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FALSIFICATION OF MEDICAL PRODUCTS: CRIMINAL LAW MECHANISM COMBATING THREATS TO PUBLIC HEALTH

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ABSTRACT

Introduction: Every civilized state has the duty to its citizens to create an effective health care system, a necessary component of which is the use of safe and high-quality medical products. This duty is based both on the standards of international law and national constitutional norms and principles. The spread of falsified medical products poses a global threat to public health, can lead to death or cause significant harm to human health. Given the extreme risk of such acts, there is a need to create and operate an effective criminal law mechanism to combat such acts.

The aim: The purpose of the article is to study the existing criminal law mechanism to combat the falsification of medical products at the international, regional and national levels (Poland and Ukraine as an example), as well as to develop proposals for improving of such a mechanism.

Materials and methods: This study is based on the empirical and analytical data of the WHO, the United Nations Convention against Transnational Organized Crime, the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (The Medicrime Convention), criminal legislation of Ukraine and Poland, General Prosecutor's Office data on the criminal liability of those who committed falsification of medicines. Totally 28 laws and papers, 25 court judgments were analyzed.

Dialectical, comparative, analytic, synthetic and system analyses research methods were used, also for interpretation purposes.

Results: Falsification of medical products worldwide is characterized by high prevalence and is one of the highly profitable activities of transnational organized crime. Therefore, an effective counteraction to these crimes is impossible through isolated actions by one separate State and requires the establishment of a multi-level integrated mechanism to combat this phenomenon. The criminal law mechanism, as a necessary component of abovementioned mechanism, should be established at the international, regional and national levels.

An analysis of the situation in Poland and Ukraine showed that the falsification of medical products is quite common in these countries, but national criminal legislation and practice of its implementation needs improvement.

Conclusions: There is a need to create and implement an effective criminal law mechanism (at international, regional and national levels) to combat the spread of falsified medical products. At the international level, in order to increase the effectiveness of this mechanism, we fully support the EU initiative to amend the United Nations Convention against Transnational Organized Crime, which would establish additional liability for the falsification of medicines. 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. At the national level, it is necessary to improve both the criminal legislation and the practice of its implementation, to intensify the activity of law enforcement agencies to combat these crimes, to ensure a fair trial and effective criminal penalties for those who have committed a crime of falsifying medical products.

KEY WORDS: falsification of medical products, counterfeit medical products, medicines, medical devices, criminal liability, criminal law mechanism, public health, The Medicrime Convention

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INTRODUCTION

Every civilized state has the duty to its citizens to create an effective health care system, a necessary component of which is the use of safe and high-quality medical products. This duty is based both on international law standards and national constitutional norms and principles. Thus, Article 25 (1) of the Universal Declaration of Human Rights (1948) proclaims the right to a standard of living adequate for the health and well-being, including medical care, and the right to security in the event of sickness [1]. According to Part

1 (11) of the European Social Charter (Revised) (1996) the parties accept as the aim of their policy, to be pursued by all appropriate means both national and international in character, the attainment of conditions in which the following rights and principles may be effectively realised: Everyone has the right to benefit from any measures enabling him to enjoy the highest possible standard of health attainable. Based on Article 11 of this document, European states, with a view to ensuring the effective exercise of the right to protection of health, undertake, either directly or

in cooperation with public or private organisations, to take appropriate measures designed inter alia: 1) to remove as far as possible the causes of ill-health; 2) to provide advisory and educational facilities for the promotion of health and the encouragement of individual responsibility in matters of health; 3) to prevent as far as possible epidemic, endemic and other diseases, as well as accidents [2]. The Constitution of the Republic of Poland (Art. 68) states that everyone shall have the right to have his health protected [3], the Constitution of Ukraine (Art. 49) proclaims the right to health protection, medical care and medical insurance [4]. As we can see, the right to health protection refers to the standards of personal and social human rights established at the universal regional and national levels. The duty of the state is to create conditions for the realization of the right to health and its security for every person.

