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Circulation of Falsified Medicinal Products and Medical Devices under the Medicrime Convention: Problems of Defining the Concept and Scope of Application

Circulation of Falsified Medicinal Products and Medical Devices under the Medicrime Convention: Problems of Defining the Concept and Scope of Application

Abstract: The article examines the circulation of falsified medical products and medical devices under the Medicrime Convention with an emphasis on the scope of this Convention. The Medicrime Convention is a basic international legal act that defines the European standards of the model of criminal law protection of circulation of medical products and medical devices against their counterfeiting (falsification). The author notes that given the importance of these provisions of the Medicrime Convention for the criminal protection of pharmaceutical activity and individual and public health, the specific content of its provisions requires independent analysis.

The article proposes to analyse the scope of application of the Medicrime Convention in view of the specific content of "subjects" to legal protection in accordance with the provisions of the Medicrime Convention. The author emphasizes the importance of scrutinizing the terms such as «medical products,» «medical device,» «medicines,» «active substance,» «accessory,» «parts,» «materials,» and «document» outlined in Article 4 of the Medicrime Convention. This scrutiny is deemed necessary to understand the legal standards governing the criminal protection of pharmaceutical activity. To achieve this, the author proposes a comparative analysis of these terms with the pertinent elements of pharmaceutical activity. The goals of this comparative analysis are twofold: a) to elucidate the role of these terms in the framework of criminal protection for pharmaceutical activity; b) to delineate the interrelationships among these concepts, thereby elucidating their significance in characterizing pharmaceutical activity as a subject of criminal law protection.

In the opinion of the author, the "national model" of criminal protection of pharmaceutical activity should be focused on ensuring the protection of primarily the rights, freedoms and interests of subjects of pharmaceutical activity, the connections between them, which ensure the circulation of medicinal products, and "stay" outside circulation of medicinal products, as well as connections between subjects of pharmaceutical activity related to their exercise of powers (professional powers) in the field of pharmaceutical activity. In addition, as the author notes, along with pharmaceutical (medical) products, "accompanying" items that ensure "handling" with pharmaceutical products or, in other words, ensure the implementation of pharmaceutical activities with

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pharmaceutical products, are subject to criminal protection: "accessories intended for use with medical devices".

The author proves that at the level of the Medicrime Convention, medical products and medicines as a separate type of medicinal products are mandatory components of the circulation of medicinal products, and in view of the above ratio of the concepts "medicines" and "medical products" is equivalent to the circulation of medicinal products only in if we take into account the two named types of medicinal products.

Keywords: Medicrime Convention, counterfeit medicinal products, medical products, draft of the Criminal Code of Ukraine, medical devices

Introduction

Mechanisms of prevention circulation of counterfeit (falsified) medical products and medicines are defined in the Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes Involving Threats to Public Health (Medicrime Convention) of October 28, 2011. In Ukraine this Convention was ratified by the Law of Ukraine "On the Ratification of the Council of Europe Convention on Counterfeiting of Medical Products and Similar Crimes Involving Treats to Public Health" on June 7, 2012 (Zakon Ukrayiny vid 07.06.2012 r. № 4908-VI). There are many questions regarding the provisions of this convention and their implementation in the national legislation of Ukraine.

The actuality of the topic is due to the fact that the Medicrime Convention is a basic international legal act that defines the European standards of the model of criminal law protection of the circulation of medical products and medicines against their counterfeiting (falsification).

According to the requirements of this Convention, the development of this model of criminal law protection must be directly related to the "injury" of public and individual health as an object of criminal law protection and the "significant amount" of danger (threat) created for such an object. In the preamble to the Medicrime Convention it is directly stated that "... counterfeiting of medical products and similar crimes by their nature pose a significant threat to health protection", and the prevention of this threat and the fight against it form according to Art. 1 of the Convention ("Objectives") of the purpose of the Convention. Achieving this goal is ensured by: "a) ensuring the criminalization of certain actions; b) protection of the rights of victims of crimes established in accordance with this Convention; c) encouragement of national and international cooperation" (Art. 1 of the Convention).

The purpose of the article is to determine the peculiarities of the circulation of falsified medicinal products and medicines under the Medicrime Convention with an emphasis on the scope of this Convention.

Analysis of scientific publications. The investigated issue did not receive adequate coverage in domestic scientific sources, therefore it is of particular relevance.

