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FALSIFICATION AND CIRCULATION OF FALSIFIED MEDICINAL PRODUCTS: DISCLOSURE OF CRIMES AND BEGINNING OF CRIMINAL PROCEEDINGS

The article explores the problems of detecting features of falsification and trafficking of counterfeit medicines and the beginning of criminal proceedings.

The purpose of the article is to study the criminalistic nature and significance of the beginning of criminal proceedings as a structural element of the crime investigation methodology, to determine the features of the beginning of the investigation of falsification and trafficking of counterfeit medicines and to determine their influence on the effectiveness of pre-trial investigation of this category of crimes.

It is substantiated that the systematization of the characteristics of the crime under investigation should be carried out according to the criterion of reason for entering information in the Unified Register of pre-trial investigations. Based on the results of the summarization of the materials of the forensic and investigative practice, special attention should be paid to revealing the signs of the investigated crime from the materials of the operative-search activity, reports of the State Service of Medicines and Drug Control, statements of the victims. This gives grounds to claim that criminal procedural and organizational and tactical features of the beginning of criminal proceedings are essential for the effective investigation of counterfeiting and trafficking of counterfeit medicines.

It was established that the specifics of the beginning of the criminal proceedings of the investigated crime, first of all, is manifested in the features of the systematization of signs of falsification or trafficking of counterfeit drugs, the need for the investigator to interact with the State Drug Service and drug control, which is due to the regulatory system of pharmaceutical activity in Ukraine. Based on the specifics of the crime under investigation, the need to highlight the identification of the characteristics of the crime in question and the features of the initiation of pre-trial investigation as an independent structural element of the forensic methodology of investigating falsification and trafficking of counterfeit medicines is substantiated.

Keywords: Falsification and circulation of falsified medicinal products: identification of features of falsification and turnover of counterfeit medicines, sources of detection of signs of crime, organizational and tactical features of the beginning of criminal proceedings, systematization of signs of adulteration and turnover of counterfeit medicines.

Formulation of Research Problem. The effectiveness of investigating counterfeiting and trafficking of counterfeit medicines

depends to a large extent on the timely initiation of criminal proceedings, complete and objective investigation of the background information about the crime, as well as the conduct of investigative (investigative), unspoken investigative (investigative) actions and tactical operations. It is at the beginning of the investigation that the foundation is laid for establishing the circumstances of the criminal offense, the guilt of a particular person, and a considerable amount of evidential information is identified and collected. As a result of such activity, the investigation versions are put forward and the tasks of the investigation are determined, appropriate decisions are made, their execution is ensured¹. The stage of gathering and verifying primary information is a must for the proper classification of crimes and the choice of areas of investigation, which primarily depends on the quality, timeliness, optimality and overall effectiveness of criminal proceedings².

Analysis of recent researches and publications. The problem of initiation of criminal proceedings has been sufficiently elaborated in the special literature, in particular, the study of this issue was undertaken by: Yu. P. Alenin, V. A. Zhuravel, MV Kapustina, G. A. Matusovsky, O. V. Oderiy, K. O. Spasenko, V. V. Tishchenko, V. Y. Shepitko and others³. At the same time, in the theory of criminalistics and the practice

¹ *Pchelina O. V.* Struktura metodyky rozsliduvannia zlochyniv u sferi sluzhbovoi diialnosti [Structure of methodology of investigation of crimes in the sphere of professional activity]. *Naukovyi visnyk mizhnarodnoho humanitarnoho universytetu*. 2014. Vyp. №10–2. S. 124 [in Ukrainian].

² *Pchelina O. V.* Struktura metodyky rozsliduvannia zlochyniv u sferi sluzhbovoi diialnosti [Structure of methodology of investigation of crimes in the sphere of professional activity]. *Naukovyi visnyk mizhnarodnoho humanitarnoho universytetu*. 2014. Vyp. №10–2. S. 124 [in Ukrainian].

