

LEGAL ASPECTS OF COUNTERACTING THE TRAFFICKING OF FALSIFIED MEDICINES IN THE EUROPEAN UNION

ASPEKTY PRAWNE PRZECIWDZIAŁANIA OBROTOWI PODROBIONYMI LEKAMI W UNII EUROPEJSKIEJ

Vitalii Pashkov¹, Aleksey Soloviov², Andrii Olefir¹

¹ DEPARTMENT OF CIVIL, ECONOMICAL AND ENVIRONMENTAL LAW POLTAVA'S INSTITUTE OF LAW YAROSLAV MUDRYI NATIONAL LAW UNIVERSITY, POLTAVA, UKRAINE

² DEPARTMENT OF MANAGEMENT AND ECONOMICS OF PHARMACY, NATIONAL MEDICAL ACADEMY OF POSTGRADUATE EDUCATION NAMED P.L.SHUPYK, KYIV, UKRAINA

ABSTRACT

Introduction: The paper identifies key risks associated with the illegal production and sale of medicines. Also there were generalized features of criminal responsibility for acts related to the trafficking of drugs in some Member States of the EU and analyzed legal means of combating the falsified drugs today. The problem concerning falsification of medicines is particularly acute not only in developing countries but also in developed ones. Fake is one in ten - twenty drug. The largest share of falsified drugs comes from the so-called «Asian tigers», already from which they come to the EU market.

The aim: In this publication authors have set following objectives: - to determine the risks associated with illegal production and sale of medicines; - organize legal means of combating the falsified medicines in the EU member states; - clarify features of criminal responsibility for acts related to the trafficking of drugs in the EU countries.

Materials and methods: The article bases on the works of scholars and experts, statistical information and other sources. Particular attention is paid to the analysis of regulations of the EU institutions and national criminal laws. So, provisions of the criminal codes of 10 EU member states were taken into account.

Results: There is a system of legal measures which counter the circulation of falsified medicines in the EU and consists of general and specific regulatory requirements, mainly of economic and legal nature. The most important role among the last play package labeling requirements for drugs and license conditions.

Discussion: In the article were discussed factors that stimulate the production and sale of falsified drugs and the risks associated with these. Demarcated the concept of «falsified medicinal product», «counterfeit drug», «substandard drug».

Conclusions: Although there are guidelines for patients to identify falsified drugs, still a major role in this process should play public authorities and enterprises. In all the countries illegal circulation of falsified drugs is prohibited under threat of criminal or administrative responsibility.

KEY WORDS: falsified drugs, counterfeit, substandard drugs, criminal responsibility, the unique identifier, Directive 2001/83/EC, Regulation (EU) 2016/161.

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INTRODUCTION

The functioning of the healthcare industry in any country is impossible without providing enough medicines for patient care [1]. As in any sphere of production relations, pharmaceutical products are often subject to falsification. The problem of turnover of falsified medicines has long historical roots. Reports of inferior therapeutic agents have found in documents of the IV century BC [2]. In modern history, serious attention has been paid to the problem of counterfeiting medicines since 1985, when the International Conference of Experts on the Rational Use of Medicines of the World Health Organization (WHO) was held and the fight against drug fraud was recognized as one of the priorities of WHO policies [3]. It is estimated that 6-10% of all medicines on the world pharmaceutical market are falsified. Trade in counterfeit medicines is increasing by around 15% a year in Europe [4]. The largest share of falsified pills come from China, India, Bangladesh, etc. [5]. India is a main «supplier» of

such products in the world (35%), followed by Nigeria (23.1%), Pakistan (13.3) and other Asian countries (14.6%) [6]. At the same time, this problem concerns not only underdeveloped but also developed countries. In recent years, medicines were the leading counterfeit products seized by European customs, ahead of cigarettes. In 2013, 99 countries collaborated on Operation Pangea VI to fight against illegal online pharmacies. It resulted in the closure of 13,700 websites and the seizure of more than 10 million drugs [7]. In 2011 the Austrian customs authorities seized 41.589 counterfeit medicinal products, the vast majority of which came from India and Singapore [2].

