

## CRIMINAL LIABILITY FOR THE TRAFFICKING IN COUNTERFEITED MEDICINAL PRODUCTS: PROBLEMS OF LEGISLATION AND ENFORCEMENT IN UKRAINE

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**Abstract:** The paper focuses on consideration of factors of international, socio-economic and legal nature that determine the dynamics and content of criminal liability for trafficking in counterfeit medicines in Ukraine. Some discussion points, both theoretical and legal, concerning trafficking in counterfeit medicines are considered. Attention is drawn to the fact that counterfeits' volume is highly dependent on the amount of patent advertising of medicines, which is an appropriate benchmark for criminals who manufacture low-quality and unregistered medicines, mainly in underground handicraft production. Particular attention is paid to the ratio of counterfeiting and patent advertising of

medicines. It is investigated Art. 321-1 of the Criminal Code of Ukraine, in accordance with the perfection and clarity of legislative definitions, their compliance with requirements of systematic interrelation of criminal law provisions, justice principles and differentiation of criminal liability. It is proved that it is important to develop our own legislative and enforcement experience in the field of preventing the trafficking in of counterfeit medicines, systematic principled approaches in the part of regulatory legal formulations and their judicial interpretation during practical application. In particular, the improvement of the criminal law in terms of ensuring the clarity of penal provisions contained in Art. 321-1 of the

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Criminal Code of Ukraine, as well as determining the place and role of the relevant article of the Criminal Code in the system of other criminal legal norms that affect the population health.

**Keywords:** counterfeiting, criminal liability, drugs, superpotent, toxic.

### Introduction

The relevance of the chosen topic is determined by many factors of international, socio-economic, legal nature that will allow time, space and subjects of certain relations to determine the dynamics and content of criminal liability for trafficking in counterfeit medicines in Ukraine, to determine the problems of legislation in this part. At the time of enforcement of the new criminal legislation of Ukraine (Criminal code..., 2001), legal protection of safety of biological, physical, psychological state of both a person and an indefinite group of persons was considered mainly from the point of view of effectiveness of illicit trafficking, prevention of narcotic drugs, psychotropic substances, poisonous and potent substances, intoxicants, poisonous and potent drugs. However, the identified trends in the constant and significant annual increase

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in the demand of the population of Ukraine for medicines that were converted to consumer goods, used by the population both in cases of direct disease treatment, and in cases of their prevention – increased the relevance of these medicines' quality, opportunities volumes of trafficking in pharmaceutical market of low-quality, counterfeit medicines.

Since 2003, the problem of preventing admission to pharmaceutical market of counterfeit medicines in Ukraine has been recognized nationwide. The Resolution of the Cabinet of Ministers of Ukraine approved the program for combating production and distribution of counterfeit medicines for 2003-2008, which provides for significant strengthening of state regulatory functions, control over the quality of medicines at all stages of their trafficking (Program of fight against production..., 2003). However, in addition to certain organizational and functional deficiencies in activities of government agencies to prevent counterfeiting of medicines (lack of proper control over trafficking, quality, import of medicines; presence of large quantity of intermediaries in trade; conflict of

interests, corruption, etc.), there were also legal factors, including criminal law, that should work to prevent drug offenses. The lack of proper and effective legislation to prevent adulteration of medicines, and determination of relatively lenient administrative penalties for such activities, not least have led to sufficiently low rates in the fight against these offenses. Therefore, in 2011, the Verkhovna Rada of Ukraine adopted the Law of Ukraine "On Amendments to Certain Legislative Acts of Ukraine on Prevention of Counterfeiting of Medicines" (Law of Ukraine "On Amendments...", 2011), which amended the Criminal Code of Ukraine. Among other things, the Criminal Code was supplemented by Article 321-1, "Falsification of medicinal products or trafficking in counterfeit medicinal products". The relevance and appropriateness of such a decision by the legislator was exacerbated by the fact that Ukraine signed the MEDICRIME Convention (Council of Europe Convention..., 2011).

Considering the time that has elapsed since criminal liability for trafficking in counterfeit medicines in Ukraine has been put on the agenda, the

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question on accumulation of certain scientific knowledge about the current state of affairs of its implementation must be raised. This problem should reproduce the peculiarities of content and dynamics of its interconnected systemic components relating to international and social conditionality of establishing criminal liability, authentic content and nature of relevant existing criminal law provisions and directions for further improvement of the criminal law, and most importantly, the problems – provisions in criminal proceedings and sentencing.

### **Materials and Methods**

The results of enforcement are one of the criteria that allows to know and evaluate the effectiveness and efficiency of criminalization and penalization of relevant socially dangerous actions. It is this data that reproduces current legal realities, hence the disadvantages and contradictions as legislative provisions, and problems of its modern judicial interpretation. It is considered the development of own law-making and law enforcement experience in the field of prevention of trafficking in counterfeit medicines, development of systematic principled approaches in the

part of regulatory legal formulations and their judicial interpretation during practical application.