³ *Alenin Yu. P.* Pochatok dosudovoho rozsliduvannia za KPK Ukrainy 2012 roku [The beginning of the pre-trial investigation under the CCP of Ukraine in 2012]. *Yurydychnyi chasopys Natsionalnoi akademii vnutrishnikh sprav*. 2013. Vyp. № 1. S. 198–203; *Zhuravel V. A.* Problemy periodyzatsii dosudovoho rozsliduvannia [Problems of periodization of pre-trial investigation]. *Visnyk Natsionalnoi akademii pravovykh nauk Ukrainy*, 2014. Vyp. № 2. S. 136–144; *Kapustina M. V.* Pochatok dosudovoho rozsliduvannia: problemy vnornuvannia [initiation of pre-trial investigation: problems of normalization]. *Naukovyi visnyk Khersonskoho derzhavnogo universytetu. Seriya : Yurydychni nauky*. 2015. Vyp. 5 (4). S. 45–49 [in Ukrainian]; *Matusovskij G. A.* Jekonomicheskie prestuplenija: kriminalisticheskij analiz [Economic crimes: forensic analysis]. Har'kov : Konsum, 1999. 480 s. [in Russian]; *Oderij O. V.* Pochatok dosudovogo rozsliduvannia kriminal'nih pravoporushen' proti dovkillja: teoretiko-organizacijnij aspekt [The beginning of pre-trial investigation of criminal offenses against the environment: theoretical and organizational aspect]. *Kriminalistika i sudebnaja jekspertiza*. 2014. Vyp. 59. S. 177–187; *Spasenko K. O.* Osoblivosti vidkrittja kriminalnogo provadzhennja shhodo porushen' pravil bezpeki pid chas vikonannja robiz z pidvishhenju nebezpekoju [Features of the opening of criminal proceedings for

of investigating crimes, a number of problems of investigating the initiation of criminal proceedings as a structural element of the method of investigation of particular types of crimes remain debatable today. It should be emphasized that in the modern forensic literature, the formation of the methods of investigation of falsification and trafficking of counterfeit medicines, the detection of signs of crime and the beginning of criminal proceedings, are not considered or considered at all in relatively reduced form. The above confirms the relevance of the topic and the need for further research on the subject.

The **Article Purpose** is to study the forensic nature and significance of the beginning of criminal proceedings as a structural element of the methods of investigation of crimes, to determine the features of detecting signs of crime and the beginning of the investigation of counterfeiting and trafficking of counterfeit medicines, to find out their impact on the effectiveness of detection and investigation of this category of crimes.

Main Research Content Presentation. It should be noted that in the forensic field today the issue of distinguishing the features of the beginning of criminal proceedings as an independent stage of investigation of crimes and, accordingly, a structural element of the forensic methodology is debatable. In this context, it is worth agreeing with V. V. Tishchenko that there can be no single established structure of crime investigation methodology, since from the information point of view the methodology is a certain body of knowledge, and from the point of view of use it is a certain algorithm of actions; in addition, the structure of the technique is influenced by its functional orientation.¹ Concerning the opening of criminal proceedings as an independent stage of pre-trial investigation, V. A. Zhuravel notes that the expediency of its separation is conditioned by the specificity of the procedural actions, from which the pre-trial investigation begins, by the circle of subjects involved in carrying out these actions (investigator, prosecutor, the applicant, etc.), the nature of the initial tasks to be solved, the need to identify the main areas of activity of the investigator². In agreement with this opinion,

breaches of security rules during the execution of work with high risk]. *Teorija ta praktika sudovoi ekspertizi i kriminalistiki*. Harkiv : Pravo, 2014. Vip. 14. S. 128–134 [in Ukrainian]; *Tishhenko V. V.* Korystno-nasil'stvennye prestuplenija. Kriminalisticheskij analiz [Self-serving-violent crimes. Forensic Analysis]: monografija. Odessa : Jurid. lit. 2002. S. 231–236 ta in [in Russian].

¹ *Tishhenko V. V.* Korystno-nasil'stvennye prestuplenija. Kriminalisticheskij analiz [Self-serving-violent crimes. Forensic Analysis]: monografija. Odessa : Jurid. lit. 2002. S. 270 [in Russian].

² *Zhuravel V. A.* Problemy periodyzatsii dosudovoho rozsliduvannia [Problems of periodization of pre-trial investigation]. *Visnyk Natsionalnoi akademii pravovykh nauk Ukrainy*, 2014. Vyp. № 2. S. 142 [in Ukrainian].

K. O. Spasenko adds to the listed factors that determine the peculiarities of the beginning of criminal proceedings as a separate element of the methodology, adds the peculiarities of the regulatory regulation of the so-called *departmental* investigation¹.