THE AIM

In this publication authors have set following objectives: - to determine the risks associated with illegal production and sale of medicines; - organize legal means of combating

the falsified medicines in the EU member states; - clarify features of criminal responsibility for acts related to the trafficking of drugs in the EU countries.

MATERIAL AND METHODS

Some aspects of legal counterwork against falsified medicines and illegal manufactures, pharmacies in the EU have been studied by scientists such, as M. Binkowska-Bury, R.C. Bird, M. Cordina, Z.E. Fijałek, N.M. Chaney, P. Januszewicz, T. Kubicb, R. Kumar, R. Magesa, A. Mazur, M.D. Nair, P.J. Philip, E. Rheims, T. Santella, A. Senterfitt, J. Sherma, S. Verma, B. Vitaris, A.I. Wertheimer, M. Wolan and others. However, despite the dire urgency of the matter, at the academic level problems of combating falsified drugs by general, special and criminal measures in a complex have not investigated.

Falsified medicinal products are often mislead the buyer in several ways (quality, components, origin etc.) and constitute acts of unfair competition. Participants of the pharmaceutical market may take different actions to fight against falsified medicines. Everyone can inform state authorities, if the impression of a fake medical product arises. In the case of this authority must take appropriate measures to prevent the break of law. Also counterfeit medicines can break intellectual property rights and aggrieved party may demand for compensation to protect their intellectual property rights. But, nevertheless, the introduction of criminal liability for such violations testifies to a special danger of crimes related to the falsification of medicines. In this vein, it is necessary to pay attention to measures of criminal responsibility provided in the criminal codes of European countries.

1. In Germany the criminal code does not contain a special rule that provides responsibility for the falsification of medicines [8]. But at the same time, the Medicinal Products Act (The Drug Law) contains special restrictions [9]. According to the articles 73, 96, 98 of this document, it is prohibited to introduce counterfeit medicinal products or counterfeit active substances into the territorial scope of the present Act. Any person who introduces a counterfeit medicinal product or a counterfeit active substance into the purview of the present Act, shall be liable to imprisonment for a term not exceeding one year or to a fine.
2. The Penal code of Netherlands provides charge for any person who sells, offers for sale or delivers food or drink or medicine, knowing that they have been adulterated, and fails to disclose this adulteration. Such person shall be liable to a term of imprisonment not exceeding three years or a fine of the fifth category (Section 330) [10].
3. The Penal code of Albania provides charge for producing, importing, storing or selling drugs which are dangerous or harmful to life or health. This offence is punishable by fine or up to ten years of imprisonment or even (when action has caused death or serious harm to the health of more than one person) by no less than five years of imprisonment (article 288) [11].
4. The Penal code of Hungary provides charge (imprisonment from one to eight years, depending on the circumstances) for any person who: falsifies, produces, imports or exports, or transports in transit, supplies, offers, places on the market or deals with falsified health care products, or acquires and/or possesses such in unreasonable quantities, or products which have not been authorized in Hungary (article 186) [12].
5. Lithuanian Criminal Code contains Article 275 on unlawful pharmaceutical activities where a natural and / or legal entity who has unlawfully manufactured medicinal products, active ingredients distributed them, may be sanctioned with a fine, arrest, or imprisonment up to two years, or even to eight years [13].
6. Pursuant to Article 194 of the Estonian Penal Code, illegal carriage of medicinal products across a state border with the intention of trafficking thereof, possession of falsified medicinal products with the intention of manufacture, production, marketing, supply, mediation or trafficking thereof, if the act does not constitute a criminal offence related to narcotic drugs or psychotropic substances, is punishable by a pecuniary punishment or up to three years' imprisonment [14].
7. In Polish criminal law there are no special rules that establish liability for counterfeiting medicinal products. But there are such closely related provisions: (1) any person who endangers the life or health of many people or property of a significant value by producing or marketing substances, foodstuffs or other commonly used goods that are detrimental to health, or pharmaceutical preparations that do not conform to binding quality standards, is subject to imprisonment for six months to eight years (Article 165); (2) any person who removes, alters or falsifies identification marks, a date of manufacture, or expiration date, is subject to imprisonment for up to 3 years (Article 306) [15].
8. According to the provisions of the Criminal Code of Romania (Article 357), the act of preparing, offering or displaying medicine that is fraudulent or substituted, which is harmful for health, shall be punishable by no less than 6 months and no more than 5 years of imprisonment and a ban on the exercise of certain rights. Besides, the act of selling medicine, while being aware that it is fraudulent, deteriorated or that their best-before date has expired, if they are harmful for health or if it lost its therapeutic value in whole or in part, shall be punishable by no less than 1 and no more than 5 years of imprisonment and a ban on the exercise of certain rights (article 358) [16].
9. In the Criminal code of Serbia there is no special offence for counterfeiting medicines, but at the same there is Article 256, according to which whoever produces for sale, sells or puts in circulation harmful medicines or medical devices, shall be punished by imprisonment of six months to five years and a fine [17].
10. The Criminal Code of the Kingdom of Spain punishes trafficking of falsified medicines (subject to imprisonment of six months to three years and special barring from profession or trade from one to three years): (1) Whoever alters, at the time of manufacture or preparation, or at a subsequent moment, the quantity, the dosage or the genuine

