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ORIGINAL ARTICLE

CONTENTS

Problems of harmonization of the criminal legislation of the certain continental law countries to ensure the protection of the circulation of medicinal products

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ABSTRACT

Aim: To find out the problems of the harmonization of the criminal legislation of the certain continental law countries to ensure the protection of the circulation of medicinal products.

Materials and Methods: This study is based on the analysis of the international legal acts, in particular, the Directives of the EU, as well as Medicrime Convention, national acts of criminal legislation of the certain continental law countries (Germany, Austria, Switzerland, Ukraine, etc.), national judicial practice, data on the number of criminal proceedings in the courts of Ukraine, criminal and medical law legal doctrine (38 normative legal acts and 15 court judgments), data of the Office of the Prosecutor General of Ukraine. Dialectical, hermeneutic, comparative, analytical, synthetic and system analysis research methods were used.

Results: The problems of harmonizing the criminal legislation of the certain continental law countries to ensure the protection of the circulation of medicinal products depend on: a) the level of legal regulation of the field of health care at the national level; b) availability of effective mechanisms for implementing the provisions of international and regional standards.

Conclusions: The formation of a model of criminal law protection of the circulation of medicinal products in continental law countries depends on harmonization with the basic international legal and regional standards and their implementation at the national level.

KEY WORDS: circulation, medicinal products, pharmaceutical activity, international standards, harmonization

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INTRODUCTION

The growth of global demand for medicinal products necessitates the existence of effective mechanisms for the protection of relations with the circulation of medicinal products. The circulation of medicinal products is an important element of the health care system both at the international and national levels. Medicinal products must meet the criteria of safety and effectiveness, there must be proper guarantees of the quality of such products, because they are primarily aimed at preserving human life and health.

The pharmaceutical markets of continental European countries have strict legal regulation. It is important to have effective norms of the criminal legislation, which ensure the protection of the circulation of medicinal products at the national level. In the vast majority of these norms have a blanket character. Not only the current international and regional regulatory legislation in the field of circulation of medicinal products, but also the blanket criminal law norms undergo periodic fundamental changes. The reason for this lies primarily in the change in the requirements of international and regional legal acts related to pharmaceutical activity, as well as in the fulfillment of those international obligations assumed by the participating countries of these international legal acts.

AIM

The aim of the article is to find out the problems of the harmonization of the criminal legislation of the certain continental law countries to ensure the protection of the circulation of medicinal products.

MATERIALS AND METHODS

This article is based on the analysis of the international legal acts, in particular, the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as well as Medicrime Convention, national acts of criminal legislation of continental law countries (Germany, Austria, Switzerland, Ukraine, etc.), national judicial practice, statistics on the number of criminal proceedings in the courts of Ukraine, criminal and medical law legal doctrine (51 normative legal acts and 15 court judgments), statistical data of the Office of the Prosecutor General of Ukraine. Dialectical, hermeneutic, comparative, analytical, synthetic and system analysis research methods were used.

RESULTS

It is proposed to consider the specifics of the harmonization of the criminal legislation of the certain continental law countries to ensure the protection of the circulation of medicinal products and the problem of its implementation with reference to the regulatory acts of the EU and international Conventions. Such legal guidelines establish the basis of harmonization and implementation of relevant norms in national legislation. Among them stand out: Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (hereinafter – Directive 2001/83/EC) [1] and Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (CETS No. 211) (hereinafter – Medicrime Convention) [2], etc. Determining the specifics of the criminal law protection of the circulation of medicinal products of the certain continental law countries, we will single out the specifics of restrictions on the use of medicinal products, which are established at the legal level.

The problems of harmonizing the criminal legislation of the certain continental law countries to ensure the protection of the circulation of medicinal products depend on: a) the level of legal regulation of the field of health care at the national level; b) availability of effective mechanisms for implementing the provisions of international and regional standards. The model to follow here is additional acts of criminal legislation of such European countries as: a) German (Medicinal Products Act of 12 December 2005 [3]), b) Austria (Federal Law of Austria on the Manufacturing and Circulation of Medicinal Products of 02 March 1983) [4]), c) Switzerland (Federal Act of Switzerland on Medicinal Products and Medical Devices (of 15 December 2000) [5], d) France (French Public Health Code [6] and additional acts that regulate the criminal law protection of the circulation of medicinal products).