Analyzing the above views, we believe that the selection of features of the beginning of pre-trial investigation as an independent structural element of the method of investigation of counterfeiting and trafficking of counterfeit medicines is due to the following factors: 1) the specifics of the procedural steps leading to the initiation of pre-trial investigation related to professional pharmaceutical activity; 2) the features of the detection sources and the reasons for initiating criminal proceedings; 3) specifics of actions regarding the primary gathering of information about a crime event; 4) determining the directions of the investigation and the scope of the investigator's tasks that are put at the beginning of criminal proceedings.

Investigating the procedural features of the initiation of criminal proceedings, it is necessary to pay attention to the specifics of the stage of pre-trial investigation, from which criminal prosecution begins today. To date, the forensic literature has expressed a rather ambiguous attitude to the changes introduced with the adoption of the Criminal Procedure Code of Ukraine in 2012, in particular emphasizing the need for a preliminary, verification, filtration stage before the main proceedings² and in its turn overly simplified procedure for opening a criminal case, not only on legal, moral, ethical but also organizational aspects. In particular, the entry in the Unified Register of Pre-trial Investigations of all statements and communications containing only general information leads to a significant increase in the amount of material that is being investigated. In turn, the intensification of the work of the investigator, the prosecutor does not contribute to the objectivity and completeness of the process of investigating the received information due to elementary unnecessary workload³.

¹ Spasenko K. O. Osoblivosti vidkrittja kriminalnogo provadzhennja shhodo porushen' pravil bezpeki pid chas vikonannja robot z pidvishhenju nebezpekoju [Features of the opening of criminal proceedings for breaches of security rules during the execution of work with high risk]. Teoriya ta praktika sudovoї ekspertizi i kriminalistiki. Harkiv : Pravo, 2014. Vip. 14. S. 130 [in Ukrainian].

² Alenin Yu. P. Pochatok dosudovoho rozsliduvannia za KPK Ukrainy 2012 roku [Beginning of pre-trial investigation under the CCP of Ukraine in 2012]. Yurydychnyi chasopys Natsionalnoi akademii vnutrishnikh sprav. 2013. Vyp. № 1. S. 199 [in Ukrainian].

³ Zhuravel V. A. Pochatok dosudovoho rozsliduvannia: deiaki protsesualni ta orhanizatsiino-taktychni problemy [Beginning of pre-trial investigations: some

Agreeing with this position, it should be noted that the need to verify criminal complaints and reports is also confirmed by the statistical information on the status of the pre-trial investigation of criminal proceedings recorded by the Office of the Prosecutor General of Ukraine.

In particular, 2 % of all criminal proceedings for adulteration or trafficking in counterfeit medicines were closed due to the absence of an event or the composition of the criminal offense. The foregoing clearly indicates that a significant portion of the information is entered in the Unified Register of Pre-trial Investigations on the basis of unsubstantiated or erroneous statements and communications.

However, the current criminal procedural legislation requires the adoption and subsequent registration in the Unified Register of pre-trial investigations of any information about a criminal offense, taking into account the following features: 1) the information should relate to a criminal offense, not to an administrative, disciplinary or other offense; 2) prior to the commencement of the pre-trial investigation, the existing criminal procedural legislation does not provide for the verification of information on a criminal offense¹. In view of the above, criminal manifestations of falsification and circulation of counterfeit medicines should be distinguished from administrative offenses, in particular, the sale of over-the-counter medicines in cases prohibited by law (Article 42-4 of the Code of Administrative Offenses), with non-compliance with the requirements of standards, norms, rules and technical conditions. the time of production, storage, transportation, sale or use of medicinal products (Articles 167, 168-1, 170 of the Code of Administrative Offenses), failure to comply with the legal requirements of officials of state bodies for the quality control of medicinal products and the conditions for their production in order to remedy breaches of the legislation on medicinal products or to impede the activities of these bodies (Article 188-10 of the Code of Administrative Offenses)². Structurally, the initial phase of the investigation includes the following activities: 1) identification of the crime or lack thereof; 2) carrying out procedural actions regarding the

procedural and organizational-tactical problems]. Visnyk Luhanskoho derzhavnoho universytetu vnurishnikh sprav imeni E. O. Didorenka. 2015. Vyp. 1. S. 252 [in Ukrainian].