composition, as authorised or declared, of a medicine, fully or partially depriving it of its therapeutic effectiveness, and thus endangers the life or health of persons; (b) Whoever, in order to dispense or use them in any way, imitates or simulates medicines or substances that produce beneficial effects for health, making them appear to be real, and thus endangers the life or health of persons; (c) Whoever, being aware of their alteration and in order to dispense or assign them to use by other persons, stores on deposit, advertises or publicises, offers, displays, sells, facilitates or in any way uses the medicines stated, and thus endangers the life or health of persons (article 362.1) [18].

For example, it is advisable to mention the special provisions of the Criminal Code of Ukraine, namely under Article 321-1: production, purchase, transportation, transfer, possession for sale or sale of knowingly falsified drugs, are punishable by imprisonment for a term of 3 to 5 years. In addition, the legislation of Ukraine includes a mechanism that encourages offenders to stop illegal activities if such actions did not create a threat to human's life or health [19].

Thus, the illegal manufacture / sale of drugs is a criminal act in all countries. Typically, if offenses result in grave consequences (injury of several persons, death of a person), for it may be provided stricter legal measures. Falsified drugs have been directly banned in Ukraine, Spain, Romania, Hungary and Estonia.

RESULTS

Falsified medicines require collaboration at national, regional and international levels between the law providers, enforcement agencies, manufacturers and suppliers [20]. In order to ensure quality and availability of medicines in 1996 the European Directorate for the Quality of Medicines and Health of the Council of Europe (EDQM) was established at the European Committee of the Council of Europe [21].

In this context an important role is played by the convention «MEDICRIME» (The Medicrime Convention Combating Counterfeiting of Medical Products and Related Crimes), that was adopted by the Committee of Ministers of the Council of Europe in 2010. As of 2016, the Convention has been signed by 24 countries, but only 9 countries (Albania, Armenia, Hungary, Moldova, Spain, Ukraine, Guinea and others) have ratified it. The Convention obliges the member states to introduce criminal, civil, administrative responsibility for the falsification of medical products. Criminal liability should be provided for the following crimes: - deliberate manufacture, delivery and trade of counterfeit medical products, active substances, components, materials and supplies (Articles 5, 6); - falsification of any documents related to medical products with a view to misleading consumers as to its authenticity (Article 7); - unauthorized production or supply of medicines and marketing of medical products that does not meet certain requirements (Article 8). The Convention provides for the need to establish effective and appropriate sanctions, for example, a temporary or permanent ban on the implementation of a certain type of economic activity, liquidation of a business

entity, confiscation (and subsequent destruction) [22].

