitary and hygienic products, mineral waters, etc. They provide treatment, disease prevention, maintenance of a healthy lifestyle or patient‘s care [1].

It is also important that all constituent elements of pharmaceutical activity "are normatively regulated, and therefore, accordingly stable and controlled by the state" [2]. However, currently the scope of such "normative regulation" does not differ in absolute integrity and stability. That was repeatedly emphasized by scientists [3]–[6]. Thus, the concept of pharmaceutical activity is normatively uncertain, which gives rise to serious discussions in the relevant fields of law and health care [7], [8].

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Acts of foreign criminal legislation distinguish types of criminal offenses related to pharmaceutical activity, which are to a certain extent (albeit with some differences in the conceptual apparatus or terminology [9]) similar.

Illustrating the criminal law protection of pharmaceutical activity, we propose to divide criminal offenses encroaching on pharmaceutical activity into typical and atypical types. We agree with the point of view that by distinguishing both this types when reviewing encroachments during comparative legal studies, it is possible to determine the features of: a) causing damage to the object of criminal law protection; b) the interrelationship of legal constructions provided for by acts of foreign criminal legislation with the committed offence and the damage actually caused by it to the object of criminal protection [10].

Such types of criminal offences should be considered atypical if their legal constructions "inadequately" reflect the "impairment" of pharmaceutical activity and the infliction of certain damage on it, that is, they provide for a certain "exclusivity" of the properties of encroachment on pharmaceutical activity and its "impairment", which is manifested in the corresponding damage.

We propose to consider atypical types of criminal offences encroaching on pharmaceutical activity in acts of foreign criminal legislation on specific examples, using the criminal legislation of certain foreign countries and to carry out our own systematization. It is proposed to distinguish such "typicality" and "atypicality" taking into account: a) the content of the encroachment (impact) on pharmaceutical activity as an object of criminal law protection; b) features of the "affectedness" of pharmaceutical activity (its individual fragments), manifested in causing damage; c) the specifics of the reflection of the specified "injury" (damage) in legal constructions that define the relevant types of criminal offences.

In the most generalized form, the "typical types" of pharmaceutical activity are those that are carried out with medicinal products: 1) manufacturing of medicinal products in pharmacies; 2) industrial manufacturing of medicinal products; 3) distribution of medicinal products (activities related to the receipt, storage, supply, transportation and import/export of medicinal products, with the exception of their sale directly to citizens for personal use); 4) import of medicinal products; 5) wholesale trade in medicinal products; 6) retail sale of medicinal products [11], [12].

Other, different from typical types, subjects of pharmaceutical activity, that is, those that are not medicinal products and/or are not included in the content of the regulatory norms that regulate the licensing of such types of pharmaceutical activity, are quite often found in the legislation of various countries, but they did not have enough scientific study in the comparative legal sense. For example, the Criminal Codes of Ukraine, Georgia and the Republic of Kazakhstan have many similar criminal offenses in the field of medical and pharmaceutical activity. This refers to failure to performance or improper performance to a patient by a medical or pharmaceutical worker, improper performance of professional duties, engaging in medical or pharmaceutical activities without proper permission, illegal abortion, and some others. However, with certain differences. For example, both the Criminal Code of Ukraine and the Criminal Code of the Republic of Kazakhstan [13] have a criminal offense that provides for criminal liability for conducting clinical trials of medicinal products. At the same time, the Criminal Code of Ukraine also establishes responsibility for violating the established order of preclinical study of medicinal products and their state registration (Article 321-2) [14], and Art. 318 of the Criminal Code of Kazakhstan also provides for criminal liability for the use of new methods and means of prevention, diagnosis, treatment and medical rehabilitation [8]. Such similarity indicates the relevance of the analysis of the criminal legislation of different countries, which will make it possible to more fully investigate the issue of criminal legal protection of pharmaceutical activity at the national level, identify possible gaps or, on the contrary, show the successful experience of legal regulation.

II. Methodology

A. Comparative Legal Method

Made it possible to identify the differences in the legal constructions of the allocation of atypical types of criminal offences encroaching on pharmaceutical activity in acts of foreign criminal legislation. The materials for such identification were the Criminal Codes of the EU (Germany), USA (the State of New York, the State of California), Brazil, Switzerland, Turkey, Estonia, Georgia, Ukraine, Kazakhstan, Tajikistan, Uzbekistan.