Presenting main material

The protection of rights provided by the provisions of the Medicrime Convention is specified in its Art. 2 "The principle of non-discrimination", and the features of "precautionary measures" and "protection of the rights and interests of victims" – respectively in Art. 18 "Precautionary measures" and Art. 19 "Protection of victims" of this Convention. It is important that "precautionary measures" are associated in the Convention with "necessary legislative and other measures to establish requirements for the quality and safety of medical products ... ensuring the safe distribution of medical products... preventing counterfeiting of medical products, active substances, excipients, parts, materials and accessories" (Art. 18), and "protection of victims" – with "necessary legislative and other measures to protect the rights and interests of victims, in particular by: a) ensuring the possibility for victims to obtain access to information related to their case and which is necessary to protect their health; b) providing assistance to victims for their physical, psychological and social recovery; c) ensuring the presence in its national legislation of the right of victims to compensation from offenders" (Art. 19).

Given the importance of these provisions of the Medicrime Convention for the criminal protection of pharmaceutical activity and individual and public health, the specific content of its provisions requires an independent analysis of "the international legal mechanism for countering the counterfeiting of medical products and similar threatening crimes laid down in the Convention health care" (Solovyov, 2019,

p. 59; Gutorova, Zhytnyi, Soloviov, 2019, p. 856–861). After all, "despite the fact that the states that signed and ratified this international document undertook to establish criminal liability for falsification and circulation of falsified medical products, until now the Criminal Code of Ukraine contains only a norm that provides for liability for such actions only with falsified medicines" (Gutorova, 2021, p. 17). Due to the relationship between the Medicrime Convention and national legislation, the following conclusion is deemed justified: "the fight against falsification of medical products and the formation of the market for quality pharmaceutical products is a strategic direction of Ukraine's activity as a signatory country of numerous conventions that have become part of national legislation" (Korolenko, p. 58).

First, it is necessary to clarify the "scope" of the Medicrime Convention. Certainly, in Article 3, under the heading "Scope," it is stipulated that "This Convention applies to medical products, whether or not they are protected by intellectual property rights or whether they are off-patent or not, including accessories intended for use together with medical devices, as well as active substances, excipients, parts and materials intended for use in the production of medical products". This means that the Medicrime Convention defines the following components of its "scope":

1) protection of medical products and medicines, as well as other items that are used together with medical products and medicines, by relevant intellectual property rights. This component is optional, since Art. 3 of the Convention contains the prescription "regardless of whether it is protected by intellectual property rights or not or regardless of whether it is unpatented or not";

2) when determining the scope of application, the legal regime of the Convention, which applies to "objects of protection": medical products and medicines, as well as other items that are used together with medical products and medicines, namely: "accessories intended for use together with medical devices, as well as active substances, excipients, parts and materials intended for use in the production of medical products".

Therefore, in order to clarify the "scope of application" of the Medicrime Convention, it is first necessary to deal with the specific content of the "subjects" of legal protection. Art. 4 ("Definition") contains definitions of the terms "medical product" and "medicines". The first "means medicines and medical devices" (p. "a" of Art. 4), and the second – "medicines for human and veterinary use, which may include: i) any substance or combination of substances presented as having properties for treating or preventing disease in humans or animals; ii) any substance or combination of substances which may be used in or administered to human beings or animals either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis; iii) an investigational medicinal product" (Konventsiya vid 28.10.2011 r.).

The term "active substance" shall mean any substance or mixture of substances that is designated to be used in the manufacture of a medicinal product, and that, when used in the production of a medicinal product, becomes an active ingredient of the medicinal product (p. "c" Art. 4); and "medical devices" – «any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software, designated by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, designated by the manufacturer to be used for human beings for the purpose of: i) diagnosis, prevention, monitoring, treatment or alleviation of disease; ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; iii) investigation, replacement or modification of the anatomy or of a physiological process; iv) control of conception; and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means (p. "e" Art. 4).

In addition, the objects of legal protection according to the provisions of the Medicrime Convention are "accessories" (according to p. "f" of Art. 4 "shall meen an article which whilst not being a medical device is designated specifically by its manufacturer to be used together with a medical device to enable it to be used in accordance with the use of the medical device intended by the manufacturer of the medical device), "parts" and "materials" (p. "g" of this article of the Convention defines that they shall meen all parts and materials constructed and designated to be used for medical devices and that are essential for the integrity thereof) and also the document, that shall mean

any document related to a medical product, an active substance, an excipient, a part, a material or an accessory, including the packaging, labeling, instructions for use, certificate of origin or any other certificate accompanying it, or otherwise directly associated with the manufacturing and/or distribution thereof (p. "h" Art. 4).

Therefore, to comprehend the meanings of the terms "medical product," "medicines," "active substance," "accessory," "parts," "medical devices," "materials," and "document," as defined in Article 4 of the Medicrime Convention and to clarify the legal standards for the criminal protection of pharmaceutical activity, it is crucial to compare these concepts with the relevant components of pharmaceutical activity. This comparison serves two main purposes: a) to define their role in the framework of criminal protection of pharmaceutical activity; and b) to illustrate the interconnections between these concepts, emphasizing their importance in establishing pharmaceutical activity as a subject of criminal law protection.