The study included statistics from the State Service for Drugs and Drug Control, statistics on criminal offenses conducted by the National Police, and data from the Unified Register of Judgments on sentences for trafficking in counterfeit drugs. Historical method was used to determine the stages of criminal responsibility for trafficking in counterfeit medicines. Sociological and statistical methods were exploited for analyzing statistics published by the State Service for Drugs and Drug Control, Prosecutor General's Office of Ukraine for criminal offenses, which are pre-trial investigated by the National Police, data from the Unified Register of Judgments on Counterfeiting of Drugs. Method of systematic analysis was depleted to compare different regulatory acts regulating trafficking in counterfeit medicines.

### **Results and Discussion**

The results of a comprehensive scientific study on the problems of counterfeiting and trafficking in counterfeit medicines, conducted by I.A. Kovalenko (2017) are important. Their

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importance for further research, law-making and enforcement activities in this field is enhanced by the fact that the author has explored a significant number of aspects (socio-economic, international, legal) that have provided an opportunity to determine the directions of further improvement of criminal law, to increase the effectiveness of enforcement.

V.O. Merkulova (2017a) analyzed separate problems of action's qualifications, the subject of which are poisonous, superpotent substances; poisonous, superpotent and counterfeit medicines, expedient definition in this conceptual apparatus' part, formulation of expanding directions of criminal liability for counterfeit medicines' trafficking. Special publications draw attention to increasing the relevance of problems related to delimitation of related criminal offenses, the ratio of their general and special structures. Special scientific publications analyze organizational and legal mechanism of counteracting the smuggling of counterfeit medicines (Avdeev, 2015), criminal-legal characteristics of objective and qualifying features of counterfeiting medicines (Baylov, 2013; Melnichuk, 2014), quality, safety and

adulteration of medicines (Varchenko, 2001), etc.

The importance of the problem under investigation is also proved by the fact that issue of expediency (impracticality) of establishing criminal liability for trafficking in counterfeit medicines became the subject of special journalistic investigations, which were based on the study of certain socio-economic indicators and relevant statistics, and reproduced public opinion on the state's opinion. In particular, articles by E. Aleksandrov (2018), Y. Butusov (2011), A. Deyev (2010), I. Lobusova (2017), O. Revenko (2019) deal with the problems of pharmacological market, ways of ensuring public health, negative trends in production and trafficking in medicines, the importance of the Internet drug trade. The appeal to the results of some journalistic research is due not least to the fact that to this day the number of issues remains significant, they do not have an unambiguous solution. The existence of certain theoretical and legal discussions concerning trafficking in counterfeit medicines only confirm complexity and multiplicity of the problems, confirm the need for their further in-depth scientific research.

Discussion on the existence of grounds for criminalization of actions related to the trafficking in counterfeit medicines started in Ukraine on the eve of the Verkhovna Rada's decision on criminal liability for this. Extremely opposite statistics was provided, and accordingly their justification. The specialists' opinions depended on the sense of counterfeit medicines, whether the fact of mass trafficking in counterfeiting was acknowledged, and, accordingly, recognition of expediency of establishing criminal liability for such and so on. Accordingly, quite different indicators were called. According to some, low-quality and unregistered medicines account for only 1.5 – 1.8% of pharmaceutical market in Ukraine, most of which is the so-called "white counterfeit", which poses no health risk or counterfeit medicines (Deyev, 2010). However, more common is the position of scientists who believe that this figure ranges from 15 to 30% (Kovalenko, 2013). In the explanatory note to the Draft of Law of Ukraine On Amendments to Certain Laws of Ukraine on Prevention of Falsification of Medicines (Draft of Law of Ukraine..., 2010) 50% has already been stated.

Some idea about trafficking in counterfeit medicines is provided by statistics on some medicines withdrawn and destroyed by the State Inspectorate for Quality Control of Medicines in Ukraine. According to these data, in 2015, 323 orders were issued to prohibit trafficking of 289 names of substandard medicines; in 2016, accordingly, there were 231 orders for 293 titles; in 2017, there were 298 orders for 283 titles; in 2018 – 272 orders for 259 titles, in the first half of 2019 – there were 151 orders for 118 names (9). The indicators are more or less stable and indicate that almost every year, with respect to nearly three hundred medicines, there is a question of non-compliance with their standard quality requirements. Does this indicate the scale of the fakes? At first glance, no. Since, based on the total number of registered medicinal products (in particular, 12 567 medicinal products were registered) (State Register of Medicines..., 2020), the names of medicinal products detected as counterfeit is no more than 2.4%. However, these data do not reveal the fakes' scale, the quantity of packages of poor quality medicines. It is the latter indicator (given the high latency of these offenses and corruption component) that

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creates a greater risk of counterfeiting because it can indicate the number of potential victims. Thus, on the eve of criminal liability for trafficking in counterfeit medicines, it was stated that in 2010 the State Inspectorate for Seizure withdrew and destroyed 2.6 million packages of poor quality medicines in Ukraine (Butusov, 2011).