¹ Vapnarchuk V. V. Pochatok dosudovoho rozsliduvannia. Kryminalnyi protses [initiation of pre-trial investigation. Criminal process] : pidruch. za red. O. V. Kaplinoi, O. H. Shylo. Kharkiv : Pravo, 2018. S. 272 [in Ukrainian].

² Pro zatverdzhennia instruktsii z oformlennia materialiv pro administratyvni pravoporushennia zakonodavstva Ukrainy shchodo zabezpechennia yakosti likarskykh zasobiv : nakaz MOZ Ukrainy vid 26.10.2001 № 428. Ofitsiyni visnyk Ukrainy vid 08.02.2002. № 4 [in Ukrainian].

primary gathering of information about a crime event¹. Let's look at each of them in more detail.

Analysis of the practice of investigating counterfeiting and trafficking of counterfeit medicines showed that the generalizing, sources of detecting signs of counterfeiting and trafficking of counterfeit medicines are:

1) healthcare sector, including materials from the departmental inspection of the State Service for Drugs and Drug Control, medical staff of a hospital or clinic, pharmacy staff;

2) customs authorities of the State Fiscal Service of Ukraine, State Border Service of Ukraine;

3) enterprises of the pharmaceutical industry and trade;

4) consumers of counterfeit medicines;

5) open source, such as social networking sites and forums;

6) operational units of the National Police of Ukraine, in particular the Department for Combating Drugs Crime, its territorial units, etc.

Filing information in the Unified Register of Pre-trial Investigations involves first identifying the signs of a crime, therefore, it is necessary to investigate the question of delimitation of the concepts of *detection* and *establishment* of crimes, as well as identifying sources of information from which the investigator, prosecutor will find out about the criminal offense and which is the reason for entering the Unified Register of Pre-trial Investigations². Criminal literature refers to the activities of law enforcement agencies aimed at obtaining information from individuals or legal entities about a crime. This process differs from crime detection in that it involves an active and purposeful activity in establishing information about the facts of the crime³. In this regard, it should be noted that the successful establishment of signs of falsification or trafficking of counterfeit medicines, first of all, requires the definition of forensic

¹ Lobunec E. S. Naznachenie i sodержaniya etapov rassledovaniya prestuplenij [Appointment and content of the stages of the investigation of crimes: monograph.] : monografiya. Moskva : JurLitinform, 2015. S. 45 [in Russian].

² Kapustina M. V. Pochatok dosudovoho rozsliduvannya: problemy vnormuvannya [The beginning of pre-trial investigation: problems of normalization]. Naukovyi visnyk Khersonskoho derzhavnogo universytetu. Seriya : Yurydychni nauky. 2015. Vyp. 5(4). S. 49 [in Ukrainian].

³ Petrosian V. H. Kryminalistychnye ta operatyvno-rozshukove zabezpechennia vyavleniya zlochyniv, vchynenykh subiektamy hospodariuvannya z oznakamy fiktyvnosti [Forensic and Operational-investigative Support for identification of Crimes Committed by Business Entities with Signs of Fictitiousness]: avtoref. dys. ... kand. yuryd. nauk. Nats. un-t derzh. podatk. sluzhby Ukrainy. irpin, 2012. S 12 [in Ukrainian].

features of crime, as well as its systematization. Thus, in the specialized literature, the criminalistic sign of a crime is understood to be a fact that acts as a result of a criminal act, which more or less likely indicates the event of the crime, its circumstances¹. Regarding the systematization of the features of crimes in the investigation of certain types of crimes, the most common criteria today are: general and individual features of crimes; stages (stages) of crime development; the way of being in the surrounding reality; the place of possible detection of signs². At the same time, in our opinion, the systematization of the signs of falsification and circulation of counterfeit medicines should be carried out by the criterion of the reason for entering information in the Unified register of pre-trial investigations.

Therefore, the reasons for entering information on falsification and circulation of counterfeit medicines in the Unified Register of Pre-trial Investigations can be: 1) notification of victims; 2) notification of officials, who became aware of the fact of falsification or circulation of counterfeit medicines during the performance of their official duties; 3) notification of pharmaceutical companies, pharmacy establishments – subjects of input control of medicinal products; 4) notification of the State Service for Drugs and Drug Control; 5) detection by the investigator or prosecutor of signs of falsification or circulation of counterfeit medicines from materials of operative-search activity; 6) detection by the investigator or prosecutor of the signs of the investigated crime from information received from the customs bodies of the State Fiscal Service of Ukraine, the State Border Service of Ukraine; 7) detection by the investigator or prosecutor of the signs of the investigated crime from mass media, forums, websites;

8) detection by the investigator or prosecutor of the signs of the investigated crime during the investigation of other crimes.

