



Wiadomości Lekarskie

Czasopismo Polskiego Towarzystwa Lekarskiego



Pamięci
dra Władysława
Biegańskiego

TOM LXXII, 2019, Nr 5 cz II, maj

Rok założenia 1928

Wiadomości Lekarskie is abstracted and indexed in: PubMed/Medline, EBSCO, SCOPUS, Index Copernicus, Polish Medical Library (GBL), Polish Ministry of Science and Higher Education.

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Credit Agricole Bank Polska S. A.: 82 1940 1076 3010 7407 0000 0000**

Cena prenumeraty dwunastu kolejnych numerów: 240 zł/rok (w tym 5% VAT)

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Cena pojedynczego numeru – 30 zł (w tym 5% VAT) + koszt przesyłki.
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**In the "Wiadomości Lekarskie" Journal (issue No 4, volume 72, 2019)
the article of Nadiia V. Shulzhenko entitled "LEGAL BASES FOR IMPROVING
LEGISLATION ON THE TRANSPLANTATION OF HUMAN
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Publisher:

ALUNA Publishing

ul. Przesmyckiego 29, 05-510 Konstancin – Jeziorna

www.aluna.waw.pl www.wiadomoscilekarskie.pl

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| | |
|--|------|
| Oleksandr V. Petryshyn, Evgenia Ya. Shapoval, Serhii M. Novik THE PHYSIOLOGICAL CHARACTERISTIC SYSTEM CONTROL OF WORKING ACTIVITY IN THE PROCESS OF TRAINING PROSPECTIVE HEALTHCARE PROFESSIONALS | 1059 |
| Maksim Y. Zak, Mykola O. Klymenko, Nataliia O. Iakovenko, Genadiy V. Grischenko MEDICO-SOCIAL VALUE OF OSTEOARTHRITIS. SECONDARY PREVENTION AND TREATMENT OF OSTEOARTHRITIS IN COMORBIDITY WITH CHRONIC GASTRITIS | 1064 |
| Valeriy Pokhylko, Olena Kovalova, Yuliia Cherniavska, Svitlana Tsvirenko, Yuliia Klymchuk DEVELOPMENT OF ARTERIAL HYPOTENSION IN PREMATURE INFANTS WITH EARLY ONSET BACTERIAL INFECTIONS: TOOLS OF CLINICAL PREDICATION | 1068 |
| Valeriy O. Zhamardiy, Viktoriya I. Donchenko, Anatoliy V. Yemets, Yevheniia O. Skrinnik PHYSICAL DEVELOPMENT BY MEANS OF FITNESS TECHNOLOGIES AS ONE OF GENERAL ASPECTS OF STUDENT'S HEALTH | 1074 |
| Julia V. Sidash, Elena V. Tkachenko POSSIBILITIES AND PERSPECTIVES OF HUMAN TYPOLOGIES TAKING INTO ACCOUNT IN DENTISTRY | 1079 |
| Mykola H. Prodanchuk, Galyna M. Balan, Nataliia M. Bubalo, Petro H. Zhminko, Oleksandr A. Kharchenko, Yevgen A. Bahlei THE PROBLEM OF ACUTE PESTICIDE POISONINGS OF AGRICULTURAL WORKERS IN UKRAINE UNDER THE CONDITIONS OF THE NEW BUSINESS PATTERNS | 1083 |
| PRACE POGLĄDOWE / REVIEW ARTICLES | |
| Valentyn M. Dvornyk, Inna V. Bielikova, Ludmyla M. Shylkina, Valentyna L. Filatova, Natalia M. Martynenko ANALYSIS OF THE MORTALITY RATE AMONG THE POPULATION OF THE POLTAVA REGION AND THE WAYS OF ITS REDUCTION | 1087 |
| Yevhen Yu. Strashko, Kateryna V. Pocheniuk, Ihor M. Skrypnyk DYNAMICS OF THE INCIDENCE, PREVALENCE AND DISABILITY OF DIABETES MELLITUS IN CHILDREN AGED 0 TO 17 YEARS IN THE POLTAVA REGION OVER THE PERIOD OF 2008-2017 | 1092 |