Countering the falsification of medicines can be carried out at the level of general regulations and with the help of special regulatory requirements. Regarding general regulations, it is necessary to note such rules: - registration procedure for admission of drugs to the market; - licensing of economic activities in the sphere of drug turnover; - introduction of obligatory conformity of producers, distributors, as well as other market participants with the requirements of good practice; - functioning of pharmacovigilance systems for medication use, state control of drug quality and compliance with licensing conditions. For example, each medicinal product must receive a marketing authorization before it can be marketed in Austria. In Finland medicinal product manufacturers must comply with good manufacturing practice for medicinal products [23]. According to Article 46 of the Directive 2001/83/EC, owner of a production license is required to: - comply with GMP rules, verify compliance by contractors; - inform owner of the marketing license and the relevant state supervisory authority about falsifications (suspicions) of medicinal products; - check the authenticity (of the individual package) and the quality of the active and auxiliary substances. Besides, at the request of a third country, the Commission shall assess whether that country's regulatory framework applicable to active substances exported to the Union and the respective control and enforcement activities ensure a level of protection of public health equivalent to that of the Union. If the assessment confirms such equivalence, the Commission shall adopt a decision to include the third country in a list [24].

In addition to general regulations, the EU directives contain a set of special economic regulations aimed at counteracting the trafficking of falsified medicines. Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC was aimed at consolidating of provisions concerning prevention of fraud in the legal supply network [25]. These positions can be divided into several groups. Articles 77, 80 of the Directive establish special requirements for licensing of wholesale trade in medicines. The licensee, among other things, is obliged: - make sure that the received medicines are not falsified, by checking the safety characteristics of the secondary packaging; - have an emergency actions plan to ensure effective implementation of the order to withdraw the drug from circulation; - keep documents on transactions of purchase and sale of drugs during 5 years; - follow the standards of the quality assessment system, etc. [25]. The requirements of Section V of the Directive «Labeling and the package leaflet» play the most important role in counteracting the trafficking in falsified medicines: in addition to the wide list of information that must be fixed on secondary packaging (if it is not available on the primary packaging), it is necessary to indicate the number of preparation's production series, assigned by the manufacturer, and a unique identifier [25].

Experts argue that distribution channels should be upgraded with the latest technological instruments like Barcode, Subsurface fast internal engraving and reading

system for anticounterfeiting applications (SFERA), Holograms, hidden identification marks, Radio Frequency Identification (RFID) chips and tags, so that individual serial numbers on each product can be tracked and traced through the supply chain [20]. Authors mention that a thin layer chromatography (TLC) is the main screening method used today to decide if a drug product meets label specifications and is legal. Drug screening TLC methods are simple, inexpensive, selective, and semiquantitative, and they can be used in the laboratory or in the field in locations such as a port of entry, distribution center, clinic, pharmacy, or hospital. TLC can give an indication whether the active ingredient is present and its level of content, and, therefore, if the product is qualified or authorized or legal on this basis. Some related substances may also be detected and quantified. However, TLC will not detect counterfeits that have wrong active or inactive ingredients if they are not visualized by the detection method being used for the correct active drug. The TLC is more informative than visual inspection, dissociation tests, or simple color reaction tests, and their standardized format, ease of performance in the field by persons without extensive technical training, and low cost are of great benefit to developing countries throughout the world in screening medicines used for fighting diseases such as TB and malaria [26].

The EU has set the objective and a deadline of 2018 to provide a system of protection patients from falsified medicines. The EU obligation demands that each packet of a prescription medicine should bear a unique number to identify individual packs. Pharmacies will need to be equipped with a scanner and a rapid link to a central computer, where an instant read-out will authenticate the unique identifier, or set off an alarm if an inconsistency is detected [27]. Commission delegated regulation (EU) 2016/161 sets out a system where the identification and the authentication of medicinal products is guaranteed by an end-to-end verification of all medicinal products bearing the safety features, supplemented by the verification by wholesalers of certain medicinal products at higher risk of falsification. In practice, the authenticity and integrity of the safety features placed on the packaging of a medicinal product at the beginning of the supply chain should be verified at the time the medicinal product is supplied to the public, although certain derogations may apply. However, medicinal products at higher risk of falsification should be additionally verified by wholesalers throughout the supply chain. The verification of the authenticity of a unique identifier (it can be correctly recognised and decoded throughout the Union by commonly-used scanning equipment) should be performed by comparing that unique identifier with the legitimate unique identifiers stored in a repositories system. When the pack is supplied to the public, or is distributed outside the Union, or in other specific situations, the unique identifier on that pack should be decommissioned in the repositories system so any other pack bearing the same unique identifier could not be successfully verified. The manufacturer shall place on the packaging of a medicinal product a unique