The pharmaceutical legislation of the certain continental law countries should be based on the norms of EU directives and regulations. However, the implementation of these norms is often a problem in legal regulation at the national level. Let us consider the example of Ukraine, which in 2014 signed the Association Agreement between the European Union and its Member States, of the one part, and Ukraine, of the other part. Harmonizing the Medicrime Convention with national legislation, Ukraine has amended the Criminal Code of with Article 321-1 "Falsification of medicinal products or circulation of falsified medicinal products". In this regard, a statistical analysis of the indicators of how the criminalization of such an act as falsification of medicinal products or circulation of falsified medicinal products in the framework of harmonization with European standards affected the implementation of law in Ukraine was carried out (Table 1).

The analysis of the collected statistical data gives reason to say that for the period from 2019 to the first half of 2024, 123 criminal offenses defined in Art. 321-1 of the Criminal Code of Ukraine were registered, of which only 9 were sent to court with an indictment. That is, only 7.3% of criminal proceedings are sent to court with an indictment. As a result, despite the criminalization of the act provided for in Art. 321-1 of the Criminal Code of Ukraine, which took place as a result of the harmonization of Ukrainian legislation with international standards, there are already problems at the national level, which consist, among other things, in the degree of severity of criminal punishment and its actual application. This is confirmed by the processed statistical data of Supreme Court in Ukraine regarding the number of persons convicted of criminal offenses under Art. 321-1 of the Criminal Code of Ukraine (Fig. 1).

Statistically the number of such persons is extremely small (4 in 2019, 3 in 2020, and 1 each in 2022 and 2023. In 2021, not a single person in Ukraine was convicted of the crime provided for in Art. 321-1 of the Criminal Code of Ukraine).

One of the directions of harmonization in Ukraine is the criminalization of acts related to the circulation of medicinal products for veterinary use (in the sense of this concept formulated in the Medicrime Convention). At the national level, the Law of Ukraine "On Veterinary Medicine" [7] of 4 February 2021 does not contain the concept of "Veterinary medicinal products" (the concept of "Veterinary product" is used instead). According to item 15 p. 1 Art. 1 of this Law, a veterinary medicinal product is "any substance or combination of substances with the declared

Table 1. General information on the number of registered criminal offenses and the results of their pre-trial investigation under Article 321-1 of the Criminal Code of Ukraine "Falsification of medicinal products or circulation of falsified medicinal products"

Year	The number of criminal offenses in the reporting period	Criminal offenses in which persons have been served with a notice of suspicion	Criminal offenses for which proceedings have been sent to court	Including with the indictment	Criminal offenses in which proceedings have been closed	Criminal offenses in which a decision has not been made at the end of the reporting period (on termination or suspension)
2019	29	2	0	2	6	27
2020	22	3	2	2	8	19
2021	21	2	0	2	2	21
2022	17	0	0	0	5	17
2023	26	5	2	2	2	24
January-August 2024	8	1	1	1	0	7

property of treating or preventing *animal* diseases…" [8]. In the current Law of Ukraine "On Medicinal Products" of 4 April 1996 [9] and the Law "On Medicinal Products" of 28 July 2022 [10], which has not yet been implemented, the meaning of the concept of "medicinal products" and the concept of "circulation of medicinal products" associated with the appointment of medicinal products to ensure the corresponding functions in the *human* body. This raises the question of the need for criminal protection of medicinal products for veterinary use and their circulation. The current Ukrainian regulatory legislation on pharmaceutical activity does not include such a component as medicinal products for veterinary use and their circulation, since medicinal products for veterinary use are not able to ensure the appropriate "state" of individual and public health of a person, as required by the Law of Ukraine "Fundamentals of the Legislation of Ukraine on health care" of 19 November 1992 [11].

However, if we take into account the international legal standards of the Medicrime Convention regarding the equal legal "regime" of medicinal products for "*human and veterinary use*" (p. "b" of Art. 4), then the regime of criminal legal protection of medicinal products for veterinary use (veterinary medicinal products) and their circulation should not differ from the "regime" of criminal legal protection of medicinal products and their circulation in the sense of item 2 p. 1 Art. 2 of the Law of Ukraine "On Medicinal Products" of 4 April 1996 and item 39 p. 1 of Art. 2 of the Law of Ukraine "On Medicinal Products" of 28 July 2022. Ensuring such compliance with the stated standards of the Medicrime Convention requires the introduction of appropriate changes to the current Ukrainian regulatory legislation in the field of circulation of medicinal products [8].