| Anna V. Fastivetz, Pavlo V. Khomenko, Valentyna V. Onipko, Anatoliy V. Emetc, Yevheniia O. Skrinnik MEDICAL ASPECTS OF SPECIALIST TRAINING IN PHYSICAL THERAPY AND ERGOTHERAPY IN THE SYSTEM OF HIGHER EDUCATION OF UKRAINE | 1098 |
| Liudmyla O. Samilyk, Valeriia O. Maliarova, Olena V. Dzhaferova, Tetyana I. Gudz, Vitaliy B. Kovalchuk COMPLEMENTARY MEDICINE: INTERNATIONAL EXPERIENCE OF FUNCTIONING AND SPECIFIC FEATURES OF THE APPLICATION IN UKRAINE | 1103 |
| Vyacheslav M. Zhdan, Iryna A. Holovanova, Maksim V. Khorosh, Mariia M. Tovstiak, Andriy M. Zinchuk COMPARATIVE ANALYSIS OF THE DYNAMICS OF MODIFIED RISK FACTORS OF NON-COMMUNICABLE DISEASES AMONG THE POPULATION OF CHINA AND UKRAINE | 1108 |
| Ozar P. Minser, Maksim M. Potiazhenko, Ganna V. Nevoit EVALUATION OF THE HUMAN BIOELECTROMAGNETIC FIELD IN MEDICINE: THE DEVELOPMENT OF METHODOLOGY AND PROSPECTS ARE AT THE PRESENT SCIENTIFIC STAGE | 1117 |
| Oleksandr Havlovskiy DYNAMICS OF THE PREVALENCE OF AFFECTIVE AND NEUROTIC DISORDERS ON THE EXAMPLE OF THE POLTAVA REGION FOR 2014-2018 | 1122 |
| Anastasiia A. Hrynzovska, Iryna A. Holovanova, Anatolii M. Hrynzovskiy LUBNY PHARMACY AS A FOUNDATING STRUCTURE OF MILITARY PHARMACY IN UKRAINE | 1126 |
| Larysa I. Arkusha, Iryna V. Hloviuk, Serhii V. Zavalniuk PROBLEMS OF COUNTERFEITING MEDICAL PRODUCTS IN UKRAINE | 1131 |
| Tetiana V. Pluzhnikova, Oksana I. Krasnova, Svitlana S. Kasinets, Svitlana M. Tanyanskaya, Natalia V. Yaroshenko, Iryna A. Kolenko ANALYSIS OF MORBIDITY AND CAUSES OF INFANT MORTALITY IN POLTAVA | 1136 |
| Oksana V. Sirenko, Elena V. Linnik, Lyubov V. Omelchuk, Vitaliy I. Bida, Serhii M. Hermanchuk, Serhii V. Irkha CURRENT LEGAL ISSUES OF CONDUCTING A FORENSIC MEDICAL EXAMINATION OF NEWBORNS' CORPSES | 1140 |
| Natalia O. Rynhach, Raisa O. Moiseenko CALCULATION OF LOSS OF CHILD MORTALITY IN UKRAINE AS AN INSTRUMENT FOR ESTIMATION OF ACHIEVEMENTS OF SUSTAINABLE DEVELOPMENT GOALS IN UKRAINE | 1145 |
| STRESZCZENIA WYSTĄPIEŃ NA KONFERENCJI / ABSTRACT BOOK | |
| ALL-UKRAINIAN SCIENTIFIC AND PRACTICAL TELECONFERENCE WITH INTERNATIONAL PARTICIPATION "POLTAVA'S DAYS OF PUBLIC HEALTH" MAY 31, 2019, POLTAVA, UKRAINE | 1150 |

PRACA POGLĄDOWA
REVIEW ARTICLE

PROBLEMS OF COUNTERFEITING MEDICAL PRODUCTS IN UKRAINE

Larysa I. Arkusha, Iryna V. Hloviuk, Serhii V. Zavalniuk

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ABSTRACT

Introduction: The provision of medical products of adequate quality should be considered as constituent element of the human right to life, inextricably linked with the right to health care protection and medical care. However, the Ukrainian market of counterfeit medical products affects the guaranteeing of the right to health care protection and medical care in Ukraine. The current situation necessitates a study of the legal regulation of counterfeiting of medical products in Ukraine and an increase in its effectiveness.

