

Some Aspects of Combating Crimes in the Sphere of Manufacturing and Trafficking Medicines: Problems of Timely Detection

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Abstract. The problems of the timely exposure of crimes committed in the sphere of production and circulation of medical supplies, by the divisions of the Department of Economic Protection of the National Police of Ukraine are considered. In particular, the reasons for the lack of reliable statistics on the number of counterfeit medical supplies in circulation in Ukraine were investigated. The provision on the feasibility of introducing labeling of medical supplies to ensure their tracking from the moment of entering the market until the moment of selling in pharmacies has been substantiated.

Keywords: medical supplies; pharmaceutical market; falsified or unregistered medical supplies; crime latency; drug labeling.

Problem statement

The domestic pharmaceutical industry is developing intensively. According to the results of the research "Pharmaceutics of Ukraine. Infographics Atlas", which was presented in the Chamber of Commerce in the spring of 2018, the volume of sales of pharmaceutical products in Ukraine in 2017 increased by 20% – up to 70 billion UAH [1]. Along with this, experts predict a further growth of the Ukrainian pharmaceutical market, taking into account the existence of a corresponding global trend. Thus, the global pharmaceutical market is growing annually by 5–6%, and according to forecasts for 2017–2021, it will grow by 34% – to \$ 14,85 billion. At the same time, countries with pharmaceutical emerging markets will give almost a quarter of this increase [1].

In general, the pharmaceutical market is a powerful industrial sector, which is among the five most profitable sectors of the world economic complex [2, p. 56].

During 2015–2017 in Ukraine, the number of valid licenses for carrying out economic activities for the production of medicines practically did not change, while the number of valid licenses for wholesale and retail trade in pharmaceuticals increased by 11%, for imports of medicines – by 15%, which to a certain extent indicates the profitability of these activities [3, p. 15].

Among the medical supplies sold in the pharmaceutical market of Ukraine, almost 70% of foreign production [3, p. 42]. At the same time, domestically manufactured medicines are also mainly manufactured from foreign-made substances.

However, recently, despite all the positive characteristics of the domestic pharmaceutical market and alongside the intensive development in Ukraine of the pharmaceutical industry, there is a shadow business in the pharmaceutical production and drug circulation, intensification of falsification of medical

supplies, resulting in a number of counterfeit, low-quality or unregistered drugs. In our state it has increased significantly. If from 2011, when criminal liability for falsification of drugs was first introduced, until August 2014, when a moratorium was imposed on inspections of pharmaceutical companies, law enforcement agencies found only three cases of clandestine production of counterfeit medical supplies (underground warehouses in Lviv, Vasylkiv, and falsification of drugs of the company "Heel"), since August 2014 and up to 2016, 18 such cases have already been recorded [4].

Analysis of recent research and publications.

Crime in the production and circulation of medicines by legal scholars A. Bailovym, Yu. Baulinym, Yu. Danilevskoiu, I. Horbachovou, O. Hrebeniuk, O. Huk, I. Kovalenkom, V. Melnychukom, V. Merkulovoou, A. Muzykoi, H. Pochkun, O. Stankevych, Ye. Streltsovym, O. Tretiakovou, I. Vartyletskoiu was mainly considered taking into account the provision of the criminal law characteristics of these crimes, disclosing the composition of these crimes, the problems of their qualifications in law enforcement practice, the provision of proposals for improving criminal standards on responsibility for committing crimes in the sphere of production and circulation of drugs, criminal law and criminological countering the treatment of counterfeit medical supplies, etc. However, require in-depth study of the question of disclosure and analysis of problems of timely exposure of law enforcement bodies of Ukraine of crimes committed in the sphere of production and circulation of drugs. This article is devoted to these questions.

The purpose of the article is to uncover the problems of the timely exposure by law enforcement agencies of Ukraine of crimes committed in the production and circulation of medicines, as well as to identify the main drawbacks of control in this area.

Presentation of the main research material.

During 2010–2015, only the State Service of Ukraine on Medicines and Medicines Control (State Medical Service) and its territorial bodies revealed more than 9,600,000 packages of substandard and falsified medicines totaling more than 270 million hryvnias [4].

To this it should be added that during 2015–2017, the State Department provided [5]:

- 98 prescriptions banning the circulation of 84 items of substandard medicines;
- 82 orders prohibiting the circulation of 57 items of counterfeit medicines.

In the world there is no uniform methodology for calculating the number of prohibited falsified series of medical supplies, therefore, various experts use different methods to calculate the percentage of falsification on the pharmaceutical market of Ukraine, as a result of which their data obtained by applying these methods differ significantly. Some experts claim that now 30 percent or more of counterfeit medicines are sold in pharmacies [6]. At the same time, official data on counterfeit in the pharmaceutical market of Ukraine is much less.

