



# International Legal Standards for the Harmonization of the Criminal Legislation of Ukraine and the Eu and its Implementation to Ensure the Protection of the Pharmaceutical Activity

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**Abstract: Background:** When harmonizing the criminal legislation of Ukraine and the EU and implementing it into the criminal legislation of Ukraine, international legal guidelines (standards) must be taken into account. **Aim & Objectives:** To investigate international legal standards of harmonization of the criminal legislation of Ukraine and the EU and its implementation to ensure the protection of the pharmaceutical activity. **Methodology: Materials:** Legislation of Ukraine, European Union, Directives, developed by the European Parliament and the Council of the European Union, recommendations represented by international voluntary group and scientific works. **Methods.** This article is based on dialectical, comparative, hermeneutic, analytical, synthetic and comprehensive research methods. **Results:** The construction of a "national model" of criminal-legal protection of pharmaceutical activity should take into account the main international legal standards and be carried out according to the rule: criminal-legal norms should ensure the protection of all types of social values, the violation of which can cause at least minimal damage to public health and the principles of its protection within and outside the circulation of medicinal products. But not selectivity. From the meaning of the Ukrainian "model", some fragments of the circulation of medicinal products fall out (creation, pharmaceutical development, research (testing), advertising and promotion of medicinal products; veterinary medicinal products do not find their criminal legal protection at all, as there are not medicinal products), as well as the existence of criminal law protection of state regulation of pharmaceutical activity is fragmentary. **Conclusions:** The procedure of harmonization of national criminal legislation with international standards should include norms according to which the prescription of medicinal products is carried out objectively, without the influence of direct and indirect financial incentives; free samples of medicines are provided subject to public restrictions and only for familiarization with new medicines, gaining experience in their use; free access to independent and objective sources of information about medicinal products presented on the market is ensured etc.

**Key Words:** Pharmaceutical activity, Pharmacia, harmonization, implementation, criminal law protection, Medicrime Convention, medicinal products, falsification, counterfeiting, veterinary medicinal products

## I. INTRODUCTION

The procedure of harmonization of national criminal legislation with international standards is usually complex and long-lasting. It must be taken into account international legal guidelines (standards). In the pharmaceutical industry attention is focused not only on regulatory legislation, but also on criminal-legal norms-prohibitions that provide criminal-

legal protection of pharmaceutical activity. The basic international legal standards of the EU for ensuring criminal protection of the circulation of medicinal products at the national legislative level are 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 [1], (it brings together all the existing provisions

in force on the sale, manufacturing, labelling, classification, distribution and advertising of medicinal products for human use in the EU [2]), Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products [3] (it establishes the principle of liability without fault applicable to European producers. Where a defective product causes damage to a consumer, the producer may be liable even without negligence or fault on their part [4]), as well as Medicrime Convention [5], (the first international criminal law instrument to oblige States Parties to criminalise: the manufacturing of counterfeit medical products; supplying, offering to supply and trafficking in counterfeit medical products; the falsification of documents; the unauthorised manufacturing or supplying of medicinal products and the placing on the market of medical devices which do not comply with conformity requirements [6]). Depending on the requirements of these standards, it is necessary to build a "national model" of criminal law protection.

## II. MATERIALS AND METHODS

### A. MATERIALS

Legislation of Ukraine, European Union, Directives, developed by the European Parliament and the Council of the EU, recommendations represented by international voluntary group and scientific works.

### B. METHODS

This article is based on dialectical, hermeneutic, comparative, analytical, synthetic and comprehensive research methods. The use of these methods was helped by comparing and analysing the international legal guidelines that affect the provision of criminal legal protection of pharmaceutical activity with the current norms of Ukrainian criminal legislation, which provide the appropriate (real, not declared at the international legal level) scope of criminal legal protection of pharmaceutical activity.

## III. DISCUSSION

Harmonizing the national criminal legislation of Ukraine to the international legal standards, the following manifestations of "affectedness" of pharmaceutical activity can be identified:

- 1) Violation of the rights, freedoms and interests of subjects of pharmaceutical activity both in the sphere of circulation of medicinal products and outside this sphere. To prevent such violations, international legal standards provide for the use of various "legal safeguards": permits related to the licensing of relevant types of activities; standards of quality and safety of the corresponding pharmaceutical products that are put into circulation and are in circulation; standards for recognizing certain items as counterfeit (falsified) and preventing their circulation; "parameters" of clinical trials; protection of personal data in the field of use of medicinal products, etc.