The aim of the research is the formation of scientifically based approaches to improve the activities on counterfeiting of medical products in Ukraine in the aspect of normative regulation.

Materials and methods: The empirical base of the research is the national legislation of Ukraine, data from the General Prosecutor's Office of Ukraine and the Unified State Register of Court Decisions. The methodological basis is a set of general and special research methods of scientific cognition, namely: the logical and normative method; statistical method, as well as methods of comparative analysis and logical methods of research.

Review: In the course of the research, the authors have analyzed international acts, national legislation of Ukraine determining the directions and specific features of the activities of state agencies in counterfeiting of medical products in Ukraine, the data of the General Prosecutor's Office of Ukraine and the Unified State Register of Court Decisions. On the basis of the performed analysis, the authors have suggested measures aimed at increasing the effectiveness of counterfeiting of medical products.

Conclusions: The imperfection of the existing system of counterfeiting of medical products in Ukraine has been proven. The authors have offered organizational measures to increase the effectiveness of counterfeiting of medical products, as well as to amend the current criminal, criminal and procedural legislation, taking into account the MEDICRIME Convention ratified in Ukraine.

KEY WORDS: falsification, medical products, counteraction, investigation, damage reimbursement

Wiad Lek 2019, 72, 5 cz. II, 1131-1135

INTRODUCTION

The realization of the inalienable human right to life is inextricably linked with the right to health care protection and medical care. At the same time, the provision of medical products of adequate quality should be considered as an integral part of these rights. As stipulated in the Fundamentals of the Legislation of Ukraine on Health Care, citizens are provided with medical products and immunobiological drugs through health care institutions that are entitled to perform this task in accordance with the law (Part 1 of the Art. 54). Health care institutions that are entitled to perform this task in accordance with the law can only dispense such medical products and immunobiological drugs that are allowed for use by the central executive agency ensuring the formation of state health policy (Part 3 of the Art. 54). The quality of medical products and immunobiological drugs must comply with the requirements of the State Drug Codex of Ukraine and the specifications approved in the prescribed manner (Part 2 of the Art. 55). Control over the quality of medical products and immunobiological drugs manufactured by the Ukrainian enterprises is exercised by the central executive agency implementing the state policy in the field of quality control and safety of medical

products (Part 3 of the Art. 55) [1]. Law of Ukraine dated from November 19, 1992 No. 2801-XII.

The aspects of ensuring the right to health care, in particular access to medical products, were considered by the European Court of Human Rights. In particular, the issues on the access to experimental drugs were researched in the judgments of the cases "Hristozov and Others v. Bulgaria" (applications No. 47039/11 and 358/12), "Durisotto v. Italy" (application No. 62804/13). The judgment of the case "Center of Legal Resources on behalf of Valentin Câmpeanu v. Romania" (application No. 47848/08) addressed the issue of not providing adequate medical care, including the aspect of failure to provide antiretroviral therapy.

The situation with the presence of the market of counterfeit drugs in Ukraine directly affects the guaranteeing of the right to health protection and medical care.

The Criminal Code of Ukraine provides criminal liability for the manufacture, acquisition, transportation, shipment, storage for the purpose of selling or selling scien-ter counterfeit drugs (the Art. 321-1).

According to the statistics from the General Prosecutor's Office of Ukraine [2], the year dynamics are as follows (Table I).

In the period from January 1, 2013 to March 28, 2019 the Unified State Register of Court Decisions revealed 27 sentences under the Art. 321-1 of the Criminal Code of Ukraine (Table II).

We believe it proves, first of all, the high latency of this crime, secondly, the difficulties in establishing the factual circumstances of this crime, thirdly, the need to clarify the methods for identifying, preventing and investigating this crime, and creating methodological recommendations for practitioners with regard to new technologies; fourth, the actual lack of studying the experience of law enforcement agencies of other countries.

THE AIM

The aim of the presented article consists in the analysis and systematization of existing problems occurring in counterfeiting of medical products in Ukraine.

The main objective of the article – is to analyze international documents, national legislation of Ukraine, data of the General Prosecutor's Office of Ukraine for the period of 2016 – 2019 and the Unified State Register of Court Decisions for the period of 2013-2018. On this basis to suggest a set of measures aimed at their elimination.