Another problem for Ukraine is the definition in Chapter II "Substantive criminal law" of the Medicrime Convention of standards regarding the types of criminal offenses related to the counterfeiting of medical products and similar crimes that threaten health care. According to the Art. 5 of the Medicrime Convention, the standard for national legislation is the adoption of the first type of criminal offense: 1) intentional manufacturing of counterfeit medical products, active substances, excipients, parts, materials and accessories (p. 1); 2) any falsification of medicinal products and, as appropriate, medical devices, active substances and excipients (p. 2). According to p. 3 of Art. 5 of this Convention: «Each State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply, or to apply only in specific cases or conditions, paragraph 1, as regards excipients, parts and materials, and paragraph 2, as regards excipients» [2]. However, the Law of Ukraine "On the Ratification of the Convention of the Council of Europe on the counterfeiting of medical products and similar crimes involving threats to public health" of 7 June 2012 [12] does not contain any reservations regarding the application and implementation in national legislation of the norms of p. 1, 2 Art. 5 of the Medicrime Convention [13]. This means that the current Ukrainian criminal legislation must meet the requirements of paragraphs 1, 2 Art. 5 of the Medicrime Convention. Countries that have ratified the Medicrime Convention and harmonized their legislation are defined in Figure 2.

DISCUSSION

The effort to create a common market for medicinal products of continental law countries led to the emergence of a unique system of pharmacy regulation. The uniqueness of this system is that it has developed a single EU market for medicinal products through a

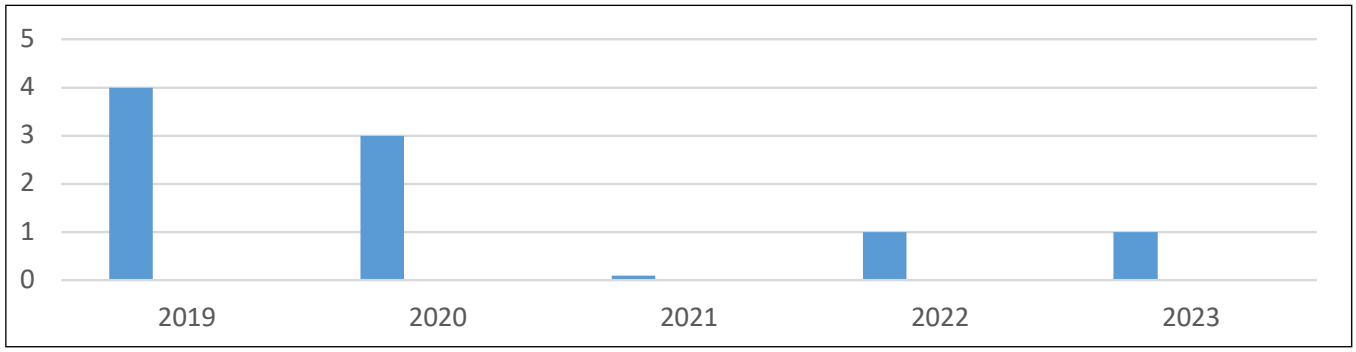

Fig. 1. The number of persons convicted of criminal offenses provided for in Art. 321-1 of Criminal Code of Ukraine «Falsification of medical products or circulation of falsified medical products».