identifier which complies with the following technical specifications: (a) The unique identifier shall be a sequence of numeric or alphanumeric characters that is unique to a given pack of a medicinal product; (b) The unique identifier shall consist of the following data elements: (1) a code allowing the identification of at least the name, the common name, the pharmaceutical form, the strength, the pack size and the pack type of the medicinal product bearing the unique identifier («product code»); (2) a numeric or alphanumeric sequence of maximum 20 characters, generated by a deterministic or a non-deterministic randomisation algorithm («serial number»); (3) a national reimbursement number or other national number identifying the medicinal product, if required by the Member State where the product is intended to be placed on the market; (4) the batch number; (5) the expiry date; (c) The probability that the serial number can be guessed shall be negligible and in any case lower than one in ten thousand; (d) Manufacturers shall encode the unique identifier in a two-dimensional barcode (it shall be a machine-readable Data Matrix and have error detection and correction equivalent to or higher than those of the Data Matrix ECC200); (e) Barcodes must conform to the International Organization for Standardisation/International Electrotechnical Commission standard («ISO/IEC») 16022:2006; (f) Manufacturers shall print the barcode on the packaging on a smooth, uniform, low-reflecting surface, besides there are special provisions about quality of the printing of the two-dimensional barcode etc. [28].

3. Section 7a of the Directive establishes special requirements for the remote sale of medicines by means of information services, for example, with regard to products that can be sold via the Internet, requirements for Internet sites, as well as to business entities that carry out such activities. The existence of special rules is due to the fact that the Internet is the main source of distribution of fakes [24]. Experts identify a growing worldwide criminal trend: in over 50% of cases, medicines purchased over the Internet from illegal sites that conceal their physical address have been found to be falsified [29].

4. In Articles 85d, 118b of the Directive 2001/83/EU special attention is paid to the need for information campaigns aimed at informing general public about dangers posed by falsified medicines [25].

5. Directive 2001/83/EC does not contain specific sanctions for the turnover of falsified medicines: 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. Also the competent authorities shall suspend, revoke or vary a marketing authorisation if the view is taken that the medicinal product is harmful or that it lacks therapeutic efficacy, or that the risk-benefit balance is not favourable, or that its qualitative and quantitative composition is not as declared. Therapeutic efficacy shall be considered to be lacking when it is concluded that therapeutic results cannot be obtained from the medicinal product (articles 116, 118a) [25].

All stake holders are encouraged to actively participate in combating falsified medicines. Pharmacists are expected to be aware and vigilant, purchasing their medicines only from a reputable source. Once a falsified product has entered the legitimate system, it becomes rather difficult to detect [30]. To successfully stem the flow of falsified medicines, we must attack both supply and demand. On the supply side, pharma companies should actively monitor their supply chains to detect the presence of counterfeits. Forging strong partnerships with enforcement authorities in each region and country is the keystone to a successful anti-counterfeiting program. On the demand side, we must continue efforts to educate patients, as well as NGOs and trade associations to raise awareness among patients to the threat that falsified medicines do pose to their health and safety. As noted by the WHO, «they can be found in illegal street markets, via unregulated websites through to pharmacies, clinics and hospitals». Counterfeit medicines are frequently smuggled into a country by those who either conceal them in electronic equipment, stuffed animals, or in false compartments constructed in shipping containers or even gas tanks of their vehicles. We have noted that those involved in the distribution of counterfeits use complex transport routes in order to evade customs controls [31]. Education efforts may include teaching consumers how to spot a fake, publishing a list of legitimate distributors, and offering warranties, guarantees, or other after-sale services [32]. Patients, who are usually the first to notice something wrong with their medicine are encouraged to make a report [30].