The statistics on pre-trial investigation of relevant criminal offenses and the case-law on this part do not add to the specificity and clarity of the matter. First of all, indicative is the data for 2018, which states that the number of reported criminal offenses in Ukraine under Art. 321-1 of the Criminal Code amounted to 38 cases; suspicion notification was served in 2 cases; proceedings are sent to court with an indictment on one criminal offense; proceedings are closed for seven criminal offenses. As a result, at the end of the reporting period no decision was taken on 37 criminal offenses (Statistics on criminal offenses..., 2020). Accordingly, the number of decisions taken by the courts of Ukraine under Art. 321-1 of the Criminal Code “Falsification of medicinal products or trafficking in counterfeit medicines” is relatively small. In the last five years

(2015-2019), fifteen sentences have been passed.

How many low-quality medicines do consumers in Ukraine buy? Is there a threat of mass uncontrolled production of counterfeit medicines? How dangerous is the situation with trafficking in counterfeit medicines in Ukraine today? Therefore, these and other related questions to date do not have specific answers as well as relevant statistics. However, we can come closer to a less objective assessment of the state of affairs in this area on the basis of an analysis of other socio-legal data that indirectly testify to the existence of significant problems in that area.

On the basis of certain generalization of socio-economic and legal factors that exist in countries that suffer from a large volume of low-quality, fake, counterfeit medicines, certain less typical tendencies that are peculiar to life activity of citizens of these countries are distinguished. Traditionally, counterfeit medicines have a wide trafficking scope where there is widespread demand for medicines, high prices are set, there is no domestic pharmaceutical industry, an inadequate control system, and there is an increase in volume of Internet

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commerce that is practically impossible to control. Attention is drawn to the fact that counterfeits' volume is highly dependent on amount of patent advertising of medicines, which is an appropriate benchmark for criminals who manufacture low-quality and unregistered medicines, mainly in underground artisanal production. If we turn to the national statistics, following these trends, as such, which indirectly indicate a significant trafficking of poor quality, counterfeit medicines, the authors should note the following.

The potential trends in sale of counterfeit, falsified substandard medicines in Ukraine can be demonstrated by the following trends observed in pharmaceutical market. The annual increase in sales of medicines is well in excess of 20%. So, in particular, in 2017 sales of all pharmacy basket products increased by 22.5% compared to 2016 and reached 89 billion hryvnias. In the medicines' market's structure, retail segment prevails, which, according to some data, is almost 85% (accordingly, hospital segment is within 15%), which indicates a considerable volume of sales of drugs through the pharmacy network. In particular, in

2017, retail sales reached USA \$ 3.3 billion (Kirilenko, 2019).

The drug sales network is growing quite rapidly and is confirmed by the data on pharmacies' quality, drug stores of some wholesale drug companies. In Ukraine, more than 500 wholesale companies are engaged in medicines' sale, which makes it practically impossible to effectively control storage and certification of medicines (Butusov, 2011). As of 2013, a large network of relevant entities has been selling medicines: 13,395 pharmacies, 593 pharmacy warehouses, 5.443 pharmacy points, 3,248 pharmacy stalls, where more than 80% of medicines are sold without a doctor's prescription (Kovalenko, 2013). It is argued that in 2009-2011 the number of applications for opening pharmacies increased almost threefold annually (Butusov, 2011).

Equally important is the ratio of the amount of counterfeits and patent advertising for medicines. After all, the advertising impact on motivational sphere of fraud is unconditional. It is precisely the prohibition of such advertising that both significantly reduces the fictitious demand for medicines and counterfeiting amount. It

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is therefore natural that in most European countries there is prohibition on medicines' advertising. However, in Ukraine, on the contrary, there is a reverse process in which we have the opportunity to be sure when watching any television program. Studies of this issue at the regional level (Odessa region) gave reason to claim that falsifications are the most commonly advertised medicines, which are the most used consumers (alcohol-containing substances; analgesics; antiseptic and antispasmodic substances; substances used in cardiology; antimicrobial agents; substances used in cardiology; meds used for colds, digestion enhancers, etc.) (Lobusova, 2017). According to the court sentences of Ukraine from 2015 till the first half of 2019 falsifications were subjected to "Ethyl alcohol – 96%", "Ethanol-96", "Festal", "Fluculd-N", "Teraflu against influenza and cold with lemon taste", "Pharmacetron", "Ketanov", "Botox®".

The risk of consumer receiving counterfeit medicines increases in direct proportion to the volume of medicines purchased online. According to the survey of households' access to the Internet, the State Statistics Committee

of Ukraine reports the following data: 72.2% of households in big cities and 61.3% in small cities use the Internet. Among the main purposes used by the Internet users are "health – medicines, medical services, nutrition tips" (Revenko, 2019). As already mentioned, one of the factors contributing to the forgery spread may be the presence of meds' high prices. According to various studies, meds' prices have increased significantly in recent years. Various indicators (from 30 to 50%) are called. Thus, in particular, according to regional data, the medicines' cost in the Odessa region increased by an average of 47% (Aleksandrov, 2018). So the cost has almost doubled and this increase applies to both domestic and imported medicines.