MATERIALS AND METHODS

The national legislation of Ukraine, international acts, statistical data of the General Prosecutor's Office of Ukraine for the period of 2016–2019, data of the Unified State Register of Court Decisions for the period of 2013-2018 were the materials for studying the methods of falsification of medical products and existing problems of counteraction in Ukraine. The methodological basis was the totality of general and special scientific methods of scientific cognition. The logical and regulatory method was used to justify the need for making amendments and alterations to the existing criminal, criminal and procedural legislation of Ukraine. The statistical method was used in the analysis of sentences on the relevant corpus delicti in Ukraine. While analyzing the data of the Unified State Register of Court Decisions, we used the methods of comparative analysis, as well as logical methods of research.

REVIEW AND DISCUSSION

The problem of counterfeit medical products is widespread not only in Ukraine (published results of scientific research in foreign editions [3, 4] testify to this).

The existing state of counterfeiting of medical products in Ukraine also requires an appropriate criminal and legal response to the relevant criminal acts, their effective investigation, and therefore there is the need to adapt the existing criminal, criminal and procedural legislation of Ukraine to international documents.

Thus, the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (MEDICRIME Convention), rati-

fied by Ukraine by the Law of Ukraine dated from June 7, 2012 No. 4908-VI, which entered into force for Ukraine on January 1, 2016, provides a positive obligation of the state to criminalize the corresponding act in the aspect of substantive law: Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law, the intentional manufacturing of counterfeit medical products, active substances, excipients, parts, materials and accessories (the Art. 5). Ukraine has criminalized this act and the Art. 321-1 of the Criminal Code of Ukraine provides liability for: manufacturing, purchasing, transporting, shipping, storing for the purpose of selling or selling scienter counterfeit medical products; the same actions committed repeatedly or by prior agreement by a group of persons, or on a large scale, or if they resulted in prolonged human health disorder, as well as the production of counterfeit medical products; actions provided in Parts 1 and 2 of this Article, if they resulted in the death of a person or other grave consequences, or committed on a particularly large scale.

This Convention establishes a number of procedural norms, and therefore it is necessary to consider the procedure of their correlation with the provisions of the Criminal Procedural Code of Ukraine dated from April 13, 2012.

Each Party shall take the necessary legislative and other measures to ensure that investigations or prosecution of offenses established in accordance with this Convention should not be subordinate to a complaint and that the proceedings may continue even if the complaint is withdrawn (the Art. 15 of the Convention). We should note that the offense under the Art. 321-1 of the Criminal Code of Ukraine is a crime of public prosecution, in this regard the commencement of criminal proceedings under the Art. 214 of the Criminal Procedural Code of Ukraine is possible without a complaint, so that the requirements of the Convention in this part are fully complied.

Investigation of criminal cases, in accordance with the Art. 16 of the Convention, should be carried out by persons, units or services competent in counterfeiting of medical products and similar crimes involving threats to public health, or that the relevant personnel have the necessary training for these purposes, including financial investigations. Such units or services shall have adequate resources. We should note that the Art. 216 of the Criminal Procedural Code of Ukraine, in accordance with the rules of the substantive jurisdiction, refers to the investigation of this crime by the investigative units of the National Police of Ukraine. It means that there is no agency that would be specialized in investigating this act, which indicates the inconsistency of the Convention in this part and the need to solve this problem. It is possible in several ways: by creating a unit within the National Police of Ukraine that would be specialized in investigating exclusively this crime (which seems at least premature, considering the dynamics of entering information into the Unified Register of Pre-Trial Investigations) or by introducing specialization of investigators to investigate a crime under the Art. 321-1 of the Criminal Code of Ukraine, who must undergo special

Table I. Criminal liability for the manufacture, acquisition, transportation, shipment, storage for the purpose of selling or selling scienter counterfeit drugs, the Art. 321-1 (2016-2019).

| | Registered | Notified about the Suspicion | Filed to the Court with Indictment | Terminated proceedings | No Decision Taken |
|------|------------|------------------------------|------------------------------------|------------------------|-------------------|
| 2016 | 27 | 5 | 3 | 8 | 24 |
| 2017 | 23 | 3 | 3 | 9 | 20 |
| 2018 | 40 | 2 | 1 | 7 | 39 |
| 2019 | 9 | 0 | 0 | 0 | 9 |