Let's look at them in more detail. As we have seen from our research, the most common reason for entering information on falsification and circulation of counterfeit medicines is to identify signs of falsification or circulation of counterfeit medicines from materials of operational and search activities. Today, the body that conducts investigative measures in this category of crime is the Department of Combating Drug Crime of the National Police of Ukraine and its territorial units. Pre-trial investigation

¹ *Matusovskij G. A., Dudnikov A. L. Kriminalisticheskaja sistematizacija priznakov hishhenij* [Forensic systematization of theft signs]. *Rassledovanie hishhenij gosudarstvennogo i obshchestvennogo imushchestva (problemy taktiki i metodiki)*. Harkiv, 1987. S. 28 [in Russian].

² *Matusovskij G. A. Jekonomicheskie prestuplenija: kriminalisticheskij analiz* [Economic crimes: forensic analysis]. Har'kov : Konsum, 1999. 480 [in Russian].

in the specified category of crimes is carried out by investigators of the National Police of Ukraine.

Signs indicating the falsification or circulation of counterfeit medicines in this case may be: a) absence of a license for production of medicines, wholesale and retail trade of medicines, import of medicines; b) the expiration of the license; c) cancellation or suspension of the license; d) availability of licenses issued to another person; e) inconsistency of the actual economic activity of the license, failure to comply with the requirements for the licensed type of activity; e) violation of conditions of licensing activity; lack of state registration of a legal entity, an individual entrepreneur; f) violation of rules, technical regulations for the manufacture of medicines; g) sale of medicines outside pharmacies, including on the Internet; h) violation of the rules for writing off and disposal of unfit medicines; i) violation of the rules of workflow; j) violation of accounting and tax reporting.

It should be noted that the materials of the operative-search activity can be the basis for starting a pre-trial investigation only if they have information about the circumstances, which may indicate a criminal offense. Such materials must be legalized by the operational unit and transmitted in due course to the investigator or prosecutor¹. Regarding the legalization of the materials of the operative-search activity, it should be noted that this is the specific activity of the operative and investigative units for granting legal force and introduction into the criminal process of the materials of the operative-search activity². In case of detecting signs of crime, the operative unit, which conducts the search and search activity, is obliged to immediately send the collected materials, which record the factual data about the unlawful acts of individuals and groups, responsible for which are provided by the Criminal Code of Ukraine, to the relevant body of pre-trial investigation initiation and conduct of pre-trial investigation in the manner prescribed by the Criminal Procedure Code of Ukraine³.

¹ *Pohoretskyi M. A.* Poniattia ta sutnist lehalizatsii operatyvno-rozshukovoi informatsii [The concept and essence of legalization of operative-search information]. *Visnyk Luhanskoho derzh. un-tu vnutr. sprav im. E. O. Didorenka.* Luhansk : Vyd-vo LDUVS, 2010. Spets. vyp. № 4. S. 34 [in Ukrainian].

² *Humenna N.* Osoblyvosti vykorystannia rezul'tativ operatyvno-rozshukovoi diialnosti v rozshukovii roboti slidchoho [Peculiarities of using the results of the operative-search activity in the investigative work of the investigator]. *Natsionalnyi yurydychnyi zhurnal: teoriia ta praktyka.* Respublika Moldova, 2014. Vyp. № 4. S. 217 [in Ukrainian].

³ Pro operatyvno-rozshukovu diialnist: Zakon Ukrainy [About operative-search activity: Law of Ukraine] vid 18.02.1992 № 2135-Xii. Vidomosti Verkhovnoi Rady Ukrainy vid 02.06.1992 r., № 22 [in Ukrainian].

The next most common reason for entering information on counterfeit medicines in the Unified Register of Pre-Trial Investigations is a notification from the State Service for Medicinal Products and Drug Control about the existence of an offense in the course of a departmental inspection. This is explained by a number of peculiarities related to the specifics of the regulatory framework in this field, as well as by the unconditional need to possess special knowledge for successful completion of the initial tasks of initiating criminal proceedings.