Correlating the "model" of pharmaceutical activity both in the sphere of circulation of medicinal products and outside this sphere, formed at the international legal and national (Ukrainian) level, it is quite obvious that the scope of the international legal "model" is wider. For example, the concept of medicinal products in the international legal model includes veterinary medicinal products [7], but not in Ukraine; therefore, the concept of circulation of medicinal products covers what is "out of its content" in the national "model" of such circulation. An illustration is the advertisement of medicinal products [8], [9], as it is directly related to the public health protection and, accordingly, the safety of pharmaceutical products, but is not singled out in those norms of the Criminal Code of Ukraine [10] that provide legal protection of the circulation of medicinal products.

Another example. The Ukrainian "model" includes only separate fragments of violation of individual and public health protection, and this is its significant drawback. However, as part of the harmonization of Ukrainian legislation to EU standards [11], during the preparation of the draft of the new Criminal Code of Ukraine, the members of the Working Group for the preparation of this draft refused to use the concepts of "licensing", "license" when defining "activity in the field of health care" and used the concept from the international practice of standard-setting - "proper permission" (Article 5.1.7 of Section 5.1 of the draft of Criminal Code of Ukraine [12]), which is larger in scope than the concept of "licensing". However, this approach, in principle, will eliminate only some defects in the criminal law protection of pharmaceutical activity, in particular, within the limits of circulation of medicinal products, since the vast majority of types of pharmaceutical activity outside the limits of circulation of medicinal products do not require licensing. Therefore, the conclusion of N. Gutorova (as a member of the said Working Group) that "a gap in the criminal law protection of relations in the field of pharmaceutical activity is the absence of a norm that would provide for responsibility for illegal pharmaceutical activity" is fully justified [13]. However, it is still not worth it to limit the ways of eliminating this gap solely due to the "introduction" of the sign "improper authorization" into the content of the elements of the corresponding types of criminal offenses. In this regard, N. Gutorova correctly observes that the danger of illegal pharmaceutical activity lies primarily in the fact that "for a significant number of medicinal products, violation of the temperature and other conditions of their storage and transportation leads to their unusability, loss of medicinal properties, and, in some cases, danger to life and health. Therefore, along with the establishment of responsibility for illegal medicinal activity, there should be such responsibility for illegal pharmaceutical

activity as well" [13]. So, the danger of illegal pharmaceutical activity may be caused by violations of the relevant "permits", but may also not be associated with such violations. However, in this case, another question arises – can the violation of specific "permits" in the field of pharmaceutical activity be considered as illegal pharmaceutical activity?

On the other hand, a positive point should be noted. The economic interests of the subjects of state regulation, which are within the limits of the state economic policy of ensuring the pharmaceutical market [14], are nevertheless taken under criminal law protection (primarily within the Article 321-1 of the Criminal Code of Ukraine "Falsification of medicinal products or circulation of falsified medicinal products" [15], [16]). After all, the economic interests of the subjects of state regulation are capable of suffering certain damage [17], since they are a mandatory element of state policy in the field of creation, manufacture, quality control and sale of medicinal products and ensure the functioning of the pharmaceutical market in Ukraine, even despite the fragmented legal provision activities of subjects of state economic policy on the pharmaceutical market [18]. Moreover, the "competition of economic interests" of business entities engaged in pharmaceutical activities, on the one hand, and the relevant entities of state regulation, on the other, is not excluded, because recently there has been a steady trend of monopolization of certain "sections" of the pharmaceutical market, in which an independent place is given to "national mega-networks" [19], [20].

- 2) Violation of relations between subjects of pharmaceutical activity, which are related to their exercise of powers (professional powers) in the field of pharmaceutical activity (including state regulation of pharmaceutical activity). The presence of such powers determines a kind of "legal personality" [21], with a help of which the specified subjects are recognized as a mandatory element of the international legal "model" of legal relations in the field of pharmaceutical activity or, generally speaking, the "model" of pharmaceutical activity. In contrast to the Ukrainian "model" of pharmaceutical activity, the analysed international legal standards provide for equality (dispositivity) of the rights, freedoms and interests of subjects of pharmaceutical activity, as well as the connections between them (for example, "making of false documents or the act of tampering with documents" [22]). After all, the international legal standards of pharmaceutical activity do not provide for the allocation within the "model" of pharmaceutical activity of such an independent element as state regulation of pharmaceutical activity.