Table II. Sentences under Art. 321-1 of the Criminal Code of Ukraine (01.01.2013-28.03.2019).

| Year | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 |
|--------|------|------|------|------|------|------|------|
| Number | 6 | 3 | 6 | 5 | 3 | 2 | 2 |

training and / or advanced training, taking into account the specifics of this crime, which also requires the investigators to have basic pharmaceutical knowledge (which is currently more realistic and affordable way).

Each Party shall take the necessary legislative and other measures, in conformity with the principles of its domestic law, to ensure effective criminal investigation and prosecution of offences established in accordance with this Convention, allowing, where appropriate, for the possibility for its competent authorities of carrying out financial investigations, of covert operations, controlled delivery and other special investigative techniques.

In terms of audits of financial statements, there is now a common problem related to the fact that the prosecution party does not have the authority to initiate audits and inspections within criminal proceedings. And in this regard, there is a problem of the validity of conducting, for example, economic expertise, since audit certificates are provided to an expert, and conducting audit activities (determination of any economic indicators by experts in the economic field without prior documentary inspections of financial and economic activities by the control subject) does not relate to the tasks of economic examination, which is provided by the Instruction on the appointment and conduct of forensic examinations and expert studies, approved by the order of the Ministry of Justice of Ukraine (as in force on December 26, 2012, No. 1950/5).

To special methods of investigation should include a complex of covert investigative (search) actions provided by the Chapter 21 of the Criminal Procedural Code of Ukraine. However, taking into account the requirements of the Criminal Procedural Code of Ukraine to the severity of crimes, they are not carried out under Part 1 of the Art. 321-1 of the Criminal Code (manufacture, purchase, transportation, shipment, storage for the purpose of selling or selling deliberately falsified drugs), in the proceedings of which such actions can be carried out, since these are crimes of moderate gravity. Thus, these tools are not applied to acts in the form of manufacturing, purchasing, transporting, shipping, storing for the purpose of selling or selling deliberately counterfeit medical products, which clearly

does not correspond to the degree of their public danger and the requirements of the Art. 16 of the Convention.

However, it should be noted that there is a positive fact that under Part 2 and Part 3 of the Art. 321-1 of the Criminal Code of Ukraine (the same actions committed repeatedly or by prior agreement by a group of persons, or on a large scale, or if they resulted in a long-term human health disorder, as well as the production of counterfeit drugs; actions provided in Parts 1 or 2 of the Article 321-1, if they entailed the death of a person or other grave consequences, or committed on a large scale), it is possible to apply the procedure provided in the Art. 250 of the Criminal Procedural Code of Ukraine, namely, to start conducting covert investigative (search) actions in the form of establishing the location of the radio-electronic means and surveillance over the person before obtaining the decision of the investigating judge in cases, when it is associated with saving lives and preventing the commission of these crimes.

In the aspect of covert measures, we should also note that such effective means within financial investigations (referred to, in particular, in the Article 16 of the Convention), as the monitoring of bank accounts can not be used in the investigation of a crime under the Art. 321-1 of the Criminal Procedural Code of Ukraine. This seems to require clarification in the aspect of expanding the scope of this covert investigative (search) action and removing the limitations of the investigative jurisdiction of criminal proceedings, where its conduction is possible [5].

Pharmaceutical and pharmacological expertise is necessary for the effective investigation of a crime under the Art. 321-1 of the Criminal Code of Ukraine. In practice, a complex forensic examination is also appointed (for example, the case No. 522/14195 / 15-k), a forensic and medical examination (the case No. 647/2502/13-k), a forensic and chemical expertise (the case No. 643/15936/15-k), a comprehensive forensic and chemical, pharmaceutical expertise (the case No. 643/15936/15-k). They are not classified as mandatory in accordance with the Art. 242 of the Criminal Procedural Code of Ukraine, although it is impossible to establish the fact of falsification of a medicinal product without them. At the same time, there is a problem in practice of expediting