There are some advices how to avoid buying falsified medicines: - before you get any new medicine for the first time, talk to a health care professional; - buy your medicines through a legal channel; - abnormally low prices, unusual packaging, shape or color of the medicine may point to a counterfeit product, so check the physical appearance of the medicine (color, texture, shape, and packaging); - check to see if it smells and tastes the same when you use it; - alert your pharmacist or your doctor if you have any doubt on counterfeiting (packaging defect, side effect etc.); - if you suffer any severe and/or unusual secondary effects talk to a doctor; - when you are buying drugs, make sure that the packaging is undamaged and that there are no visible anomalies on the box, in the instructions for use, the blister pack, or in the drugs themselves, etc. [33].

DISCUSSION

Most often the subject of falsification are expensive drugs, yielding high profits even with a small sales volume, and widely used (cheap) medicines bringing in profit due to a large volume of sales. Among them the first place in the number of falsifications is occupied by antimicrobials, including antibiotics, antimalarial drugs, anti-tuberculosis, antiretroviral drugs, the second – antihistamines, the third – hormones and steroids [3]. Besides falsified can apply to both branded and generic products [29]. Experts argue that «The biggest problem is the so-called lifestyle

area, which includes anabolic steroids, hair growth means, potency or slimming products [5]. The following methods of falsification are widely used: - an excellent imitation (copy) of active substance and packaging of a well-known brand; - imitation of drugs, which does not contain active substance (insufficient quantity or another substance, that does not correspond to Information on the package); - preparations containing contaminants or toxic substances [2]; - products with fake packaging [29]; - products which deliver false information about their composition or their real source; - products which may be ineffective [33].

The global pharmaceutical markets have always suffered from a spate of falsified products including fake, spurious, substandard and fraudulent preparations. Since generic drugs attract low prices and margins, the high cost economies of the developed countries of North America, Europe and Japan are more than likely to turn to the low cost economies of India, China and Brazil to outsource their drug needs [34]. That is why fake drugs income to develop markets from other countries. There are two important factors responsible for the global counterfeit drugs phenomenon in Central-East Europe. First, the insufficient knowledge about counterfeit medicine among professional health care workers and government administration, mainly regarding the police and customs service. The majority of physicians (73.5%) and almost 30% of nurses said that they do not warn patients against counterfeit medicines. Second, reluctance of pharmaceutical companies to publicize their data about counterfeit drugs. Although the pharmaceutical industry suffers multi-billion euro losses, it still unwillingly acts against illegal competition. Many companies do not want to publish reports on the counterfeiting of their products and do not share the information with the police or warn their patients. They are afraid that their image may be ruined, resulting in sales decreases [4]. According to the economical rules pharmaceutical manufacturers find more profitable investments in marketing and sales, rather than the development of new drugs [1].

WHO identifies the following common factors contributing to the falsification of medicines: - imperfection of the regulatory framework; - incompetence of national authorized bodies or their absence, as well as their ineffective interaction; - failure to comply with requirements of the current legislation; - insufficiently stringent penalties; - corruption and conflict of interest; - transactions involving many intermediaries; - demand exceeds supply; - high prices; - improvement of illegal production of medicines; - inefficient regulation in exporting countries and free trade zones [2]. A number of cases have been documented within EU member states. For example, in 2006/2007 a seizure of counterfeit heparin (Belgium/Germany) was found to contain a heparin like contaminant which was added to heparin resulting in allergic reactions and possibly caused deaths in 81 cases [30]. Polish authorities have shut down a factory in Koronowo, near the city of Bydgoszcz capable of making millions of counterfeit medicines. Over 100,000 counterfeit erectile dysfunction pills were seized along

with 430,000 vials of steroids of all brands. The group had its own websites and even brands with anti-counterfeiting authentication codes [35]. Also organized criminals cut huge profits by smuggling counterfeit drugs into Germany. Unlike traditional drugs, counterfeit pills are quite easy to smuggle and they can be sold for high prices. Criminal law Professor Arndt Sinn has an answer why the counterfeit drug business is booming: «Why should I kill myself as a criminal with dangerous drug stores, if the profit margins for counterfeit drugs are much bigger? From one kilo of raw cocaine worth 1000 euros you can make 45,000 euros, from one kilo of Viagra active ingredient Sildenafil, which is sold for 50 euros, you can easily earn 90,000 euros». [5].

