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REVIEW ARTICLE
PRACA POGLĄDOWA**TENDENCIES FOR THE FALSIFICATION OF MEDICINAL PRODUCTS IN UKRAINE: GENERAL ANALYSIS AND AREAS OF COUNTERACTION**

DOI: 10.36740/WLek201912214

Borys O. Lohvynenko¹, Viktor S. Sezonov², Tetiana A. Frantsuz-Yakovets³¹ DNEPROPETROVSK STATE UNIVERSITY OF INTERNAL AFFAIRS, DNIPRO, UKRAINE² KHARKIV RESEARCH EXPERT AND FORENSIC CENTRE OF THE MINISTRY OF INTERNAL AFFAIRS OF UKRAINE, KHARKIV, UKRAINE³ IVANO-FRANKIVSK INSTITUTE OF LAW, NATIONAL UNIVERSITY «ODESSA LAW ACADEMY», IVANO-FRANKIVSK, UKRAINE**ABSTRACT****Introduction:** Ukrainian counterfeit pharmaceutical market affects pharmaceutical manufacturers' image and threatens citizens' lives and health.**The aim:** of the article is to identify and systematize the causes and methods of pharmacy drugs' falsification, grounding the need for certain areas of counteraction.**Materials and methods:** Empirical base includes Ukrainian legislation, international acts, statistical data of the WHO, State Register of Medicinal Products of Ukraine, General Prosecutor's Office of Ukraine, Unified State Register of Court Decisions, media materials, journalistic investigations. Methodological basis is a set of general and special research methods of scientific cognition.**Conclusions:** Expired drugs' repackaging; production in non-licensed enterprises; replacement of drugs by non-pharmacological substances, etc. were established as the most common methods of falsifying pharmacy drugs in Ukraine. The authors systematized the reasons for uncontrolled production's growth, established distribution channels for pharmacy drugs in Ukraine and offered the most effective ways for counteracting drug falsification.**KEY WORDS:** falsification, pharmacy drugs, methods of commission, causes, counteraction

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INTRODUCTION

The presence of a counterfeit pharmaceutical market in Ukraine both threatens the life and health of citizens of Ukraine, affects the image of the leading manufacturers of the Ukrainian pharmaceutical market [1], and creates a threat to the economic and political security of the state in the whole. 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 [2].

According to the World Health Organization (hereinafter referred to as the WHO) for 2017 [3], every 10th medicinal product in states with low and medium-level economies (where Ukraine belongs) is counterfeit¹ [4]. Substandard drugs are "genuine medicines which have not passed the standards and quality testing protocols set for them" The WHO and International Pharmacopoeias have previously determined these standards and quality tests. Counterfeit medicines are a type of substandard drugs. There is no international consensus regarding the definition of counterfeit medicines, and the WHO defines them as "drugs that

are deliberately and fraudulently mislabeled with respect to identity and/or source" [5].

Currently, it is estimated that 10–15% of the global drugs supplied are counterfeit. The prevalence is higher in developing countries in Africa and in some areas of Asia and Latin America where up to 30–60% of drugs on the market are counterfeit. India is a major supplier of poor-quality drugs whereby 35–75% of fake/counterfeit drugs globally originate from India [6].

Analysis of the data contained on the official website of the General Prosecutor's Office of Ukraine indicates a rather low level of revealing the facts of manufacture, purchase, transportation, shipping, storage for the purpose of sale or marketing of obviously falsified medicines, the commission of which there is criminal liability under the Art. 321-1 of the Criminal Code of Ukraine (the data in the Fig. 1 indicates about this). At the same time, 27 sentences were revealed in the Unified State Register of Judicial Decisions (hereinafter referred to as the USRJD), under this article of the Criminal Code of Ukraine (2013 – 6; 2014 – 3; 2015 – 6; 2016 – 5; 2017 – 3; 2018 – 2; 2019 – 2).

The current situation testifies to the latency of the manifestations of criminal activity associated with the

¹ As at April 18, 2019 the State Register of Medicinal Products of Ukraine has registered 13 311 of medicinal products, where, 4 054 are from national manufacturers, and 9 257 – from foreign ones [3].