The falsification of medicinal products is mainly carried out in countries where there is no domestic pharmaceutical industry. Extending this view, it can be noted that this situation may also apply to those countries where domestic production is negligible. The data from the special studies confirm that such countries include Ukraine, in which most medicines are of foreign origin. According to some data, more than 70% (Kovalenko, 2013). In support of such a

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statement the data of the State Register of Medicines of Ukraine testify: as of May 2016, 12 567 medicines (3 774 domestic; 8 793 foreign) were (State Register of Medicines..., 2020). In addition, it should be borne in mind that about 600 manufacturers are sold on the Ukrainian pharmaceutical market, of which only 140 are Ukrainian enterprises (State Register of Medicines..., 2020). Accordingly, it is reasonable to argue that smuggling of goods through the customs border continues to be one of the main channels of counterfeit medicines' supply (Lobusova, 2017).

However, there is no less danger in the production of substandard and unregistered medicines in underground handicraft production, where large-scale illegal production of medicines with cheaper, substandard components, with non-observance of technologies, is most often occurring. According to the State Service for Medicines and Drug Control in Odessa region, in 2017, mostly counterfeit medicines are manufactured in underground workshops, at enterprises that are not licensed (Lobusova, 2017). The validity of this claim is also confirmed by our research regarding the relevant analysis of courts' sentences in

Ukraine in relation to persons who committed acts, provided for in Art. 321-1 of the Criminal Code, from 2015 to the first half of 2019 (more specifically in the following).

Aggregation of data on the rate of growth of drug trade, significant expansion of pharmacy network, distribution of medicinal products and their trade via the Internet (against background of lack of proper state control, corruption component and high latency of offenses) indirectly testify to the fact that trafficking in fake, counterfeit, poor-quality medicines in Ukraine not only pose a significant threat to public health, but also that the extent of this threat will increase. Therefore, the authors need to talk not only about the problems of criminal liability for trafficking in counterfeit medicines, but also to determine ways to further expand the scope of criminal law in this part.

Since Art. 321-1 of the Criminal Code is a novel, objectively raised questions at the level of specific scientific research on the perfection and clarity of legislative definitions, their compliance with the requirements of systematic interrelation of criminal law provisions, principles of justice and differentiation of criminal liability. The

subject of the analysis of scientists is correlation of content and essence of the main and qualified composition of crime, its individual features, problems of conceptual apparatus, the fair ratio of act's gravity and amount of criminal responsibility (punishment) for a given socially dangerous act.

On the basis of system-legal analysis and interpretation of content and essence of the current criminal law norms (in particular, dispositions, sanctions, incentive rules, notes, etc.), which as an object of crime contain indications of poisonous or potent drugs, falsified medicines. 305, 306, 321, 321-1 of the Criminal Code, scientists concluded that there were certain contradictions in them, lack of clarity and completeness in determining the grounds and conditions of criminal liability, need for further clearer differentiation and individualization of criminal responsibility and punishment for trafficking in counterfeit medicines measures depending on degree of offence's public danger (drugs health hazard), finally – feasibility significant extension of this responsibility. As a justification for the above, the authors propose to consider separate doctrinal provisions based on systematic analysis

of current criminal law conducted by I.A. Kovalenko, V.O. Merkulova.

Substantial change in the art. Art. 305, 306, 321 of the Criminal Code, in which, accordingly, the legislative novelty is the responsibility for smuggling of counterfeit medicinal products, for funds' using from trafficking in toxic or potent drugs, for trafficking in toxic or potent drugs. Emergence of a new Article 321-1KK, which establishes responsibility for adulteration of medicinal products or trafficking in counterfeit medicines (Criminal Code..., 2001), reinforced the relevance of a proper interpretation of legislative provisions in delimitation of related crime warehouses, clarity and consistency of these norms, both in terms of conceptual apparatus and in determining the appropriate list of actions to be criminalized. The Criminal law contains the same concepts (terms), which in terms of content may differ:

– the concepts of poisonous or potent substances in content and structure include poisonous and superpotent medicines (Art. 201);

– poisonous or potent substances and poisonous or superpotent medicines are already delineated (Art. 306, 321);

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– falsified medical measures are distinguished (Art. 305, 321-1); falsified medicinal measures are distinguished (Art. 305, 321-1) (Criminal Code..., 2001).

How appropriate is such a different content of these concepts in the criminal codes we have specified. This problem deserves further more thorough research not only from the point of view of comparing the considered norms as contiguous, but also in order to clarify certain features in the competition of general and special criminal law norms (Merkulova, 2017b). It is proved that establishment in 2011 of criminal liability for smuggling of counterfeit medicines (Art. 305), falsification of medicinal products or trafficking in counterfeit medicines (Art. 321-1) is only a partial solution to problem of criminalization of socially dangerous acts, the subject of which are counterfeit medicines (Criminal Code..., 2001). The complexity and versatility of controlling drug trafficking, insufficient level of effectiveness of certain governmental and organizational measures should be considered as a basis for expanding the scope of criminal-legal measures in relevant crime prevention, to be reproduced in establishing more severe

responsibility for all those types of criminal behavior. related to adulteration of medicines.