First of all, the above definition of the concept of "medical device" means its generic nature in relation to the concepts of "medicines", "medicinal products" and "medical device". After all, according to the provisions of p. "a" of Art. 4 of Medicrime Convention, the concept of a medical device includes medicines and devices for medical purposes, and in the definition of medical products (p. "b"), a separate component of the latter is called medicines. Therefore, the relationship between the concepts of "medical device" and "medicinal product" and "medical device" is based on the relationship between the generic concept of "medical device" and its independent types – "medicines" and "medical products". The concept of "medicines" is a separate type of "medical products". Therefore, the scope of the concepts "medicines" and "medical products" do not coincide (the first concept is smaller in scope than the second).

Secondly, according to the provisions of p. "b" of Art. 4 of the Medicrime Convention, the content of the term "medicinal products" is formed only from medicines, which are a separate type of medicinal products and by their nature are "presented" in two types: "medicines for human use" and "medicines for veterinary use" (Ryshchenko, Shapovalova, Shapovalov, 2013, p. 41). In view of this, a medicinal product is a type of medical device and includes in its content an independent variety – a medicines, which can be of two alternative types (for human or veterinary use).

Thirdly, the concept of "active substance" is a mandatory feature of the concept of "medicines", its constituent component. Unlike medicines, an active substance cannot be considered a type of medicines, since according to p. "c" of Art. 4, the active substance is used in the production of any medicines, regardless of the types of it (including the medicines as its separate variety, and therefore the active substance is a component, an ingredient of any medicines).

Fourthly, within the framework of the Medicrime Convention, a medicinal product and medicines, considered as a distinct category of medicinal products, are integral components of the overall process involving the circulation of medicinal products. The equivalence between the terms "medicinal products" and "medicines" in the context of the circulation of medicinal products is contingent upon recognizing these two specified types of medicines. In other words, according to the requirements of the Medicrime Convention, the components of the circulation of medicines are 1) the circulation of medicines for human use and 2) the circulation of medicines for veterinary use. This is a fundamental difference from the national level of legislation, which relates the concept of medicines only to "the purpose for the treatment or prevention of diseases in humans ... the purpose for the prevention of pregnancy, restoration, correction or change of physiological functions in a person" (§ 2 p. 1 Art. 2 of the Law of Ukraine "On Medicinal Products" of April 4, 1996) and the fact that they are "applied or administered to a person ... for the treatment or prevention of human diseases..." (p. 1 Art. 2 of the Law of Ukraine "On Medicinal Products" of July 28, 2022, which has not yet been put into effect). It means that at the national level the concept of "circulation of medicines" does not include "medicines for veterinary use" and, accordingly, "circulation of medicines for veterinary use". Hence, on a national scale, "medicines for veterinary use" and the "circulation of medicines for veterinary use" can be considered somewhat distinct from the broader circulation of medicines within pharmaceutical activity, which constitutes the object of criminal law protection.

Consequently, there are certain differences in the definition of the scope of criminal law protection of medicines circulation and pharmaceutical activity in

general at the level of the Medicrime Convention and at the national level. Given the established standards of the Medicrime Convention in the criminal protection of components of pharmaceutical activity, the feasibility and impracticality of including at the national level the object of criminal protection of "medicines for veterinary use" and "circulation of medicines for veterinary use" requires further justification. After all, the disregard of international legal standards regarding the "dual nature" of medicines and their use (meaning the demarcation at the level of international legal standards when defining medicines for human and veterinary use) still occurs at the national level, when the draft Criminal Code of Ukraine proposes to define the concept of "medicines" taking into account the separation of such types of medical products as "medicines" and "veterinary product" (Kryminal'nyy kodeks Ukrayiny: proekt stanom na 22.05.2023 r.). It is obvious that the given approach of the developers of the Criminal Code of Ukraine project is based only on the requirements of the current national legislation that regulates the circulation of medicinal products and "excludes" such circulation of veterinary medicinal products, and in no way contributes to the harmonization of Ukrainian criminal legislation and EU legislation in accordance with the requirements of the Convention Medicrime. Therefore, one should agree with the conclusion of N. Gutorova (she is a member of the working group for the preparation of the draft of the Criminal Code of Ukraine), although it was expressed by her back in 2019, but it is still relevant today: "...until now Ukraine has not fulfilled its international legal obligations regarding the recognition as a crime of falsification and circulation of falsified medicinal products means for veterinary use, medical devices, as well as active substances, excipients, parts, materials and accessories" (Hutorova, 2021).