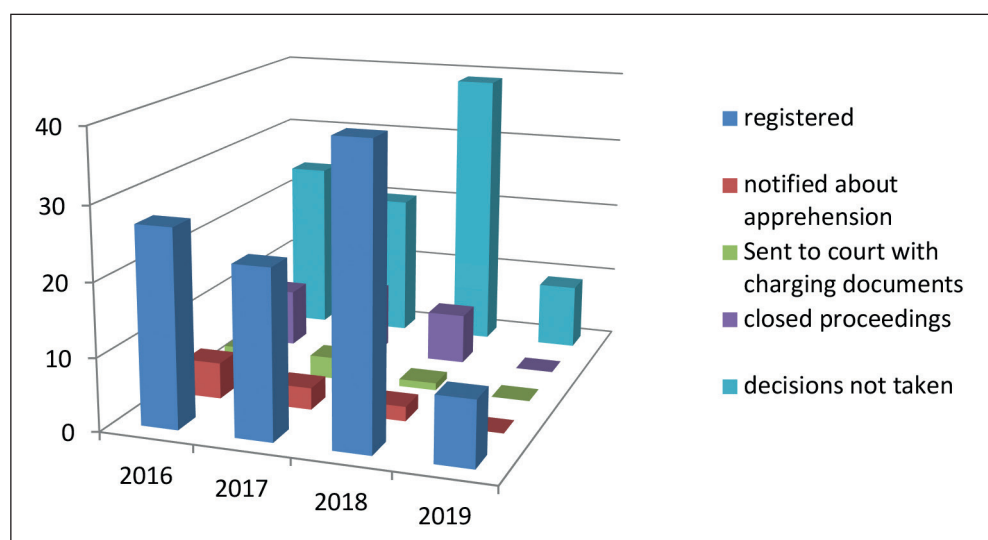


Fig. 1. Data of the General Prosecutor's Office of Ukraine for 2016-2019 in regard to criminal proceedings under the Article 321-1 of the Criminal Code of Ukraine.

falsification of medicinal products, the professional skills of criminals, as well as the insufficient effectiveness of the activities of state, law enforcement and judicial authorities. The aforementioned undermines the possibility of the proper implementation of the social and law enforcement functions of the state, since the state demonstrates powerlessness both in terms of controlling the quality of drugs and in terms of the criminal reaction to socially dangerous acts associated with their falsification.

THE AIM

The aim of this article is to determine and systematize the methods of falsification of medicinal products, the reasons of their commission, as well as to justify the need for some areas of counteraction to such a multifaceted phenomenon.

To achieve this aim, the following **main tasks** have been defined: 1) to study the existing methods of falsifying medicinal products taking into account current conditions in Ukraine; 2) to identify and systematize the reasons for their commission; 3) to suggest certain directions of counteraction to these phenomena.

MATERIALS AND METHODS

The materials for determining the causes, researching methods of falsification of medicinal products and possible areas of counteraction in Ukraine are Ukrainian legislation, international acts, statistics of the WHO, the State Register of Medicinal Products of Ukraine, the General Prosecutor's Office of Ukraine for 2016-2019, the USRJD (27 sentences), as well as media materials and the results of journalistic investigations. The methodological basis was the combination of general scientific and special scientific methods of scientific cognition, which were used in conjunction and ensured the comprehensiveness, completeness and objectivity of the study. The method of

system analysis made it possible to formulate the reasons for the falsification of medicinal products. The formal and legal method was used in the analysis of legislative acts of Ukraine. The statistical method, logical methods, and comparative analysis method were used to analyze the data from the WHO, the State Register of Medicinal Products of Ukraine, the General Prosecutor's Office of Ukraine, and court decisions of the Unified State Register of Judicial Decisions, as well as own findings. The hermeneutic method was used to establish the essence of the concepts of "medicinal products" and "drugs".

REVIEW AND DISCUSSION

In accordance with paragraph. 1, Part 1 of the Article. 2 of the Law of Ukraine "On Medicinal Products" dated from April 4, 1996 (No. 123/96-VR) [7] a falsified medicinal product is a medicinal product deliberately labeled with not identical (not corresponding) data (one or more) about a medicinal product with the corresponding name entered in the State Register of Medicinal Products of Ukraine, as well as a medicinal product deliberately faked in another way that does not meet the data (one or more), including the composition, about a medicinal product with the appropriate name entered into the State Register of Medicinal products of Ukraine. At the same time, paragraph 4, Part 1 of the Art. 2 of the same Law contains the concept of "finished medicinal products", which means medicinal products, medicines, drugs, i.e., dosed medicinal products in the form and condition in which they are used, having passed all stages of production (manufacture), including final packaging.

We believe that the concept of "medicinal products" is not clear enough and is applied both to substances, whose use is aimed at treatment, prevention and diagnosis, and determines some special actions, techniques and methods of using such substances. Therefore, it would be more appropriate to use the term of "drugs", which more accurately

defines the technological readiness of a drug substance for consumption in the manner of a certain form having a brand name, and it is these drugs that are included in the State Register of Medicinal products of Ukraine.