In a point of fact, particular importance should be given to the relevant predicate crimes in case of legalization (laundering) of proceeds from their trafficking, to the increased severity of punishment for funds' using from their sale. Modern socio-economic and legal factors testify to expediency of establishing criminal liability for legalization (laundering) of criminal proceeds from the trafficking in counterfeit medicines, and hence their definition as a crime subject in Art. 306 of the Criminal Code (except for toxic, superpotent medicines and other crime objects) (Merkulova, 2017b). Besides, among the problems of clarifying further directions of expanding the sphere of criminal regulation of relations, the subject of which are medicines, the question becomes more urgent of responsibility of legal entities for funds' using, obtained from trafficking in counterfeit medicines. It is a component of further and more in-depth study criminal grounds and conditions for establishing liability of an entity in the case of commission any actions by authorized person, the subject of which

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is counterfeit medicines (Kovalenko, 2017).

No less fundamental there are proposals for further differentiation of criminal liability depending on the quality of counterfeit medicines, the nature of their impact on person's life and health. The fact of safety, harmfulness, significant danger of counterfeit medicines should be taken into account during forming the main and aggravated especially aggravated crime, to influence the criminal responsibility and punishment. It is not meaningless the thought that signs and properties of special subject of a crime (availability of specialist knowledge, performing of professional duties in the field of health care) should be considered by legislator as aggravated ones (especially aggravated) circumstances that enhance the severity of criminal liability (Kovalenko, 2018).

At the same time, the content of criminal provisions, which determine the grounds for criminal liability for trafficking in counterfeit medicines, provides grounds for different scientific interpretation, and in accordance with discussion on the perfection of the current version of Art. 321-1 of the Criminal Code. In particular, on the basis

that legal literature some scientists distinguish "false" and "counterfeit", counterfeit products are not always false, which in the Convention (MEDICRIME) refers separately to the need to introduce criminal liability for manufacture of counterfeit medical products and trafficking in counterfeit medical products. It is proved the expediency of a clear delineation in the norm of false and counterfeit medicines, establishment of less stringent liability for falsification of medication data only, including copyright infringement (Kovalenko, 2017).

If the latter deserves support, then the allocation of counterfeit medicines in the content of Part 1 of Art. 321-1 of the Criminal Code is not appropriate. In this case, particular attention is paid to the factors that, in terms of etymological content and substance, counterfeit medicines in which external data on these products are counterfeit are a component of counterfeit medicines, when both medicines data and content of these counterfeits can be counterfeit. Thus, counterfeit medicines are a broader concept (social and legal category) that includes counterfeit medicines. This is confirmed by the content of the relevant

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international legal and domestic legislative provisions. In the Council of Europe Convention on the Suppression of the Falsification of Medical Products and Related Health Threatening Offenses (MEDICRIME), "falsification" is a fairly broad concept encompassing any falsification of documents relating to medical products, any unauthorized manufacture and supply of medicines and marketing of medical devices that do not meet certain requirements (Council of Europe Convention..., 2011). In addition, according to the legal definition in Art. 1 of the Law of Ukraine "On Medicines" the concept of "falsified medicines", this concept covers all cases of deliberate forgery of information about medicinal product entered in the State Register of Medicinal Products of Ukraine (non-identical marking, non-compliance with the registered composition, etc.) (Law of Ukraine "On Medicines" ..., 1996).

However, the study and analysis of court sentences of different regions of Ukraine for the last five years, which prove the acts' qualification and establish the guilt under Art. 321-1 of the Criminal Code "Falsification of medicinal products or trafficking in counterfeit medicinal products" provide

specific grounds for deepening the discussion on clarity and validity of the current version of main and aggravated crime (Part 1 and Part 2 of Art.321-1) Article which provides for liability for a qualified act (Part 2 of Art. 321-1) (Criminal Code..., 2001). In addition, there are significant differences in the court's interpretation of these provisions when considering the case and making relevant decisions.

First, we must address the problem of correlation of such concepts as "manufacture" and "production" of counterfeit medicines. "Manufacturing" is a component of main criminal offense (Part 1 of Art. 321-1) with a milder penalty (from three to five years in prison). At the same time, the legislator defines "production" in Part 2 of Art. 321-1 of the Criminal Code as a qualifying feature, with a significant increase in the sentence severity (from five to eight years' imprisonment with property confiscation). This approach of the legislator provided the basis for some scientific discussion. In particular, I.A. Kovalenko believes that criminal-law value of alternative actions that make up the content of a socially dangerous act (production, manufacture, purchase, transportation, transfer, storage for sale,

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sale of deliberately falsified medicines) should be the same. The main essence of scientist's rationale is that one should follow a unified approach to those dispositions' design where the illicit trafficking in health dangerous substances (drugs, psychotropic substances, their analogues, precursors, poisonous or superpotent substances) medicines, etc. Accordingly, it is advisable to start a list of alternative actions that make up the content of transferring of counterfeit medicines in Part 1 of Art. 321-1 of the Criminal Code, on "production" (Kovalenko, 2017).