B. Systemic Analysis

Used to systematize the elements of criminal offences in acts of foreign criminal legislation in terms of identifying atypical types of criminal offences encroaching on pharmaceutical activity in a systemic understanding with all the factors that influence such content.

III. Results and Discussion

The systematization of atypical types of criminal offences encroaching on pharmaceutical activity in acts of foreign legislation is carried out according to criteria related to various methods of legislative consolidation of the features of these types of criminal offences, namely:

a) individualization of the features of specific types of medicinal products that are in circulation (illegal circulation) (in this case, the foreign legislator applies "extra" specifics when defining such features in the relevant legal constructions without their necessary generalization);
b) a certain typification of the signs of medicinal products of specific types (without "necessary" individualization);
c) ignoring the connection of the subject of a certain type of criminal offence with specific signs of pharmaceutical activity;

d) ignoring the specifics of the act committed by a particular person (regardless of whether he/she is recognized as a subject of pharmaceutical activity or not), causing "injury" (disorganization) of pharmaceutical activity (its individual fragments).

Atypical types of criminal offences that encroach on pharmaceutical activity include those in the content of which legal constructions a foreign legislator:

1) singles out the individual characteristics of specific medicinal products in circulation (without the appropriate level of typification of these characteristics).
For example, in S 6811 of Art. 137 of the Education Law of the State of New York [15], USA establishes requirements for any person who sells at retail or gives away in tablet form bichloride of mercury, mercuric chloride or corrosive sublimate, unless such bichloride of mercury, mercuric chloride or corrosive sublimate, when so sold, or given away. But nothing contained in S 6811 of Art. 137 shall be construed to prohibit the sale and dispensing of bichloride of mercury in any form, shape, or color, when combined or compounded with one or more other drugs or excipients, for the purposes of internal medication only, or when sold in bulk in powder form, or to any preparation containing one-tenth of a grain or less of bichloride of mercury [4].
Another example is Art. 234 (1) of the Criminal Code of the Republic of Tajikistan [16] "Illegal circulation of ferula resin", where the legislator distinguishes such types of criminal offence as "illegal gathering, processing of ... medicinal products" (part 1) [1]. Moreover, in the same part of Art. 234 (1) of this Criminal Code, the legislator singled out such a medicinal product as "ferrule resin" as an independent subject of criminal offence: "Illegal gathering, processing, manufacturing of medicinal products, storage, transportation or sale to another person ferula resin in small quantities" (according to the note to this article of the Criminal Code, "a quantity that exceeds two kilograms of ferula resin, or more than 20 destroyed ferula bushes" is considered insignificant). In Part 2 of Art. 234 (1) of the Criminal Code of the Republic of Tajikistan provides a qualifying feature for the specified actions with ferula resin - "large size", which, according to the note to this article of the Criminal Code, is considered "an amount of more than 10 kilograms of ferula resin, or more than 100 destroyed ferula bushes";
2) does not sufficiently typify the species characteristics of medicinal products in circulation.
An example can be the rule of letter "c" of item 4331 of Article 20 (Chapter 9, Section 2) of the Business and Professions Code of the State of California [17], USA on violations of the rules of retail sale of veterinary food-animal drug: “A person licensed as a veterinary food-animal drug retailer that fails to place in charge of that veterinary food-animal drug retailer a pharmacist or designated representative, or any person who, by himself or herself, or by any other person, permits the dispensing of prescriptions, except by a pharmacist or designated representative, or as otherwise provided in this chapter, is guilty of a misdemeanour” [18].
Art. 202 of the Republic of Uzbekistan Criminal Code [19] "Violation of the order of use of animal or plant life" establishes responsibility for "violation of the rules ... of collecting or harvesting wild plant species of medicinal ... plants" [20]. Art. 270 of the Brazil Civil Code provides punishment for the poisoning of drinking water, both for public and personal use, food products or medicinal products intended for consumption [2]. In Art. 278 of the Brazilian Civil Code punishes the manufacture, sale, offering for sale, storage for sale or transfer in any way for use of substances harmful to health, even if they are not intended for food or medical purposes;
3) distinguishes subjects of pharmaceutical activity when determining actions that can be committed by any person regardless of his/her "belonging" to such a subject.
Thus, part 2 Art. 187 of the Turkish Criminal Code provides punishment for the production and sale of narcotic drugs, creating a danger to people’s lives and health, if these actions are carried out by a doctor or pharmacist [5]. Another example of an atypical approach is the norms of part 3 Art. 190 of the Turkish Criminal Code, which establishes punishment for the assistance of medical and pharmaceutical employees in the use of narcotic drugs or stimulants by persons (such assistance is carried out by: providing a special place, equipment or materials; applying measures that make it difficult to be detained).
The approach of the Swiss legislator provides punishment for doctors, dentists, chiropractors, pharmacists, midwives, psychologists and their assistants for disclosing a secret that was entrusted to them in connection with their profession or that they became aware of in the course of their professional activities on requirement (S 1 Art. 321 of the Swiss Criminal Code) [6]. Based on this rule, punishment also applies to students disclosing a secret they learned about during their studies. In addition, violation of professional secrecy is punishable even after the end of professional practice or training.
In Art. 268 of the Brazil Criminal Code establishes a penalty for violating the regulations of state authorities to prevent the emergence or spread of infectious diseases (and this article does not specify the characteristics of a person who commits such a violation). At the same time, the punishment is increased by one third if the person who committed the specified violation is an employee of a health care facility, a doctor, pharmacist, dentist or nurse. At the same time in Art. 269 of the Criminal Code of Brazil establishes a penalty of imprisonment from six months to two years and a fine for failure to notify a doctor of an illness by a state body