It is unlikely that in the modern world one can find a person who has never ever used medicines. Many people of the world who suffer from chronic and incurable diseases are forced to take medicines daily and in large quantities. A comfortable or at least acceptable standard of living for these people depends on the quality of medicines and other medical products. Sometimes the proper quality of these products is a necessary condition for survival of part of humankind. Although accurate statistics on quantities of poor-quality medical products worldwide doesn't exist for now, however, cases of significant harm to life and health of a large number of people due to their use are not rare.

Among the most serious effects of the use of falsified medicines the following should be mentioned [5]. In 1995, during a meningitis epidemic in Niger, over 50 000 people were vaccinated with a counterfeit vaccine, resulting in 2500 deaths. [6]. Quite stunning statistics are presented by J. Chirac saying that every year over 200 000 people die because they receive falsified medicines for malaria [7]. Recently, significant publicity has been given to the so-called "heparin case". Over 80 lethal cases in United States have been linked to the use of falsified heparin manufactured in China [8]. Over 125 people died in Pakistan from the use of the falsified generic product isosorbide-5-mononitrate, which contained a toxic quantity of the active substance [9]. The World Health Organization (WHO), given the extreme danger of spreading fake medical products, has determined that combating this negative phenomenon is one of its main activities.

Consequently, the spread of falsified medical products poses a global threat to public health, can lead to death or cause significant harm to human health. Given the extreme risk of such acts, there is a need to create and implement an effective criminal law mechanism to combat such acts.

THE AIM

The purpose of the article is to study the existing criminal law mechanism to combat the falsification of medical products at the international, regional and national levels (on the example of Poland and Ukraine), as well as to develop proposals for improving of such a mechanism.

MATERIALS AND METHODS

This study is based on the empirical and analytical data of the WHO, the United Nations Convention against Transnational Organized Crime, the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (The "Medicrime Convention"), criminal legislation of Ukraine and Poland, General Prosecutor's Office data on the criminal liability of those who committed crimes of medicines falsification. Totally 28 laws and papers, 25 court judgments were analyzed.

Dialectical, comparative, analytic, synthetic and system analyses research methods were used, also for interpretation purposes.

RESULTS AND DISCUSSION

The historical analysis of the formation of an international mechanism to prevent the spread of counterfeit medical products, which was carried out in the monograph "Preventing the spread of falsified medicines at the international and national level" [5], shows that for the first time the question of the need to jointly combat the spread of counterfeit medical products was raised at the international level in 1980s [10, p. 689]. The attention of the international community to the problem of falsified medical products (including medicines) was first drawn by the Conference of Experts on the Rational Use of Drugs held in Nairobi in 1985. The attending experts recommended that the WHO, together with other international governmental and non-governmental organizations, should study the feasibility of setting up a Accounting Chamber to collect data and to inform governments about the nature and extent of counterfeiting [11].

Two stages of the WHO's activity in this sphere should be highlighted. At the first stage, efforts were mainly focused on strengthening control over the quality of medical products, which was supposed to help prevent falsification. Thus, in 1988 WHO Resolution WHA 41.16 "Rational Use of Drugs" [12, p.19-20] was adopted. This Resolution recommended that the Director-General of the WHO should initiate programmes for the prevention and detection of the export, import and smuggling of falsely labelled, counterfeited or substandard pharmaceutical preparations [13]. In WHO Resolution WHA 52.19 Revised drug strategy (1999) [14], countries were recommended to establish and enforce regulations that ensure quality standards for all pharmaceutical materials and products manufactured in, imported to, exported from, or in transit through their territory. The above-mentioned WHO Resolution, which was welcomed by the EU, gave rise to the adoption of Directive 2003/94/EC "The principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use" [15].

At the second stage, an international mechanism to combat the falsification of medical products has been created and launched. In February 2006 the WHO in order

to facilitate harmonization of national laws and develop a uniform approach to falsified medicines understanding initiated the *International Medical Products Anti-Counterfeiting Taskforce (IMPACT)* [16]. In 2011 WHO established a “Member State mechanism”, which would be vested with expert functions and assist The International Conference of Drug Regulatory Authorities (ICDRAs). Basic provisions on “Member State mechanism”, a new practical activity of the WHO, are set forth in the document of the 65th World Health Assembly [17].