Certain considerations will allow to determine on the appropriateness of current version of the norm under consideration, regarding the different nature and comparative degree of danger of "manufacture" and "production" of counterfeit medicines. At first glance, etymologically, these two categories mean to make, produce, create any product (Ozhegov, 1988). Moreover, in the Resolution of the Plenum of the Supreme Court of Ukraine "On case law in cases of kidnapping and other illegal handling of weapons, ammunition, explosives, explosive devices or radioactive materials" (No. 3)

(Resolution of the Plenum..., 2002) under the illicit manufacture offered to understand any deliberate, committed without legal permission, actions for their creation (Pluzhnik, Kornienko, 2017). Therefore, the approach to interpreting the "manufacture" concept is quite broad. However, production has its essential characteristics: the result is obtained during a certain systematic production process, in the presence of certain production relationships, using production capacity, etc. In particular, in this sense is perceived the "production" of drugs – as a commercial industrial method of manufacturing certain substances in pharmaceutical enterprise (Melnik, Khavronyuk, 2008). It is therefore unconditional that the law must define these two concepts separately, since their substantive nature is different.

However, we believe it exists certain and significant difference in interpreting the content, nature and importance of each of the listed alternative actions of crime's objective side in relation to narcotic (psychotropic) substances compared to danger degree of committing similar actions in relation to counterfeit medicines. If the unlawfulness of committing actions means that they are committed in

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violation of current legislation, which establishes a special legal regime for their trafficking, then the mere fact of counterfeit medicines is illegal and criminal. The main difference and peculiarity in dealing with this issue must be related to medicines' properties that are the subject of a very important common use, the quality that a person hopes for during treatment or preventive measures. He/she does not expect danger. While drug use (abuse) occurs on a voluntary basis, there is aware of negative consequences of this for your own health (and even life).

Serial, systematic production of counterfeit medicines in large quantities, using production facilities, skilled personnel (specialists in the relevant field) is too dangerous for the population of Ukraine. Accordingly, the "production" of counterfeit medicines is much more dangerous, than all other alternative actions defined in Art. 321-1 of the Criminal Code. Therefore, this act should be regarded as more serious in relation to other alternative actions of crime's objective side and accordingly "production".

However, the domestic courts deciding on merits, formulating in motivating part of the sentence of

prosecution, specifying the specific act, place, time and method of committing it, have quite different approaches to interpreting such categories as "manufacture" and "production". Thus, the Judgment of the Berislav district court of Kherson region (2015), stated that A. had searched and adapted the premises for manufacturing falsified medicinal product (premises of the former milking block), purchased and installed the equipment for bottling alcohol. Actions were qualified under Part 2 of Art. 321-1 of the Criminal Code as production (except for other actions – transportation, storage for the purpose of sale, sale of deliberately falsified medicines) (Judgment of the Berislav District Court of Kherson region..., 2015). A similar approach is observed in the Judgment of the Svyatoshinsky District Court of Kyiv (Judgment of the Svyatoshinsky District Court..., 2017): search and adjustment of premises, placement of equipment, purchase of raw materials, etc. are considered as components of "production" (Judgment of the Svyatoshinsky District Court..., 2017). In the Judgment of September 16, 2015, a judge of the Moscow District Court in Kharkiv described the actions that involved the garage rental, purchase

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and placement of the necessary equipment for counterfeiting "Lemon-flavored Teraflu and cold," as "production". However, the term "production" is often used in the meaning of a sentence (Judgment of the Moscow District Court..., 2015).

Thus, the practice of law enforcement proves the absence of clear, uniform understanding of content and nature of categories. However, this would be of little importance if the degree of public danger of these acts is identical. However, the separation by the legislator of "production" as a grave act, in principle, reinforces the importance of a proper interpretation of legislative provisions, since it is connected with the justice of criminal justice, conformity of punishment severity of act's gravity. Summarizing the content of sentences in this part allows us to note that substandard counterfeit medicines were manufactured mainly by handicrafts in the presence of appropriate equipment, which was installed in different premises (underground shops, garages, warehouses, etc.). Accordingly, such actions must be qualified as "manufacture" under Part 1 of Art. 321-1 of the Criminal Code.

Practice proves that no evidence of long-term health disorder, death of person or other grave consequences has been identified. It is difficult to prove these qualified and especially qualified traits without having objective data on results of the adverse effects of counterfeit medicines on people's health. There is virtually no question of taking actions of a particularly large size that are more inherent in the use of production capacity. Only in one sentence do actions qualify for attribute (among others) as having been committed in large sizes. The fact that the law does not specify what we mean by "large" and "especially large" amounts of the harm caused, increases the value of judicial discretion. Thus, according to the Judgment of the Moscow District Court of Kharkiv of January 27, 2016, the amount of "Teraflu from cold and cold with lemon flavor" (6,642 bags), "Pharmacetron" (total 9,653 bags) were withdrawn at market value for the amount 204.349, 95 UAH. They are recognized as a large-scale act (Judgment of the Moscow District Court of Kharkiv..., 2016).