Fifth, medical devices are outside the boundaries of the circulation of medicinal products (in a broader sense – medicinal products, if their veterinary use is taken into account according to the requirements of the Medicrime Convention), that is, the circulation of medical devices is an independent component of pharmaceutical activity as an object of criminal protection. Moreover, the Medicrime Convention does not formulate categorical requirements about which legal constructions of types of criminal offenses and in what way the circulation of medicinal products and circulation of medical devices should be taken into account: within the limits of one norm (one legislative act), which provides in its content a "single" type of criminal offense related to encroachment on the circulation of medicinal products and medical devices (an example is the provisions of the Swiss Federal Law on Medicinal Products and Medical Devices of December 15, 2000 (Medicrime convention. Switzeland) or within different norms (one norm provides for a type of criminal offense that encroaches on the circulation of medicinal products (medicines), and in the other – one that encroaches on the circulation medical devices). An illustration of the latter approach is the provision of additional acts of German criminal law, which are the German Laws on the circulation of medicinal products of August 24, 1976 and on medical devices as amended of August 7, 2002, as well as the Austrian Federal Laws on the Production and Distribution of Medicinal Products of March 2, 1983 and on medical products of October 28, 2021 (Medicrime convention. Germany; Medicrime convention. Austria).

Sixth, the object of criminal protection defined in the Medicrime Convention also includes objects that: a) are integral components of medicinal products and medical devices (for medicinal products, such components are active substances and excipients (p. "c", "d" of Art. 4 of the Medicrime Convention), and for medical devices – their "parts" and "materials", defined in p. "g" of Art. 4 of the Medicrime Convention); b) are not such integral components of the medicinal product and medical devices – "accessories" and "documents", defined respectively in p. "f" and p. "h" of Art. 4 of the Medicrime Convention. Therefore, the Medicrime Convention defines independent concepts that are not directly medicines and medical devices, their integral components (although functionally and legally related to them), but at the level of this Convention are recognized as independent components of criminal protection. The inclusion of the specified "accessories" and "documents" in the object of criminal protection should be explained primarily by the "measures to protect the rights and interests of victims" provided for in the Medicrime Convention (Art. 19). One of such measures of Art. 19 of the Medicrime Convention recognizes "ensuring [...] that victims have access to information that [...] is necessary for the protection of their health" (p. "a"). Therefore, accessories and documents provide

access to information that is necessary to protect their health and is referred to in p. "a" of Art. 19 of the Medicrime Convention. From the point of view of the requirements of this Convention, the specified accessories and documents are specific legal "means" of protection, primarily of the individual health of a specific person, the provision of which is carried out by obtaining the information necessary for the protection of their health. Therefore, any influence on "accessories" and "documents", defined respectively in p. "f" and p. "h" of Art. 4 of the Medicrime Convention, "automatically" prevents access of persons to the information they need, "infringes" on their right to this access and creates a threat to their health. Hence, the question of how national legislation "perceives" the need for criminal protection of such "accessories" and "documents" needs to be resolved.

Conclusions

1. Taking into account the above, the "national model" of criminal protection of pharmaceutical activity should be oriented towards ensuring the protection of primarily the rights, freedoms and interests of subjects of pharmaceutical activity, the connections between them, which ensure the circulation of medicinal products, and "are" outside the limits of circulation of medicinal products, as well as connections between subjects of pharmaceutical activity related to their exercise of powers (professional powers) in the field of pharmaceutical activity. This "orientation" of criminal law protection should be carried out at the level of national legislation (the mandatory "subject" of pharmaceutical activity and its criminal law protection, which has the broadest (general or generic) content, should be singled out). To designate such a "subject" at the international legal level, such uniform concepts as: "pharmaceutical product", "medical product" and others are used.

2. Together with pharmaceutical (medical) products, "accompanying" items that ensure "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" (Art. 3 of the Medicrime Convention). In addition, the Medicrime Convention also recognizes documents that ensure the circulation of pharmaceutical (medical) products as "accompanying" documents (hence the prohibition of forgery of these documents and their use as pre-forged; the commercial use of such documents is separately prohibited);

3. Independent objects of criminal law protection are integral components of pharmaceutical products (for medicinal products, these are active substances and excipients, and for medical devices, their parts and materials). According to Art. 3 of the Medicrime Convention, they are "intended for use in the production of medical products", that is, they ensure the use of medical products. Therefore, the analysis of the criminal law protection regarding the circulation of counterfeit (falsified) medical products and medicinal products under the Medicrime Convention is an aspect that necessitates further scholarly elaboration.

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