However, it should be noted that criminal law mechanism to combat the falsification of medical products **at the international level** needs to be improved. Despite the fact that the falsification of medical products and, above all, medicines, poses a serious threat to health of humanity and also belongs to the main activities of international organized crime, this crime cannot be classified as a type of transnational crime in accordance with international law. The problem is that criminal liability for transnational crimes, which include falsification of medical products, cannot be ensured by the efforts of one country. There is a need to solve issues such as extradition of convicts, mutual legal assistance and other aspects of international cooperation in the field of criminal justice. The international legal mechanism that effectively solves these problems is approved by the United Nations Convention against Transnational Organized Crime (Palermo Convention) [18]. Therefore, **we fully support the EU initiative to amend the United Nations Convention against Transnational Organized Crime, which would establish additional liability for the falsification of medicines** [19, p. 8].

The next level of the criminal law mechanism to combat the falsification of medical products is the **level of the European region**. The main international document at this level is the “Medicrime Convention” which was signed on October 28, 2011 in Moscow the Russian Federation and entered into force on January 1, 2016. This Convention is the first international criminal law instrument to oblige States Parties to criminalise: 1) the intentional manufacturing of counterfeit medical products, active substances, excipients, parts, materials and accessories (Art. 5); 2) committed intentionally, 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 (Art. 6); 3) the making of false documents or the act of tampering with documents, when committed intentionally (Art. 7); 4) committed intentionally, in so far as such an activity is not covered by Articles 5, 6 and 7: the manufacturing, the keeping in stock for supply, importing, exporting, supplying, offering to supply or placing on the market of medicinal products without authorisation where such authorisation is required under the domestic law of the Party or medical devices without being in compliance with the conformity requirements, where such conformity is required under the domestic law of the Party; 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 (Art. 8); the intentional aiding or abetting and attempt to commit any of the offences established in accordance with this Convention (Art. 9).[20] As we can see, according to the plan of the developers of this document, criminalization and punishment should cover the whole “chain” of spreading of various types of counterfeit medical products.

As of February 20, 2019, out of 47 Council of Europe Member States, 23 states have signed the “Medicrime Convention”, but only 12 of them ratified it. 5 states – non-members of Council of Europe (Benin, Burkina Faso, Guinea, Israel and Morocco) also have signed this Convention and 3 of them (Benin, Burkina Faso and Guinea) ratified it. [21]. It is noteworthy that Ukraine is a state that was one of the first to sign and ratify this Convention. At the same time, Poland has not signed this document yet.

Despite the fact that for Ukraine this Convention entered into force on January 1, 2016, it is not yet fully implemented in the national criminal legislation. To date, the falsification of medical devices and medicines for animals has not been criminalized, and no criminal law measures have been established for legal entities. It should be noted that in Ukraine the lack of legislative regulation of medical devices has a negative impact on the quality of medical care [22; 23]. In addition, the commission of an offences by persons abusing the confidence placed in them as professionals, manufacturers or suppliers as well as the offences committed having resort to means of large-scale distribution, such as information systems including the Internet, were not recognized as an aggravating circumstance.

In fact, only 25.5% (12 from 47) members of The Council of Europe have entered into forces the “Medicrime Convention” for more than 7 years from the time when this treaty was opened for signing. Unfortunately, this situation does not allow using the opportunities provided by the Convention for effective cooperation at the national and international levels between different sectors of government, coordination measures at the national level, preventive measures for the use of public and private sectors and protection of victims and witnesses.[20] The abstention of any country from joining this Convention weakens the effectiveness and speed of international cooperation of national law enforcement and judicial authorities with the relevant services of other states in this area [24]. Thus, **the improvement of the criminal law mechanism to combat the falsification of medical products at the European regional level requires intensifying the process of “Medicrime Convention” ratification.**