According to the WHO data, “this issue affects all countries in all regions of the world from North America and Europe to the South from Sahara, Southeast Asia and Latin America. What used to be a problem for developing countries and low-income countries today concerns everyone” [8]. This is evidenced by the results of the research accomplished by international scholars [e.g.: 9; 10; 11 and others], as well as the effectiveness of law enforcement agencies of other states. In 2013, as a result of one of the largest operations in the last decade under the anti-counterfeit drug program, Chinese law enforcement agencies confiscated almost 9 tons of drugs and raw materials for them about 2.2 billion Yuan (\$ 326,4 million) worth. Prescription of medicinal products – is varying from acute respiratory viral infections to heart diseases. Sales of drugs were carried out through the use of 140 websites, which were also blocked as a result of the operation. Besides, 149 US citizens died in 2008 as a result of the production of falsified drugs (“heparin”) manufactured in China [12]. According to the results of an investigation conducted by the Food and Drug Administration of China in 2016, it became known that up to 80% of clinical trials in China were partially or fully falsified, on the basis of which decisions were made on the admission of new drugs to the market [13].

In accordance with the analysis of court decisions of the Unified State Register of Court Decisions, mass media and sociological research, the most spread methods of falsification of medicinal products in Ukraine are: repackaging of expired medicinal products [14; 15]; production at enterprises that do not have the license [16]; replacement of medicinal products with substances that are not pharmacological [14]; change in production technology in order to underestimate the amount of the pharmacological component [17; 18]; production of so-called drugs – simulators having a different therapeutic effect [19]. Detection of the organized criminal group in Kharkiv City in 2014 can be considered as one of the high-profile cases of the industrial production of counterfeit medicinal products, the activities of which included all of the above-mentioned methods. Joined parties of the organized criminal group launched a clandestine manufacture of flu and ARVI medication called “Pharmatsitron” and “Terafliu”. Besides, they purchased 60 bags of expired drug called “Fliukold”, which was mixed with powdered sugar and packaged in sachets. The manufacture was carried out in rented garages, and sales were carried out by mail in the cities of Kharkiv, Kyiv, Cherkasy, Mariupol. The total cost of seized counterfeit goods (without seized equipment) amounted to more than 204 thousand UAH. [15; 17; 18].

It is also worth noting that sometimes a manufacturer, in order to evade taxes, produces a full-fledged copy of a real drug that has not passed a special audit.

Analysis of modern methods of the medicinal products' falsification makes it possible to distinguish the mandatory stage of such a criminal activity as sale of medicinal

products. We would like to note the tendency of selling counterfeit products through special Internet websites (which may be phishing ones) by creating an extensive distribution network based on network marketing (with the participation of medical personnel). At the same time, sales of counterfeit medicinal products are significantly increasing (according to the report from “Mark Monitor” for 2017, 67% of respondents trust online pharmacies, and 29% of consumers buy medicines online through mobile applications, social networks and online platforms [20]). There is also a “tossing” of business cards, price lists with unregistered medicinal products to medical institutions.

Attractive for the sale of counterfeit medicinal products is the pharmacy network existing in Ukraine (as of January 1, 2019, there are 16.4 thousand pharmacies and 4.2 thousand pharmacy points in Ukraine [21]). So, in 2017, the Security Service of Ukraine liquidated organized criminal group that launched a large-scale production of a wide range of medicinal products in one of the warehouse premises of Odessa City. To sell counterfeit products the criminals used their own network of pharmacies, as well as drugstore networks in other regions of Ukraine. The amount of counterfeit sold – is more than 30 million UAH, unsold drugs seized in the amount of more than 5 million UAH [22].

The channel of counterfeit medicinal products' sales are medical facilities. So, in 2018, the National Police of Ukraine together with the Security Service of Ukraine discovered in Kyiv an enterprise that produced counterfeit medicinal products (cases of injection into cylinders and the sale of technical oxygen through medical institutions in different cities of Ukraine were identified, which created a threat to the life and health of patients) [23]. Despite the detention of accomplices to the crime, there were issues about their corrupt relations with officials of medical institutions, where the specified counterfeit products were sold or used.

A separate area of criminal activity is the production and marketing of counterfeit steroids and so-called slimming drugs. Such counterfeit products are produced as in previous cases in artisanal conditions (in private houses, garages, unused production facilities, etc.). Sales are most often carried out through trainers of fitness centers or through Internet websites. So, in December 2018, the Security Service of Ukraine revealed in Kyiv region a local resident who ordered anabolic steroids in other countries for the manufacture of counterfeit medicines. The surreptitious workshop was organized in his own private house, sales were carried out through the website in different regions of Ukraine, as well as through the trainer of one of Kyiv fitness centers [24].

In Ukraine, there are cases of the production of counterfeit products for the purpose of marketing in other countries. So, in January 2019 law enforcement officers of Ukraine uncovered a resident of Khmelnytsky region, who sold home-made steroids and weight loss drugs through online store, designed for customers from Europe and Ukraine. The laboratory was equipped in his own apartment; the components of counterfeit drugs were purchased in China via the Internet [25].