Falsified medicines give rise to multiple risks: - they don't ensure quality, security nor therapeutic efficacy, because they may be not approved by National Health Agency, so they can endanger patient's health; - the spoilage of products due to the possibility of improper storage conditions; - they can cause harm and expenses for caregivers [29]; - if the adulterated products contain the same substances as the original one, their uneven maintenance in preparations is not excluded (the active substance may be either too much or too little); - due to the ineffectiveness of counterfeit drugs, treatment can be delayed, or, starting too late with the use of original drugs, runs the risks of being useless; - they can feed a parallel and freeloading economy, which is contrary to sustainable development; - patients lose confidence in medicines, health systems [31].

Counterfeit medicines may be known by many names – counterfeit, spurious, falsified, fake [31]. Let's try to understand this issue. The concepts of «falsified drugs», «counterfeit drugs», «substandard drugs» have certain differences legally. Very often falsified and counterfeit medicines are used synonymously, but they have different meanings. Low-quality drugs that have become unusable due to the expiration of expire date (violation of the conditions for their storage, sale, transportation. «Counterfeit» means drugs, production and further sale of which are carried out intentionally under a different means of individualization (trademark) without a permission from rightholder. It is a violation of intellectual property rights. According to WHO definition a counterfeit medicine is a product that is intentionally and illegally equipped with a marking that distorts the authenticity or the manufacture. As a rule, falsified products are also substandard and counterfeit. Falsified preparations can be classified into «black» and «white». «White» are such preparations, the qualitative and quantitative composition of APIs corresponds to the marking. As a rule, they are falsified by the manufacturer's trademark, but often their quantitative composition can be disrupted, other auxiliary substances can be used and ingredients usually do not meet requirements of the Pharmacopeia). In highly developed countries those fully meet requirements of the Pharmacopeia. «Black» are those medicines which qualitative and quantitative composition does not correspond to the labeling: instead of the claimed amount, the API contains a different (smaller) quantity, or another, cheaper API, or it is not available at all. Turnover

of «black» drugs provides the highest profit, but they may be easily identified by professionals and patients. For this reason they are presented in undeveloped countries with a weak system of state quality control [36].

In this regard, we must agree with the definition of falsified medicines, which is fixed in the Article 1 of the Directive 2001/83/EC, according to which falsified medicinal product – any medicinal product with a false representation of: - its identity, including its packaging and labeling, its name or its composition; - its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; - its history, including the records and documents relating to the distribution channels used [24]. For example, the definition of falsified medicines in the Penal Code of Netherlands does not correspond to this norm, since they are understood as low-quality drugs [10]. Although falsified medicine can be a good product. It is important to note that counterfeit drugs can be manufactured by officially registered and licensed manufacturers, and by persons who do not have appropriate permits. In the first and in the second case, such activity is illegal. The only difference is that in the second case there is also an additional offense – illegal entrepreneurial activity.

CONCLUSION

Thus, falsified medicines cause both social and economic harm to society. Falsified, counterfeit and substandard medicines should be distinguished. Although there are recommendations for patients to identify falsified drugs, the main value in countering their turnover is the law. Countering can be carried out at the level of general regulations, as well as through special regulatory requirements. The last one can be divided into economical (establish rules for market participants how to identify and remove falsified medicines) and those which impose sanctions for offenses. In accordance with the special EU directives legislation on medicines of the EU member states has a similar character. In all examined countries, the turnover of falsified medicines is strictly prohibited and criminal or administrative liability is provided for such acts. At the same time, there is no single approach to criminal liability and it is determined by national governments.

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ADDRESS FOR CORRESPONDENCE

Pashkov Vitalii

Department of Civil, Commercial and Environmental Law, Poltava Law Institute, Poltava, Ukraine
tel.: +380-532-560-148
e-mail.: poltava_inst@nulu.edu.ua

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