Attention should also be paid to the terminology used in the international documents for definition of falsified medical products. For some time, such products were designated by the term “counterfeit medical products” in WHO documents, later the abbreviation SSFFC (substandard/spurious/false-labelled/falsified/counterfeit) was commonly used in relation to falsified medicines. However, on May 29, 2017, at the 70th World Health Assembly, it was decided to use the unified term “substandard and falsified medical products” (SF) for designation in all future documents [25]

The basis for legal regulation of preventing the spread of falsified medicines among *EU territory is the Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products* [26], which entered into force on January 2, 2013. It amends Directive 2001/83/EC on the Community code relating to medicinal products for human use. EU Member States use quite a severe authorization procedure on their territories, i.e. a procedure for admission to the common market of the EU. Key characteristics evaluated during the authorization procedure are the quality, safety and efficacy of a medicine. EU Member States expect to achieve such characteristics by using a number of measures. For example:

- the basis for preventing the spread of falsified medicines must be primarily an efficient control over the origin and quality of an active substance, such as: 1) an obligation of manufacturers to use only an active substance that is manufactured in compliance with GMP requirements and distributed in compliance with GDP; and 2) registration of manufacturers, importers and distributors of an active substance;

- the enhancement of requirements for the labelling of medicines, i.e. the use of a unique identifier (2D code of the format GS1 ECC200). We believe it would be reasonable to expand the use of such labelling firstly into the territory of a subregion or region and subsequently worldwide. However, such a transition is costly;

- the strengthening of administrative measures (registration of trade agents, authorization of all participants in the circulation of medicines to inform competent public authorities of cases of falsified medicines, threats to human life and health);

- the establishment of a single system within the EU that will help inspect all participants of medicines circulation on a regular basis. Such inspection may be carried out both on the territory of the EU and on those of other countries;

- informational methods (informing about officially registered participants in medicines circulation, reporting cases of medicines falsification).

- the maintenance of “white” and “black” lists of medicines. Thus, the “white” list will include prescription medicines that require no additional identification and coding due to a) their low price; b) limited output; c) impossibility to counterfeit due to the physical and chemical properties of a medicinal product, etc. The “black” list will include OTC (over the counter) medicinal products that: a) are expensive; b) are in great demand; c) are from famous brands; and d) of which falsifications have entered the circulation. The “white” and “black” lists are planned to be used at the EU level. Moreover, manufacturers or wholesale distributors of medicines will not be able to influence the process of including medicines in any particular list. [5, p. 63, 64]

Preventive measures of this Directive to combat the falsification of medical products were considered necessary to be combined with measures of a criminal law nature.

Thus, in accordance with Art. 118a (1) “the Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all necessary measures to ensure that those penalties are implemented. The penalties must be effective, proportionate and dissuasive.” [26]

Therefore, the next issue that needs to be analyzed to achieve the aim of this study is *the functioning of the criminal law mechanism to combat the falsification of medical products at the national level (Ukraine and Poland examples)*.

Polish legislation criminalizes the falsification of medicinal products in the Art. 124 b of The Pharmacy Law [27] and Art. 165 of The Penal Law [28]. According to Art. 124 b of the Pharmacy Act criminal punishment (fine, restriction of liberty or deprivation of liberty for up to 5 years) is established for a person who makes a falsified medicinal product or a falsified active substance, supplies, sells or provides free of charge, or stores for this purpose a falsified medicinal product or falsified active substance. Art. 165 of The Penal Law states that: whoever causes danger to the life or health of many persons or property of a considerable value by producing or marketing of pharmaceutical preparations which do not conform to binding quality standards shall be subject to the penalty of the deprivation of liberty for a term of between 6 months and 8 years (§ 1); if the consequence of the act specified in § 1 is the death of a person, or grievous bodily harm to many persons, the perpetrator shall be subject to the penalty of the deprivation of liberty for a term of between 2 and 12 years (§ 3). According to the findings of Polish researchers (*Iga Kalinowska Maksim*), the Art. 124 b of The Pharmaceutical Law is special with respect to the Art. 165 of the Criminal Code of Poland. Such a relationship involves the priority of the latter. [29]

The Criminal Code of Ukraine establishes criminal liability for these offences according to the Art. 321¹ “Falsification of medicines or circulation of falsified medicines” and Art. 305 “Smuggling of narcotics, psychotropic substances, their analogues or precursors or falsified medicines” [30], which was adopted in 2011. This article states that manufacturing, buying, transporting, sending, storing with the purpose to sell, or selling deliberately falsified medicine shall be punishable by deprivation of liberty for a term of three to ten years or deprivation of liberty for life with confiscation of property. According to the Art. 305 smuggling of falsified medicines, that is their movement across the customs border of Ukraine outside the customs control or by concealing from the customs control shall be punishable by deprivation of liberty for a term of five to twelve years with confiscation of property.