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when such notification is mandatory.

The Criminal Code of Ukraine also has an atypical approach. Thus, in the criminal offenses provided for by Art. 306, 307, 309, 310, 311, 313, 314, 316, 317, 318, 319, 321, 322 of the Criminal Code of Ukraine the sign of an act is its "illegality" (the concept of "illegal" is directly established in the norms of these articles of the Special Part of the Criminal Code of Ukraine) [21], it is important to note that the atypicality of the approach, when in the disposition of Art. 145 of the Criminal Code of Ukraine "Illegal disclosure of confidential medical information" does not contain the concept of illegality, but the title of this article indicates "illegal" disclosure of a medical information (by the way, the indication of illegality is found in the title of Article 142 "Illegal experimentation on a human being" and disposition of part 1: "illegal performance of ... experiments"). Since the title of the article of the Special Part of the Criminal Code of Ukraine is not a component of the disposition of the criminal law norm that determines the signs of the elements of a criminal offense, the absence of the disposition of Art. 145 of the Criminal Code of Ukraine, the sign "illegal" should be considered as a certain legislative defect.

Approach in determining the signs of the type of criminal offense provided for in Art. 145 of the Criminal Code of the Republic of Tajikistan "Disclosure of medical secrets" can also be defined as atypical. In part 1 of this article, the content of the disclosure of a medical secret is specified through "disclosure by a medical, pharmaceutical or other employee without professional or official necessity of information about a disease or medical examination of a patient". After all, not only a doctor as a medical employee, but also a pharmaceutical employee is recognized as the bearer of the medicinal secret. Obviously, such an atypical approach has certain disadvantages, the main of which are: 1) the Criminal Code of the Republic of Tajikistan distinguishes between the concepts of "medical activity" and "pharmaceutical activity" (Art. 210), and therefore the mandatory elements of medical and pharmaceutical activity are different (first of all, their subjects are different persons). A pharmaceutical employee cannot carry out activities that are medical, and vice versa. Therefore, the "mixing" of elements of medical and pharmaceutical activity in the criminal legislation indicates an atypical approach of the legislator in determining the type of criminal offense; 2) secondly, in Part 1 of Art. 145 of the Criminal Code of the Republic of Tajikistan indicates that the disclosure of medical secrets occurs in the absence of "professional or official necessity". The concept of such "necessity" is not disclosed in this article of the Criminal Code, which "makes" it evaluative and requires the need to establish each time those factual circumstances that exist outside the professional or official activities of such employees and form the factual and legal meaning of such "necessity" (the factual is connected with the appropriate set of actually existing factual circumstances of the committed – legal facts, and the legal - with the exercise by these employees of the powers they are given by virtue of their professional or official position);