In almost 74% of cases during the analyzed period, the qualification of acting in court sentences was the same –

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under Part 2 of Art. 321-1 of the Criminal Code, even if the act was regarded as "manufacture" of counterfeit medicines. The reason for this decision was that in all cases there was a criminal offense based on complicity – a group of persons by prior conspiracy. There had been a preliminary conspiracy of at least three persons who not only had previously agreed to commit it, but also shared functions among the group members. In some cases, it is indicated that not all group members are established. The quantitative sign of complicity (three or more persons) and the fact of division of functions indicate the fact of committing a socially dangerous act by an organized group.

However, only two of the fifteen sentences referred to the qualification of an act as committed by an organized group, which again testifies to different approaches to interpreting and substantiating the identified and proven qualified characteristics of a crime. In addition, we should pay attention to the fact that the situation becomes typical when several qualifying circumstances in perpetrator's actions (organized group, production, large size) lead to such liability that would be borne by a person if available of only one of

these circumstances. After all, all these features are provided in the same rule (Part 2 of Art. 321-1) (Criminal Code..., 2001). The absorption effect works. Therefore, there is no reason to consider questionable justice of such criminal justice in terms of proportionality of gravity of the committed and punishment severity. In this regard, it is necessary to approach the basic differentiation, qualified and especially qualified composition of a crime in a more differentiated manner, taking into account the peculiarities of act committing in Ukraine (for example, to distinguish a feature – committing an act within an organized group).

However, the largest amount of issues concerns the court's order of sentencing. Carrying out a general systematic legal analysis of the facts contained in motivating and resolute part of a sentence, which give a definite idea of the current tendencies in domestic judicial interpretation of relevant criminal legal provisions, in terms of their compliance with punishment principles, release gives reason to conclude that there are problems of a purely enforceable nature.

The consideration result of respective criminal proceedings for the

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period from 2015 to the first half of 2019 was that the court passed acquitting Judgment in one case, in three cases the court applied Part 1 of Art. 321-1 of the Criminal Code, in 11 sentences (74%) the court proved the need to qualify the action under part 2 of Art. 321-1 of the Criminal Code, which determines the penalty for manufacture, purchase, trafficking, storage for sale, sale of deliberately falsified medicinal products, committed with qualifying circumstances (by prior conspiracy a group of persons, in large size, committed a long breakdown) as well as manufacture of counterfeit medicines. The sanction provides for a sentence of imprisonment of five to eight years with property confiscation. Given the current version of law sanction, the authors should emphasize that property confiscation is defined as mandatory additional punishment, which significantly increases the severity of criminal repression.

However, only when considering two cases under Part 2 of Art. 321-1 of the Criminal Code the court concluded that it was advisable to serve the court sentence (more than six years of imprisonment with property confiscation in one case, with

confiscation of counterfeit medicines in another). In all other cases, the court, proving the guilt of a person under Part 2 of Art. 321-1 of the Criminal Code, decides on release from serving a sentence on the basis of Art. 75 of the Criminal Code. It should be noted that a similar decision was made in respect of convicts under Part 1 of Art. 321-1 of the Criminal Code. In almost all cases, such a decision was made on the basis of approval of plea agreement: a sentence of imprisonment of no more than five years was agreed and the very fact of release from serving a probation sentence. It draws attention to the fact that, under virtually the same conditions (qualification of action under Part 2 of Article 231-1 of the Criminal Code, existence of plea agreement, the existence of mitigating circumstances), the court establishes quite different periods of trial. The probationary period ranges from 1 to 3 years. However, the duties imposed on the court by a person exempt from serving a sentence are virtually the same in all cases: appearing periodically for registration with probation authority, informing the probation authority of residence change, work and study (Part 1 of Art.76), not to travel outside Ukraine without

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agreement with the authorized body for probation (Part 2 of Art. 76) (Criminal Code..., 2001). Therefore, first of all, these are the duties which the court is obliged to place on the guilty person (except the latter). Consequently, no other person's responsibilities as defined in paragraphs 1, 3-6, p. 2 of Art. 76 of the Criminal Code, as such, which should enhance the educational impact of probation on released person.

In most cases, the court also makes a decision to confiscate counterfeit medicines, or states “without confiscation of counterfeit medicines”, although the sanction does not specify special confiscation. This approach of the court can be justified by provisions of the General Part of the Criminal Code on the grounds and procedure for using of special confiscation (Art. 96-1, 96-2), which prove the validity of such court decisions in the case of intentional act, for which punishment as imprisonment is provided. However, if the crime object were the means, they were the means or instrument of committing crime.

A more significant problem is the other: in almost all cases of conviction under Part 2 of Art. 321-1 of the Criminal Code either does not mention the property confiscation at all,

or its non-application is connected with the agreement of a certain type of punishment (without confiscation), or the very fact of exemption from punishment on the basis of Art. 75-77 of the Criminal Code. The latter is a typical decision of the Darnytskyi District Court of Kyiv of March 11, 2019, which states that a person has been found guilty of committing a crime under Part 2 of Art. 321-1 of the Criminal Code, assigned to it by the parties to agreement on recognition of guilt of punishment for five years of imprisonment with property confiscation. Apply Art. 75, 77 of the Criminal Code and release from punishment with a trial period of 3 years without confiscation of property (Judgment of the Darnytsia District Court..., 2019).