Comparison of criminal sanctions imposed in Ukraine and Poland for falsification of medicines and circulation of falsified medicines clearly demonstrate the commitment of the Ukrainian legislator to the severity of punishment as an effective countermeasure. It is evidenced by the presence in the Art. 321¹ (p. 3) of The Criminal Code of Ukraine such a punishment as deprivation of liberty for life. It should be

noted that so far this is the only example of the establishment in Ukrainian criminal legislation of the most severe type of punishment for committing a crime not related to murder or attempted murder.

However, despite the extraordinary severity of the punishment established by law, in fact, the courts do not apply it. For example, in November 2012 in Lviv region a criminal group was discovered, which was engaged in falsification and sale of falsified medicines for several years. It was detected 597 types of medicines and health-care products at unlicensed warehouses, which had characteristics of being falsified. The criminal group deliberately sold medicines and other medical products that could harm human life and health, a part of legal but expired medicines was re-labelled showing different expiration dates. It should be noted that this group has falsified the most advertised medicines in Ukraine. Falsified medicines entered the circulation mostly through a pharmacy network, in most cases through individual entrepreneurs. Despite the fact that the members of this group agreed to cooperate with the investigators, the source of supply of raw materials for the manufacture of falsified medicines has not been detected. Seven members of the criminal group, among whom four were employees of pharmacies, were convicted on the basis of Art. 321¹ p. 2 of the Criminal Code of Ukraine. Each was sentenced to five years of deprivation of liberty, from which they were released on probation. As you can see, the participants in this criminal group did not suffer any real punishment. [31] Such decisions of the Ukrainian courts unfortunately reflect the established practice of applying punishment for these crimes. This practice requires changes, since the actual impunity of criminals who commit falsification of medicines, testifies to the ineffectiveness of the criminal law mechanism to combat these crimes.

Obviously, the application of criminal liability for falsification of medicines, both in Poland and in Ukraine, is still quite rare. Patryk Słowik referring to the data of the National Prosecutor's Office states that in 2015 there are no indictments under Article 124 b of the Pharmaceutical Law, in 2016 there were three, in 2017 - six, in the first four months of 2018 - one [32]. In Ukraine, according to the General Prosecutor's Office, in the last five years (the period from 2013 to 2018), 25 criminal cases have been initiated under Art. 321¹ of the Criminal Code [33]. During this period, the courts issued 25 sentences under this article, of which 23 convictions, 2 - acquittals [34]. However, the researchers note that these statistics reflect the effectiveness of law enforcement agencies to combat such crimes, rather than the actual state of crime in this area. [32, 35]

CONCLUSIONS

There is a need to create and implement an *effective criminal law mechanism to combat the spread of falsified medical products* that pose a global threat to public health, can lead to death or cause significant harm to human health. It is necessary that such a mechanism exists at the international, regional and national levels.

In order to increase the effectiveness of the criminal law mechanism *at the international level*, we fully support the EU initiative to amend the United Nations Convention against Transnational Organized Crime, which would establish additional liability for the falsification of medicines.

Improving the criminal law mechanism to combat the falsification of medical products *at the European regional level* requires intensifying the process of "Medicrime Convention" ratification and full implementation of rules on criminal liability for falsifying medical products into national criminal legislation.

At the national level it is necessary to improve both the criminal legislation and the practice of its implementation, to intensify the activity of law enforcement agencies to combat these crimes, to ensure a fair trial and effective criminal penalties for those who have committed the falsifying medical products.

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