The State control over the quality of medicines is carried out by the State Service for Drugs and Drug Control, State Services on Medicines and Drug Control in the region and in Kyiv by checking the compliance of economic entities with the requirements of the legislation on the quality of medicines and in the defined by the legislation cases of laboratory analysis of drug samples¹. Thus, the initiation of criminal proceedings is possible as a result of receiving a report on the commission of a criminal offense, which was established in the course of both scheduled and unscheduled inspection by the bodies of the State Service of Ukraine for Drugs and Drug Control². Scheduled inspections are carried out in accordance with the annual plan of implementation of state supervision (control) measures by the State Service for Medicinal Products and Drug Control for the respective calendar year. Unscheduled inspection is carried out on the grounds stipulated by the Law of Ukraine «On basic principles of state supervision (control) in the sphere of economic activity».

The content of such checks is to be carried out by the officials of the aforementioned bodies: 1) verification of supporting documents for the series of medicines; 2) selective visual inspection of the compliance of medicinal products with the requirements of the quality specification. In case of non-compliance of the medicinal product with the requirements of specification of quality based on the results of visual inspection, detection of discrepancies in the accompanying documents to the series of medicinal products, or violation of the established conditions for the manufacture of

¹ Deiaki pytannia derzhavnoho kontroliu yakosti likarskykh zasobiv : postanova Kabinetu Ministriv Ukrainy [Some issues of State Control of the Quality of Medicines: Resolution of the Cabinet of Ministers of Ukraine] vid 03.02.2010 № 260. Ofitsiyni visnyk Ukrainy vid 19.03.2010, № 17 [in Ukrainian].

² Pro zatverdzhennia Polozhennia pro Derzhavnu sluzhbu Ukrainy z likarskykh zasobiv ta kontroliu za narkotykamy : postanova Kabinetu Ministriv Ukrainy [About the consolidated Regulation on the State Service of Ukraine for Medicinal Drugs and Drug Control: Decree to the Cabinet of Ministers of Ukraine] vid 12.08.2015, № 647. Ofitsiyni visnyk Ukrainy vid 18.09.2015, № 72 [in Ukrainian].

the medicinal product at the prescription pharmacy, storage, transportation and sale of the medicinal product, which may adversely affect its quality, authorized persons make a decision on the selection of samples for laboratory analysis, the results of which conclude as medicines. On the basis of the results of the conclusion on the quality of samples of medicinal products issued by the laboratory, an order is issued to suspend the circulation of the corresponding series or all series of medicinal products in the region or throughout the territory of Ukraine and an urgent notification of the detection of counterfeit medicinal products.

The State Service of Ukraine for Drugs and Drug Control, in compliance with the provisions of the Memorandum of Cooperation between the State Service of Drugs and Drug Control and the National Police of Ukraine, dated July 3, 2017, immediately sends to law enforcement authorities inspection materials containing signs of manufacturing counterfeit medicines, purchase, transportation, transfer or storage for sale or illicit sale of counterfeit medicines.

Signs indicating the falsification or circulation of counterfeit medicines in this case may be: a) availability of a negative opinion on the quality of the medicinal product; b) issuing a prescription for stopping the circulation of a medicinal product in the region or throughout the territory of Ukraine; c) detection of violations of technological regulations for the production of counterfeit medicines; d) drawing up protocols on administrative offense, bringing to administrative responsibility.

The current situation has several aspects that have both a positive and a negative impact on the investigation process. In particular, experts who test drug for falsification actually give pre-qualification of the event prior to criminal proceedings, which significantly reduces the possibility of false or unjustified criminal offense, and significantly facilitates the investigator's work to verify the commission of a crime.

Obtaining information on falsification or trafficking of counterfeit medicines in accordance with the procedure of notification of the State Service of Ukraine for Drugs and Drug Control has documentary confirmation, in particular, as part of the inspection materials, the investigator is provided with:

- 1) acts on the results of verification of compliance by the business entity with the requirements of the legislation on quality assurance of medicinal products;
- 2) acts of sampling of medicinal product for laboratory testing of their quality;
- 3) an order imposing a ban on a medicinal product;
- 4) urgent reports on the detection of counterfeit medicines;
- 5) a prescription on elimination of violations of the legislation of Ukraine on medicines.