#### IV. RESULTS

Ensuring the harmonization of the criminal legislation of Ukraine with international standards and the implementation

of EU legislation into the criminal legislation of Ukraine requires an increase in the Ukrainian "model" of the scope of criminal legal protection of pharmaceutical activity both in the sphere of circulation of medicinal products and outside this sphere at least "to the level" proposed by international legal standards. Moreover, this should be done despite the existing differences in the components of the legal mechanism for regulating pharmaceutical activity at the international legal and national levels.

The construction of a "national model" of criminal-legal protection of pharmaceutical activity must take into account the main international legal standards and be carried out according to the rule: criminal-legal norms must ensure the protection of all types of social values, the "damage" (violation) of which can cause at least minimal damage to the public health and the principles of its protection both in the sphere of circulation of medicinal products and outside this sphere. And not selectivity, as it is now. From the meaning of the Ukrainian "model", some fragments of the circulation of medicinal products fall out (creation, pharmaceutical development, research (testing), advertising and promotion of medicinal products; veterinary medicinal products do not find their criminal legal protection at all, as there are not medicinal products), as well as the existence of criminal law protection of state regulation of pharmaceutical activity is fragmentary.

The Ukrainian "model" provides for the advantage of criminal law protection of the interests of the state regulation of pharmaceutical activity compared to the interests (primarily economic) of other subjects (pharmacies, distributors, manufacturers of medicinal products). We are talking about subjects of pharmaceutical activity that are related to receiving income from the circulation of medicinal products. As part of the harmonization of national Ukrainian legislation with international standards, it is proposed to establish the norm that prescribing medicinal products is carried out objectively, without the influence of direct and indirect financial incentives; free samples of medicinal products are provided subject to public restrictions and only for familiarization with new drugs, gaining experience in their use; free access to independent and objective sources of information about medicinal products presented on the market is ensured.

The presence of such an element as state regulation is an essential feature of the Ukrainian model of pharmaceutical activity (since its mandatory subject is the state, which primarily uses imperative methods of pharmaceutical activity regulation). This affects criminal law enforcement. Despite the imperative nature of state regulation and its "detachment" from economic (commercial) interests in the field of pharmaceutical activity, the main international legal standards directly provide for the need for criminal protection of certain components of such state regulation, namely: state registration, licensing, patenting procedures, supervision (including the quality and safety of pharmaceutical products), state regulation of types of pharmaceutical activity, protection of personal data during application and use of individual phar-

maceutical products, as well as protection of pharmaceutical products by individual objects of intellectual property rights.

Let's consider the procedure of harmonization and implementation in the national criminal legislation using some examples.

The Medicrime Convention defines standards regarding the types of criminal offenses related to the counterfeiting of medical products and similar crimes that threaten health care. According to the Article 5 of this Convention, the international legal standard for national legislation is the recognition as a type of criminal offense: 1) "intentional manufacturing of counterfeit medical products, active substances, excipients, parts, materials and accessories" (paragraph 1); 2) any falsification of "medicinal products and, if necessary, medical devices, active substances and excipients" (paragraph 2).

Here, falsification applies only to certain types and varieties of medical products, which are defined in paragraph 2 of Article 5 of the Medicrime Convention, namely: "medicinal products and ... medical devices, active substances and excipients". At the same time, the meaning of the concept of "manufacturing of fake/production of counterfeit" in terms of its "subjects" (but not in terms of actions committed in relation to such "subjects") is different. In paragraph 1 of Article 5 of the Medicrime Convention refers to the "manufacturing of counterfeit medical products, active substances, excipients, parts, materials and accessories", and in point "j" of Article 4 of this Convention, "counterfeit" means only an act regardless of the "subject": "false representation as regards identity and/or source". In view of this, according to the Medicrime Convention, falsification can be considered manufacture of counterfeit only when any intentional manufacture of counterfeit items related to medical products misleads as to authenticity and (or) source.

This approach of the Medicrime Convention should be taken into account as an international legal reference for the correlation of the mentioned concepts, which are used in the content of the elements of specific types of criminal offenses provided for by the Criminal Code of Ukraine.