So, in 2018, the State Committee for State Service cited the following statistics regarding imported foreign-made medicines imported to Ukraine [5]:

- in 2015 – 0,12%;
- in 2016 – 0,12%;
- in 2017 – 0,004%.

Information about identified and prohibited by the State Committee of the Republic of Belarus on medicinal products of inappropriate quality is sent to law enforcement agencies.

According to experts, on the whole, in Ukraine, State Medical Service found in circulation counterfeit medicines, along with low-quality and unregistered medicines, constitute no more than 1,5–1,8% [7]. However, these indicators characterize only the amount that was discovered, that is, the domestic pharmaceutical market is characterized by a high latency of crimes related to falsification of medical supplies.

Evaluation of the effectiveness of the state control bodies needs to be improved [8, p. 7]. Now available to the public information about the quality of medicines in circulation is limited. This makes it difficult to assess the results of the work of regulatory bodies (for example, on the dynamics of reducing the share of low-quality and counterfeit medicines on the market as compared with the input parameters (number of inspections and expenses for them)). Now

the number of inspections remains the main indicator of success for regulatory bodies.

In open access there is no reliable statistics on identified counterfeit drugs. There is no single electronic base of counterfeit in the sphere of production and circulation of medicines and methods for calculating the share of counterfeit in the pharmaceutical market [8, p. 68]. The absence of such information makes it impossible to monitor the fight against counterfeit and low-quality drugs and to evaluate the results of the work of the relevant state regulatory body in this field of activity. This assessment should be based on an analysis of the effectiveness of using funds to ensure the safety and quality of medicines and demonstrate progress in reducing the share of low-quality and falsified goods on the Ukrainian market [8, p. 68]. And this is very important from the point of view of the development of instruments for monitoring and adjusting the size of state financing of regulatory bodies. It is a situation when the main indicator of the effectiveness of the controlling body is the number of inspections [8, p. 68].

Therefore, it is advisable to develop a method for calculating the share of counterfeit and low-quality medicines on the market, as well as to create an electronic database of counterfeit and low-quality medicines [8, p. 70].

In addition, it is necessary to increase the transparency of the quality control system of medicines and introduce an effective mechanism for public monitoring of its effectiveness. To this end, it is necessary to develop criteria for the effectiveness of the state drug quality control system, to which include indicators of results (and not the process!) Work to ensure the quality of medicines, including an indicator of the volume of detected poor quality and falsified pharmaceutical products in Ukraine and its share in the pharmaceutical market, and also to introduce a public disclosure of information on the performance of regulatory bodies.

Ensuring the proper quality of medicines essentially depends on the proper organization of the control, its effectiveness and efficiency. However, the criminal proceedings of this category, completed in the court of conviction, account for a few.

So, in spite of impressive data on substandard, unregistered and falsified medicinal products

identified in recent years by the State Medical Service and its territorial bodies, judicial practice on these facts is insignificant. So, according to court statistics of the State Judicial Administration of Ukraine under art. 321-1 of the Criminal Code of Ukraine (Criminal Code of Ukraine) were convicted [9]:

– in 2017 only 4 people: 2 people – according to part 1 of art. 321¹ of the Criminal Code of Ukraine and 2 more people – under part 2 of art. 321¹ of the Criminal Code of Ukraine (one of them was deprived of liberty for more than 5 years to 10 years, inclusive, another was released from punishment – with probation, additional types of punishment were applied to one person – confiscation and punishment were given in aggregate);

– in 2016 – 3 people: one person for each of the three parts of art. 321¹ of the Criminal Code of Ukraine (the same 3 people were released from punishment with probation);

– in 2015 – 9 people: 8 people – according to part 2 of art. 321¹ of the Criminal Code of Ukraine and 1 – for hours 3 art. 321¹ of the Criminal Code of Ukraine (the same 9 people were exempt from punishment with probation, while for one person additional types of punishment were used – confiscation and a total punishment was imposed) except 9 people convicted under art. 321¹ of the Criminal Code of Ukraine, two more cases were closed;

– in 2014 – 6 people: 4 people – according to part 1 of art. 321¹ of the Criminal Code of Ukraine and 2 people – for part 2 of art. 321¹ of the Criminal Code of Ukraine; of these 6 people, one person was punished with imprisonment for 1 year, another 4 people were exempted from punishment with probation, and two types of punishment were respectively imposed on additional types of punishment – confiscation and the punishment was given in aggregate;