At the same time, it should be borne in mind that since the inspection itself is rather lengthy, the notification of the offense is received

after a considerable period of time. In this regard, it is unacceptable for investigators to await the results of the review of the State Service of Ukraine for Drugs and Drug Control, as this may affect the amount and quality of information retained about the crime and, ultimately, the quality of the investigation as a whole. Statements and notifications are a common reason for reporting crime. Signs indicating falsification or circulation of counterfeit medicines in this case may be: a) the presence of appeals, letters, complaints, citizens' statements regarding the quality of medicines;

b) incidents between medical staff and patients; c) fixation in the medical records of patients' abnormal reactions to drugs. Examining allegations or reports of adulteration or trafficking in counterfeit medicines as a pretext for initiating a pre-trial investigation, it should be noted that the primary basis for such notification is the *detection* of something unusual, inconsistent, or incorrect in the medicinal product by the pharmaceutical industry. For example, patients may find the difference (appearance, smell, taste, sensation of touch, impact of the product) between the counterfeit product and the drug they are familiar with through consumption¹. The most common features that should be addressed in the presence of suspected adulteration are: a) spelling errors in the instructions; b) font differences; c) violation of the integrity of the packaging; d) unclear quality of engraving or printing; e) lack of information on the country of the manufacturer or the manufacturer's factory; f) absence of marking, registration number; e) no expiry date.

First of all, it is necessary to study the packaging of the medicinal product, to evaluate its quality, font and the presence of spelling errors, which may be on the packaging itself and in the instructions for use. The materials of which the packaging and instructions are made must be of high quality, the colors are rich, the text is clearly visible, without gaps. The instructions should be printed, not copied.

As practice shows, the common reason for entering information on falsification and circulation of counterfeit medicines is also the notification of authorized employees of pharmacy establishments (retailers) and authorized employees of enterprises (entities of wholesale trade), conditioned by the quality control in Ukraine. medicines upon receipt, carried out by visual inspection or laboratory examination of the quality of the medicinal products at the time of their receipt².

¹ iRACM. A practical guide for EU investigations on Falsified Medicines. Draft guide version 20 – 2014. URL : <http://www.globalforumljd.org> (data zvernennia 12.07.2019).

² Pro zatverdzhennia Poriadku kontroliu yakosti likarskykh zasobiv pid chas optovoi ta rozdribnoi torhivli : nakaz Ministerstva okhorony zdorovia Ukrainy

During the visual examination, the authorized person checks the conformity of the obtained medicinal products with the accompanying documents regarding the quantity, dosage, batch numbers, expiration date, registration status, name, dosage form, manufacturer. Each batch of medicinal product must be accompanied by copies of the quality certificate of the batch of medicinal product issued by the manufacturer (for imported medicinal products by the importer (manufacturer or person representing the manufacturer of medicinal products in the territory of Ukraine)), the conclusion on the quality of imported medicinal products in Ukraine (for medicinal products). means of foreign production) and the conclusion on compliance of biological drugs with the requirements of national and national and international standards (for medical immunobiological preparations), certified by the seal of the supplier.

In case of establishment of pharmacy establishments and enterprises by employees during such control of violations, the act on the detected defects of medicines in respect of which there are suspected of falsification, as well as the falsified medicines, shall be forwarded to the State Service for Drugs and Drug Control together with a simultaneous notification law enforcement agencies on detected signs of adulteration or trafficking of counterfeit medicines.

Signs indicative of falsification or circulation of counterfeit medicines in the following circumstances may be: lack of complete documentary support for the circulation of medicines; the presence of individual errors in the shipping documents; defects in the packaging or labeling of the medicinal products described above; suspicion of the fictitiousness of the legal person – the seller, in particular, the absence of statutory or other primary accounting documents.

Information received from the customs authorities of the State Fiscal Service of Ukraine, the State Border Service of Ukraine may give rise to criminal proceedings regarding suspected possession of counterfeit medicines found at the customs border of Ukraine. Specificity of such goods as medicines makes it impossible for the customs authorities to directly check their quality¹. Considering the peculiarities of the order of

[About Confirmation of the Procedure for the Control of Medicinal Brightness Having Hacked a Pid Hour of Wholesale and Distribution Tornovly: a Directive of the Ministry of Health of Ukraine] vid 29.09.2014 № 677. Ofitsiyni visnyk Ukrainy vid 16.12.2014, № 98 [in Ukrainian].