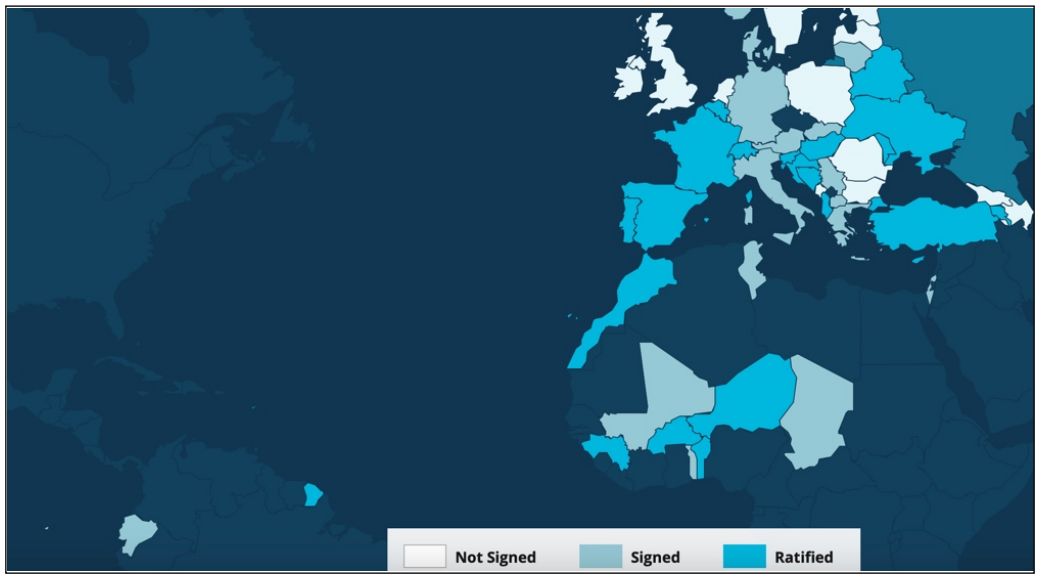

Fig. 2. Countries that have ratified the Medicrime Convention and harmonized their legislation [14].

standardized system of legislation and a harmonized system of procedures for the manufacture and circulation of medicinal products.

Today, the EU regulates pharmaceutical activity between member states and establishes standards that ensure a high level of public health protection and the quality, safety and effectiveness of medicinal products, and member states implement these norms into their national legislation in order to develop their own internal market, and as well as the promotion of innovation [15].

Acts of the main and additional legislation of Switzerland, Germany and Austria provide the largest amount of criminal protection of pharmaceutical activity. Its "blocks" can be certain legislative guidelines for the improvement of the criminal legislation of Ukraine and the construction of its own model system of norms that provide criminal legal protection of pharmaceutical activity [8].

Harmonizing the sphere of circulation of medicinal products to European standards, Ukraine used the main norms of international legal acts as sources of "secondary EU law" preparing the draft of Law of Ukraine "On medicinal products", which was adopted as a law on July 28, 2022. Including those, attention is focused on the norms regarding the features of legal protection of the circulation of medicinal products. After all, at the time of the preparation of this draft law and its adoption, there was "a need ... to review the principles of regulation in the field of circulation of medicinal products, to increase the level of quality, efficiency and safety of medicinal products, as well as their availability" [16]. The harmonization of norms of EU regional standards had a direct impact on provision, including criminal law protection of relevant fragments of pharmaceutical activity.

The scientific discussion is largely focused on the issue of incomplete fulfillment by Ukraine of international legal obligations undertaken during the implementation of harmonization measures [17], in particular after the ratification of the Medicrime Convention [13, 18, 19]. Improving the criminal law mechanism to combat the falsification of medical products at the European regional level requires intensifying of The Medicrime Convention ratification process and full implementation of rules on criminal liability for falsifying medical products into national criminal legislation [20].

CONCLUSIONS

1. In order to properly ensure the criminal legal protection of the circulation of medicinal products, it is necessary to establish which negative, unfavorable actions committed by people are so dangerous for society that the legislator can recognize them as criminal offenses, as well as to determine the punishment that may be appointed by the court on behalf of the state for committing such acts. In the certain continental law countries, such determinations are made on the basis of norms of criminal legislation.
2. The formation of a model of criminal law protection of the circulation of medicinal products in continental law countries depends on harmonization with the basic international legal and regional standards and their implementation at the national level. Such standards determine the main components of the circulation of medicinal products and the connection of such components with the mechanism of state regulation. Moreover, some of the elements of such a mechanism are distinguished as independent and operate under the appropriate legal regime (for example, the "pharmacovigilance system", which is used to collect information about the risks of medicinal products for the health of patients or the population).
3. The term "falsification" in the sense of the Medicrime Convention is used in the official text of this Convention in p. 2 of Art. 5 "Manufacturing counterfeits", when it comes to the need to recognize as a criminal offense the falsification of medicinal products, medical devices, active substances and excipients. Taking into account that in the content of p. 2 of Art. 5 of the Medicrime Convention refers to the "manufacturing of counterfeit medical products, active substances, excipients, parts, materials and accessories", then at the level of the Medicrime Convention, the concepts of "falsification" and "manufacturing of counterfeits" should cover the same actions. This approach of the Medicrime Convention should be taken into account as an international legal reference for the further correlation of the mentioned concepts, which are used in the content of the compositions of specific types of criminal offenses provided for by the Criminal Code of Ukraine.

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CONFLICT OF INTEREST
The Authors declare no conflict of interest

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