This decision gives reason to believe that, firstly, the punishment which implies confiscation of property may be agreed; secondly, that on the basis of Art. Art. 75, 77 of the Criminal Code can be exempted from property confiscation. This approach is not justified in interpreting existing legislation. The subject of reconciliation must be both legal qualification with indication of the relevant article and punishment specified in sanction of this

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article (Art. 472) (Criminal Procedure Code of Ukraine..., 2018).

Accordingly, if the fact of conviction under Part 2 of Article 321-1 of the Criminal Code is agreed, the minimum punishment in this case is imprisonment for a term of five years with confiscation of property, however, if you are guided by the complex content of Part 2 of Article 75 of the Criminal Code. It refers to the possibility of agreement (on the basis of approval of plea agreement) release from serving a sentence of probation and the content of Article 77 of the Criminal Code, which determines the types of additional punishments that can be applied in the case of release with probation. The authors conclude that a person who has been punished with confiscation of property (even if the plea agreement is approved) cannot be released. Article 75, 77 of the Criminal Code) shall not be grounds for exemption from this additional punishment, but a court may only on the basis of Art. 69 of the Criminal Code in the presence of several circumstances that mitigate punishment and significantly reduce the act's severity. However, only one sentence – the judgment of the Shevchenkivsky District Court of Zaporizhzhia of

November 15, 2018 states that according to Part 1 of Art. 69 of the Criminal Code, in the presence of several circumstances that mitigate punishment and significantly reduce the severity of an act committed, the guilty person may not impose additional punishment a confiscation of property (Judgment of the Shevchenkivsky District Court..., 2018). Therefore, in our opinion, there is a breach of the systemic link between the provisions of the General and Special Part of the Criminal Code.

### **Conclusions**

Summarizing the above the authors should emphasize the following. Statistical data on the activity of state bodies in the field of quality control of medicinal products, the results of pre-trial investigation and trial of criminal offenses in the sphere of trafficking in counterfeit medicines, certain trends in development of pharmaceutical market, etc. prove the objective conditionality and timeliness of activity criminalization under consideration in Ukraine. The materiality of trafficking in counterfeit medicines' harm (real and potential) should be assessed taking into account a significant number of negative factors that affect this action prevalence

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(uncontrolled trafficking, without prescription implementation of the vast majority of medicines, latency, corruption). Accordingly, the degree of social danger of action in today's rather complex period of life of society in Ukraine will only increase.

In this regard, it is important to develop our own legislative and enforcement experience in preventing trafficking in counterfeit medicines, to develop systematic, principled approaches to regulatory formulations and their judicial interpretation during practical application. In particular, the improvement of criminal law should be aimed at ensuring the clarity of criminal law provisions contained in Art. 321-1 of the Criminal Code, apply to both dispositions and sanctions. The main direction of improvement should be to clarify the characteristics of basic and qualified, especially the qualified composition of the criminal offense. Bringing the legislative provisions in line with differentiation principle of liability makes the relevance of punishment's severity of more relevant to properties of counterfeit medicines (their degree of health danger), characteristics of crime subject, cohesion degree of accomplices, etc. The spread of

sphere of acts' criminalization, which are the subject of counterfeit medicines, must be reproduced in establishment of criminal liability of legal entities for legalization (laundering) of criminal proceeds from trafficking in counterfeit medicines.

Equally relevant is the question of determining the place and role of Art. 321-1 of the Criminal Code in the system of other criminal law norms that affect the population health. The similar (in some cases the same) object and object of assault determine the relationship between the actions, which can be correlated as related crime, as general and special crime. The importance in determining both similar and demarcating features inherent in actions, whose responsibility under Art. 201, 209, 305, 306, 321, 321-1 of the Criminal Code. Substantial changes in the wording of relevant criminal law provisions, the formulation of new crime scenes enhance the relevance of their proper interpretation both in theory and in law during the acts' qualification, demarcation of adjacent crime scenes, solving the issue of competition between general and special norms, etc. After all, if there are system-forming links in criminal law provisions, it is necessary to

pay attention to these connections, to take into account their essence when interpreting the criminal law.

The study of current case law on the adoption of sentences and penalties imposition for trafficking in counterfeit medicines proves that there are significant problems in law enforcement, in approaches to interpret the current legislation. Failure to comply with the principle of criminal law regarding the ratio of mitigating and aggravating circumstances, taking into account the ratio of the sanction of the article and the order of exemption from probation, value of confiscation as additional punishment, the ratio of confiscation and special confiscation, etc., are indicated. All of these issues should be the subject of a more in-depth study, since there are significant differences in the assessment of practically similar (in some cases identical) acts' circumstances, facts of misinterpretation of the current criminal legislation. Which indicates the urgent need for some generalization of court decisions and the provision of appropriate recommendations to the courts.

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