¹ Volkova N. V. Mytni orhany v systemi derzhavnoho kontroliu yakosti likarskykh zasobiv [Customs authorities in the system of state quality control of medicines]. Visnyk Akademii mytnoi sluzhby Ukrainy. Seriya : Pravo, 2009. № 2. S. 68 [in Ukrainian].

movement of medicines, the possible forms of customs control should be recognized: 1) verification of supporting documents and other information for customs control; 2) consumers of counterfeit medicines; 3) oral questioning of citizens and officials of enterprises; 4) accounting for moving drugs; 5) перевірка системи звітності та обліку ліків, що переміщуються через митний кордон України; 6) inspection of territories and premises of temporary storage warehouses, customs licensed warehouses and other places where medicines are located¹. The head of the relevant customs authority or his deputies having considered the materials on violation of the customs rules and having established the presence of sufficient data indicating the signs of falsification and circulation of counterfeit medicines, shall transfer the collected materials to the body of pre-trial investigation for the initiation of pre-trial investigation.

Therefore, signs that may indicate fraud or circulation of counterfeit medicines found at the customs border of Ukraine can be:

a) availability of deficiencies in the accompanying documents and other information subject to customs control; b) availability of defects in appearance of medicines, packaging, marking; c) absence of medicinal products subject to customs clearance in the register of medicinal products of Ukraine; d) the negative opinion of the laboratory on the quality of the medicinal product and others.

The media often cover the facts of the offenses, including the falsification and trafficking of counterfeit medicines. In case of self-disclosure by the investigator or prosecutor in the media of reports of detected facts of falsification or trafficking of counterfeit medicines or consequences of use of medicines suspected of falsification, this is a reason for submitting information to the Unified Register of Pre-trial Investigations and to commence criminal proceedings.

Conclusions. The above gives grounds to claim that there are criminal procedural and organizational and tactical features of the beginning of criminal proceedings concerning the investigation of falsification and trafficking of counterfeit medicines and the possibility of considering it as a separate element of the structure of the relevant forensic methodology. The specifics of the initiation of criminal proceedings of the investigated crime are primarily manifested in the features of

¹ *Shevchuk O. M. Osoblyvosti zdiisnennia mytnoho kontroliu za peremishchenniam likarskykh zasobiv cherez mytnyi kordon [Peculiarities of implementation of customs control over the movement of drugs across the customs border]. Visnyk Kharkivskoho natsionalnoho universytetu vntrishnikh sprav. 2011. № 4. S. 318 [in Ukrainian].*

systematization of signs of falsification or trafficking of counterfeit medicines, the need for interaction of the investigator with the State Drugs Service and drug control, which is conditioned by the system of regulatory regulation of pharmaceutical activity in Ukraine. Knowledge of the investigators of the complex features of committing falsification and trafficking of counterfeit medicines will allow to ensure the timely opening of criminal proceedings, promptness in conducting investigative (investigative) and silent investigative (investigative) actions and will contribute to the effectiveness of pre-trial investigation and solving criminal cases.

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ФАЛЬСИФИКАЦІЯ ТА ОБІГ ФАЛЬСИФІКОВАНИХ ЛІКАРСЬКИХ ЗАСОБІВ: ВІЯВЛЕННЯ ОЗНАК ЗЛОЧИНУ ТА ПОЧАТОК КРИМІНАЛЬНОГО ПРОВАДЖЕННЯ

У статті досліджуються проблеми виявлення ознак фальсифікації та обігу фальсифікованих лікарських засобів й початку кримінального провадження. Виходячи з результатів узагальнення матеріалів судової та

слідчої практики, особлива увага приділяється виявленню ознак досліджуваного злочину з матеріалів оперативно-розшукової діяльності, повідомлень Державної служби з лікарських засобів та контролю за наркотиками, заяв потерпілих. Обґрунтовується роль та вагоме значення кримінально-процесуальних та організаційно-тактичних особливостей початку кримінального провадження для ефективного розслідування фальсифікації та обігу фальсифікованих лікарських засобів.

Ключові слова: фальсифікація та обіг фальсифікованих лікарських засобів, виявлення ознак фальсифікації та обігу фальсифікованих лікарських засобів, джерела виявлення ознак злочину, організаційно-тактичні особливості початку кримінального провадження, систематизація ознак фальсифікації та обігу фальсифікованих лікарських засобів.

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