the appointment of examinations, in particular, related to amendments and alterations to the Criminal Procedural Code of Ukraine on the possibility of attracting an expert only by the investigating judge and the court. The literature suggests propositions to change this procedure [6]. At the same time, one can now state that the adoption of the Law of Ukraine No. 2147-VIII created conditions for the loss of objects, tools, traces of crimes, and prevention of the implementation of a complete, timely and objective pre-trial investigation of a significant number of crimes. Besides, the investigative judges, who now have to consider a petition for examination, often have lack of the necessary knowledge on the subject of expert research, as well as the capabilities of a particular type of examination. The real need for an examination of the relevant criminal proceedings and the formation of the list of questions that are offered for an expert, are open questions. And this may entail certain unjustified refusals to satisfy the relevant petitions of the parties [7].

The Article 19 of the Convention provides that Each Party shall take the necessary legislative and other measures to protect the rights and interests of victims, in particular by providing, in its domestic law, for the right of victims to compensation from the perpetrators. It should be noted that the civil legislation of Ukraine provides compensation for harm caused by injury or other harm to health, which may occur as a result of the use of counterfeit medical products. An individual or a legal entity caused harm to an individual by injury or other harm to his health is obliged to compensate the victim for earnings (income) lost by him due to the loss or reduction of professional or general working capacity, as well as to compensate additional expenses caused by the need for enhanced nutrition, sanatorium-and-spa treatment, the purchase of drugs, prosthetics, external care, etc. (the Art. 1195 of the Civil Code of Ukraine dated from January 16, 2003). The procedure for the realization of this right within criminal proceedings is manifested in the institution of a civil claim in criminal proceedings. To establish the amount of harm that is subject to compensation due to the harm to human health, it is necessary to use special knowledge, where an expert (experts) should be involved in accordance with the Art. 242 of the Criminal Procedural Code of Ukraine. At the same time, it should be noted that there are gaps in the criminal procedural regulation of involving an expert to determine the harm to human health, since this case is not related to cases of mandatory involvement of an expert (the Art. 242 of the Criminal Procedural Code of Ukraine), which requires correction and amendment to the Criminal Procedural Code of Ukraine.

CONCLUSIONS

Analysis of criminal activities related to falsification of drugs, as well as the state of counteraction to its manifestations, makes it possible to offer the following measures aimed at increasing the effectiveness of such counteraction: the creation of special state authorities of public administration for the pharmaceutical industry; change (simplification) of the licensing system of pharmaceutical enterprises, the

transparency of the activities of state agencies endowed with such powers, their reduction; the introduction in Ukraine of an automated tracking system for drug turnover using a unique identifier; equipping drug packages with special protective “locks” that do not allow changing the content; introduction of electronic recipes; carrying out (without exceptions) inspections of imported drugs in places of entry into Ukraine in order to identify and confiscate counterfeit medical products; establishing interaction between bona fide drug manufacturers, government agencies (including law enforcement agencies), the media and public organizations; raising public awareness about the existing system of drug protection from counterfeiting.

In order to improve the effectiveness of investigating crimes under the Art. 321-1 of the Criminal Code of Ukraine, it is necessary to make amendments and alterations to the Criminal Code and the Criminal Procedural Code of Ukraine, namely: to refer the crime under the Art. 321-1 of the Criminal Code of Ukraine, to serious crimes, by changing the sanction in Part 1 of the Art. 321-1 of the Criminal Code of Ukraine, in particular, by providing the sanction of more than 5 years of imprisonment; to regulate the proper legal procedure providing inspections and audits in the framework of criminal proceedings, in particular the possibility to appoint inspections and audits by the investigating judge at the request of the parties; to change the procedure of involving an expert, providing the possibility of involving an expert by the parties and victims, including on the basis of an agreement between the defense party, the victim and the forensic institution; to establish the provisions on the mandatory involvement of an expert to determine the physical harm to human health in the Art. 242 of the Criminal Procedural Code of Ukraine, which is obligatory within criminal proceedings under the Art. 321-1 of the Criminal Code of Ukraine in order to fully and complete establishment of the actual circumstances.

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According to the order of the Authorship

Conflict of interest:

The Authors declare no conflict of interest

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Received: 24.03.2019

Accepted: 06.05.2019