4) singles out persons who cannot be considered subjects of pharmaceutical activity, while characterizing actions that may be committed, including by these subjects.
   For example, in Art. 331 of the Penal Code of Estonia establishes responsibility for such a "fragment" of the illegal circulation of medicinal products in the broadest sense, as manufacture, acquisition, possession or use without a doctor's prescription of narcotic drugs and psychotropic substances (that is, in the case when within the scope of the specified circulation we are talking about narcotic medicinal products and psychotropic medicinal substances) by a person who is imprisoned, arrested or taken into custody [22];
5) defines actions that are quite specific in terms of their "medical nature", which are not the most common acts of foreign criminal legislation.
   Thus, Art. 136 "Creating a danger to human life and health" of the Criminal Code of Georgia [23] provides for such a crime as genetic manipulation - that is, the creation of a creature similar to a person [12]. Art. 135 establishes criminal responsibility for the illegal trade of blood or its components. In Art. 144 of the Criminal Code of Ukraine provides for criminal responsibility for forcibly or fraudulently extracting blood from a person for the purpose of using it as a donor.
   Another example is the actions defined in Art. 283, 284 of the Criminal Code of Brazil. In Art. 283 of this Criminal Code establishes a punishment for suggesting or announcing a cure from an illness by secret or infallible means. In Art. 284 of the Criminal Code of Brazil provides punishment for folk healing treatment: a) related to the appointment, administration or routine use of any substance; b) by making certain gestures, expressions or any other means; c) by making a diagnosis;
6) singles out the peculiarities of the packaging methods and the results of the packaging of medicinal products as independent signs of criminal offences related to the falsification of medicinal products.
   For example, Art. 275 of the Brazil Criminal Code punishes the use of a wrapper or container with a false indication, including a wrapper or container of food, therapeutic or medicinal products, when the substance indicated on them is not contained inside or is contained in a smaller amount than indicated on them;
7) separates the properties of falsified medicinal products from medicinal products marked with means of individualization or identification.
   Thus, according to S 6811 of Art. 137 of the Education Law of the State of New York, USA any person who uses a forgery, imitation, simulation, or falsely repre-

sentation or without proper authority uses any mark, stamp, tag, label or other identification device authorized or required by rules and regulations, commits a misdemeanour. In the same S 6811 of Art. 137 of the Education Law of the State of New York provides that any person who, for the purpose of counterfeiting, imitating, or misrepresenting medicinal products or medical devices or cosmetics, or in the absence of the necessary authority in relation, shall use in doing so any mark, stamp, a tag, label or other means of identification is committed by a misdemeanour;

8) provides for types of criminal offences related to corruption in the field of health care.

Thus, in S 299a of the Criminal Code of the Federal Republic of Germany "Accepting a bribe in the field of health care" establishes a penalty for a person who, being a representative of the medical profession in connection with the performance of his professional activity require a benefit for himself or a third person, receives a corresponding promise or this benefit as a counter-obligation for the fact that he unfairly favors another person in the conditions of national or international competition: 1) when prescribing medicinal products, healing or auxiliary substances or medical devices; 2) when purchasing medicinal products, healing or auxiliary substances or medical devices, respectively, intended for direct use by a representative of the medical profession or his professional assistant, or 3) when referring patients or material for medical research [10].

Therefore, atypical types of criminal offenses in acts of foreign criminal legislation reflect the specific "exclusivity" (from general legislative norms-rules) of the content of encroachment on pharmaceutical activity as an independent object of criminal law protection and express the "impairment" of pharmaceutical activity, manifested in the occurrence corresponding damage to it, and are also related to the specifics of the content of legal constructions that determine the corresponding types of criminal offenses.

IV. Conclusion

We think that the detection of atypical types of criminal offences encroaching on pharmaceutical activity does not mean errors of legal technique in acts of foreign criminal legislation, but is carried out on the basis of the norms of regulatory (blanket) legislation in the field of pharmaceutical activity. We believe that the detection of atypical types of criminal offenses and their systematization are related to the possibility of identifying the "impairment" of certain fragments of pharmaceutical activity (its mechanism) and can be generally presented as: a) medicinal products as an object, handling which ensures the circulation of specific, individually determined medicinal products; b) the specificity of the order of circulation of such individually determined medicinal products; c) the economic (commercial) nature of the interests of subjects of pharmaceutical activity, the implementation of which ensures (should ensure) the circulation of medicinal products; d) the economic (commercial) nature of the activities of the subjects of pharmaceutical activity, which affects the receipt of income within the limits of the circulation of medicinal products.

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