It is important that according to Article 6 ("Supplying, offering to supply, and trafficking in counterfeits") of the Medicrime Convention, national criminal legislation should provide for such types of criminal offenses as: "the supplying or the offering to supply, including brokering, the trafficking, including keeping in stock, importing and exporting of counterfeit medical products, active substances, excipients, parts, materials and accessories" (paragraph 1). Since, according to paragraph 2 of this article of the Medicrime Convention, the state has "the right not to apply, or to apply only in specific cases or conditions, paragraph 1, as regards excipients, parts and materials", it is worth paying attention to the absence of such reservations upon ratification of the Medicrime Convention by the criminal legislation of Ukraine. This means that the state undertook to provide for such a "conventional" type of criminal offense as intentional supply, offer to supply and trade counterfeit medical products, active substances, excipients, parts, materials and accessories (on the basis of

paragraph 1 Article 6 of Medicrime Convention).

When comparing the types of "similar crimes" defined in Article 8 of the Medicrime Convention, and the types of criminal offenses defined in Articles 5-7 of Medicrime Convention we come to such an opinion that: a) defined in letter "a" paragraph 1 of Article 8 "manufacturing" (its subject is medicinal products and medical devices) is a special type of "manufacturing" specified in paragraph 1 of Article 5 of the Convention and the subject of which is "counterfeit medical products, active substances, excipients, parts, materials and accessories", as well as specified in paragraph 2 of Article 5 medicinal products, medical devices, active substances, excipients, parts, materials; b) stipulated in letter "a" paragraph 1 of Article 8 "the keeping in stock for supply, importing, exporting, supplying, offering to supply or placing on the market" (their subject is medical products and medical devices) is a special type of action as defined in paragraph 1 of Article 6 "supplying or the offering to supply, including brokering, the trafficking, including keeping in stock, importing and exporting (the subject of these actions is "counterfeit medical products, active substances, excipients, parts, materials and accessories"); c) an independent type of action, which is defined in letter "a" paragraph 1 of Article 8 and does not constitute a special type of "manufacturing" (paragraph 1 of Article 5 of the Medicrime Convention), it is "placing on the market" medicinal products and medical devices; d) provided for in letter "b" paragraph 1 of Article 8 "commercial use of original documents" is an independent type of action, since in this paragraph of Article 8 of the Medicrime Convention contains a special reference to "... outside their intended use". Therefore, "commercial use of original documents" does not constitute a special type of the provision provided for in paragraph 1 of Article 7 "the making of false documents or the act of tampering with documents".

Another example, which requires the procedure of harmonization of the criminal legislation of Ukraine with international standards and the implementation of EU legislation into the criminal legislation of Ukraine, is the provision of full-fledged criminal legal protection of the circulation of falsified veterinary medicinal products.

According to the current Ukrainian legislation, medicinal products for veterinary use and their circulation are not an integral component of the circulation of medicinal products and pharmaceutical activity as an object of criminal law protection. In the current Law "On Medicinal Products" dated April 4, 1996 and the Law "On Medicinal Products" dated July 28, 2022 (the last one has not yet been implemented), the meaning of the concept of "medicinal products" and the concept of "circulation of medicinal products" is linked with the appointment of medicinal products to ensure the corresponding functions in the human body.

It should be noted that the current Ukrainian regulatory legislation on pharmaceutical activity does not include such a component as medicinal products for veterinary use and their circulation (even in the content of those components of

pharmaceutical activity that "are" outside the sphere of the circulation of medicinal products and/or within the limits of state regulation of pharmaceutical activity), 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 national legislation in the field of health care.

After all, according to the current regulatory legislation of Ukraine in the field of pharmaceutical activity, medicinal products for veterinary use (in the sense of this concept formulated in Medicrime Convention) and their circulation are outside the limits of pharmaceutical activity. But 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" (letter "b" paragraph 1 of Article 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.

## V. CONCLUSIONS

Criminal legal protection of pharmaceutical activity should be carried out with the help of the following basic international legal standards:

- 1) At the level of national legislation, a mandatory "subject" of pharmaceutical activity and its criminal law protection, which has the broadest meaning, should be distinguished. To indicate this "subject" at the international legal level, such uniform concepts are used as: "pharmaceutical product" (Directive of the Council of the EU 85/374/EEC), "medical product" (Medicrime Convention), etc.  
A counterfeit (falsified) medical product is not a type of medical product, but its circulation and introduction into circulation, supply, import, export and trade are included in the prohibitions established in the implementation of pharmaceutical activities (this is explained by the fact that circulation and introduction into circulation falsified pharmaceutical products capable of creating a danger to individual and/or public health, as well as violating the established state of its legal protection).
- 2) Along with pharmaceutical (medical) products, "accompanying" items that provide "handling" with pharmaceutical products or, in other words, ensure the implementation of pharmaceutical activities with pharmaceutical products, are subject to criminal protection: "accessories intended for use together with medical devices appointment" (Article 3 of the Medicrime Convention). The Medicrime Convention also recognizes documents that ensure the circulation of medical products as "accompanying" documents (herefrom the prohibition of forgery of these documents and their use as pre-forged; a separate prohibition of the commercial use of such documents is provided for).
- 3) Independent objects of criminal law protection are integral components of medicinal products (these are active substances and excipients), and medical devices (their parts and materials). According to Article 3 of the Medicrime Convention, they are "intended for use in the manufacturing of medical products", that is, they ensure the use of medical products.
- 4) the concept of pharmaceutical activity (within and outside the limits of the circulation of medicinal products) as an object of criminal law protection should include: manufacture, use, export, import, circulation, introduction into circulation (placement on the market), labelling, sale. Special types of pharmaceutical activity include the circulation and introduction into circulation of counterfeit (falsified) pharmaceutical (medical) products.
- 5) State regulation of pharmaceutical activity may be related to state registration procedures, as well as obtaining permits (license, patent) and compliance with established permits (licensing, patenting) in relation to the implementation of certain types of pharmaceutical activity. In addition, the "pharmacovigilance system", ensuring the quality and safety of pharmaceutical products in circulation, state regulation of manufacture, use, circulation, introduction into circulation, research (testing) of pharmaceutical products, as well as legal the regime of protection of personal data in the field of application and use of medicinal products, the legal regime of protection of pharmaceutical products by certain objects of intellectual property law. That is, in order to acquire the legal significance of a type of pharmaceutical activity, the relevant persons must acquire the status of its subjects and comply with the established permits for the implementation of specific types of pharmaceutical activity.
- 6) Taking into account the separation of the provisions on "commercial use" in international legal acts, the national criminal legislation should also ensure the protection of any legitimate commercial (economic) benefit received by subjects of pharmaceutical activity in the process of engaging in its specific types, and prohibit any manifestations of undue benefit in the implementation of pharmaceutical activity. That is, to establish criminal legal measures for violation of this prohibition, and regardless of which items the type of pharmaceutical activity relates to medical products, medicinal devices, raw materials which they produced for or their accessories, etc. However, the establishment of these prohibitions should not interfere with the criminal law protection of those fragments of pharmaceutical activity that do not provide for the receipt of any commercial (economic) benefit by its subjects, because these fragments ensure the protection of individual or public health exactly under the condition of free use of the corresponding pharmaceutical products.

According to Article 8 "Similar crimes involving threats to public health" of the Medicrime Convention, member states are obliged (without any reservations) to recognize in their national criminal legislation as types of criminal offenses specific actions in combination with other factual circumstances that "do not fit in" (exit outside the borders) in the following types of criminal offenses related to: 1) "intentional manufacture of counterfeit medical products, active substances, excipients, parts, materials and accessories", as well as falsification of medicinal products; 2) any falsification of "medical devices, active substances and excipients"; 3) intentional supply, offer regarding supply and trade in counterfeit medical products, active substances, excipients, parts, materials and accessories; 4) making of false documents or the act of tampering with documents related to medical products or pharmaceutical activity in general.

Such specific acts constituting "similar crimes that threaten health protection" in Article 8 of the Medicrime Convention recognize: a) the manufacturing, the keeping in stock for supply, importing, exporting, supplying, offering to supply or placing on the market of: i) medicinal products without authorisation where such authorisation is required under the domestic law of the Party; or ii) medical devices without being in compliance with the conformity requirements, where such conformity is required under the domestic law of the Party; b) the commercial use of original documents outside their intended use within the legal medical product supply chain, as specified by the domestic law of the Party." Therefore, it is necessary to find out the essence of "similar crimes" and the specific of their provision in the national Ukrainian criminal legislation.

The Medicrime Convention obliges the state to provide criminal legal protection of medicinal products for "human and veterinary use" (letter "b" paragraph 1 of Article 4), but it "does not interfere" in the state's choice of methods of such provision at the level of legislative technique, legislative constructions, their content, etc. The main thing is that this protection be ensured by national criminal legislation, but in what "legislative way" this will be done depends on the mechanism of criminal law regulation of each state and is a "dispositive requirement" for each state. This is confirmed by the fact that certain provisions of the Medicrime Convention are formulated according to the dispositive principle.

## CONFLICTS OF INTEREST

No conflicts of interest have been declared by the authors.

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