Analysis of the methods and items of falsification of medicinal products indicates that they connected with the demand for certain types of medicinal products in a particular region. So, according to the research company “Grand View Research”, the volume of the global biosimilar market will increase by an average of 34.2% annually till 2025 (2016 – \$ 4.36 billion) [26] that indicates the possibility of these types of drugs’ falsification increase. A similar situation may arise with the predictable growth of the global market for pneumococcal vaccines and oncologic drugs.

CONCLUSIONS

The results of the conducted study make it possible to argue that the reasons for the growth of uncontrolled production and the establishment of distribution channels for medicinal products in Ukraine are:

- low level of control by the state and law enforcement agencies over the implementation of existing laws;
- inefficient activities of organizations involved in establishing compliance of medicinal products, registered in Ukraine, with international requirements, as well as verification of the quality of drugs while their production and marketing, which leads to impunity for manufacturers of counterfeit products, and the high selling price (at low cost) makes it attractive for organized crime;
- insufficient level of the implementation of pharmaceutical practices [27] (GMP – Good Manufacturing Practice);
- lack of real copyright protection in Ukraine. The initiative of copyright holders for specific pharmaceutical products to ensure and protect them could increase the effectiveness of counteracting the production and marketing of counterfeit medicinal products;
- the availability of modern equipment to produce counterfeit medicinal products, which creates uncontrolled growth in the pharmaceutical market;
- the tendency of the population of Ukraine to self-diagnosis (out of 10 patients, only 3 visit physicians), self-medication, self-prescription of medicinal products based on advertising products, the advice of friends and pharmacists (sometimes participating in criminal sales schemes of counterfeit medicinal products), as well as a significantly lower cost of non-prescription medicinal products;
- a high level of corruption of state officials working in the pharmaceutical and healthcare sectors;
- the lack of drugs in an epidemic situation create shortage and the possibility of the distribution of counterfeit products.

The following areas are the most effective for countering the falsification of medicinal products:

- the reform of state public agencies of pharmaceutical industry (by reducing their amount, modifying powers and competences, etc.). It should be noted that the Cabinet of Ministers of Ukraine, in April 2019 has approved the Concept of state policy to prevent the falsification of medicinal products and a plan of measures aimed at its implementation [28]. However, this Concept is only

a general plan of activities aimed at counteracting the falsification of drugs, without defining specific terms for the implementation of some activities [29]. Besides, to ensure the reality of the implementation of this Concept, it would be advisable to organize and conduct public hearings, where pharmaceutical market participants could determine the stages of suggested counteraction system implementation;

- with regard to the approval of this Concept, it is necessary to organize an automated system for tracking the turnover of medicinal products using a unique identifier. Starting from February 2019, two-dimensional barcodes (“cryptographic protection”) are introduced in European countries instead of barcodes, which contain much more information about the medicinal product, as well as an indicator by which each specific medicinal product can be tracked (from manufacturer to a patient (consumer) [30]. Mandatory implementation of drug labeling has been envisaged since 2020 in the Russian Federation [31];
- the creation of specialized groups within the structure of the customs agencies of Ukraine, with the inclusion of specialists (experts) who could conduct expert research as soon as possible without causing material and moral damage to conscientious consignors or consignees. The main objective of the such groups’ activity is to ensure inspections of imported drugs at import points of Ukraine, with the aim of identifying counterfeit medicinal products with their subsequent seizure from circulation (or confiscation);
- the introduction of electronic document management system in the pharmaceutical sector, including the electronic system for licensing the activities of business entities (this will ensure transparency in the activities of state agencies with the appropriate authority and will help to reduce corruption in this field). Besides that, an introduction of electronic prescriptions to purchase medicinal products outside the region, where the prescription was given (we can use the experience of Estonia and Finland as an example) can be considered as an integral part of such an electronic system. Using this form of prescription will reduce the frequency of the participation of medical employees in criminal schemes of production and marketing of counterfeit medicinal products;
- taking into account the experience of European countries, equipping drug packages with special protective “locks”, which will ensure their integrity and the impossibility of replacing contents;
- in order to prevent falsification of medicinal products, it is necessary to increase the level of awareness of the population (not only patients), including by informing about the existing system of protection of medicinal products from falsification. This is especially due to the possibility of using the constantly updated mobile application “Medicines Control” launched in 2016 [32], which provides the ability to verify drugs registered in the List-register of the Ministry of Health of Ukraine;
- conduction of briefings, conferences and other joint events, joint development of strategic programs to combat the falsification of medicinal products in order to exchange

information and establish interaction between bona fide drug manufacturers, state agencies (including law enforcement agencies), media and public organizations.

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