– in 2013 – 13 people: 4 people – according to part 1 of art. 321¹ of the Criminal Code of Ukraine, 6 people – for part 2 of art. 321¹ of the Criminal Code of Ukraine and 3 – for part 3 of art. 321¹ of the Criminal Code of Ukraine, of which 1 person was deprived of liberty for a term of over 3 years to 5 years inclusive, 9 people were released from punishment with probation, up to 3 people were subjected to an additional type of punishment – confiscation,

of them up to two people were also punished by aggregate;

– in 2012 – 4 people: 2 people – according to part 1 of art. 321¹ of the Criminal Code of Ukraine and 2 people – for hours 3, art. 321¹ of the Criminal Code of Ukraine, of which 3 people were exempted from punishment with probation and a fine was imposed on one person.

We support the scientific position on this issue I. Horbachova, who considers the reasons for such a state of judicial statistics or the existence of difficulties in implementing the provisions of this article of the Criminal Code of Ukraine, or the actual impossibility to identify the perpetrators [10, p. 228].

So, the majority of falsifiers of medicines manage to evade responsibility, therefore effective control is required from both the controlling authorities of the executive and the law enforcement agencies.

Judicial statistics from 2012 to 2017 under art. 321-2 of the Criminal Code of Ukraine is absent altogether, that is, under this article, persons were not convicted during this period. Bye according to art. 321² of the Criminal Code of Ukraine are missing both judicial and investigative practices. Regarding judicial statistics under art. 305 of the Criminal Code of Ukraine, it should be noted that this article takes into account criminal acts related both to the smuggling of counterfeit drugs and to the smuggling of narcotic drugs, psychotropic substances, their analogues or precursors, that is, data on the smuggling of counterfeit drugs are not separately identified, therefore provide information about judicial statistics under art. 305 of the Criminal Code Ukraine makes sense.

Along with the lack of effectiveness of the state system of control of the pharmaceutical industry, there are problems in the activities of the practical units of the Department of Economic Protection of the National Police of Ukraine (DZE NPU) to identify these crimes.

So far, the directions of the operative search for relevant information on criminal and other offenses committed in the sphere of production and circulation of medicines, the units of the Department of Computerization and Dentistry of NHE do not always pay enough attention. The main reasons for this are:

1. The weakness of the operational positions in this field of activity does not allow the employees of the Department of Public Opinion Physics of the NHRI to timely receive the necessary and reliable information.

2. Insufficient level of training of employees of the Department of Computerization and Drug Control of NHRI, capable of conducting work on the timely detection of criminal activities of business entities engaged in the illegal distribution of falsified drugs on the pharmaceutical market.

In addition, there are difficulties arising in the process of counteracting the said criminal and other offenses related to the lack of awareness of the employees of the Department of the Department of economic and economic activity of the NHRI with the peculiarities and regulatory regulation of economic activities in the pharmaceutical industry. In practice, there are no scientifically developed – taking into account the current state of the problems of counteracting crimes and other offenses committed in the sphere of production and circulation of medicines – methodological materials on organizing the detection and prevention of these crimes and other offenses.

Law enforcement agencies in the fight against the spread of counterfeit drugs on the pharmaceutical market have serious difficulties due to the imperfection of the legal framework, contradictions in the interpretation of the law, the lack of generalization of legal and judicial practice, as well as scientifically based recommendations on the qualification of socially dangerous acts of this category.

In 2012–2013, the introduction of drug labeling was discussed for a long time in order to ensure their tracking from the moment they entered the market to the time they were sold in pharmacies. This step was considered as a tool to fight counterfeiters on the pharmaceutical market, as well as a means to combat corruption related to the possibility of selling drugs purchased for public funds (primarily in pharmacies in hospitals). The necessary software was purchased, the cost of marking was calculated (from 0.01 to 0.08 UAH per package) [8, p. 64].

A pilot project for the introduction of individual external labeling of drug packaging

has been developed by the State Committee of Services. It was supposed to apply an individual number to the packaging of each medicinal product. Marking the outer packaging of each drug in the form of a two-dimensional bar code that conforms to the GS-1 standard, minimized the possibility of fraud in legal circulation, and also provided an opportunity to identify drugs in real time [11].

The impetus for labeling discussions was the intention to introduce mandatory labeling of prescription drugs over the next few years in the EU [8, p. 65]. Accordingly, participants in the pharmaceutical market feared that because of this, the volume of counterfeit drugs in Ukraine could increase if a similar system was not introduced. However, this project, despite the efforts made, has not been implemented.

We consider it is necessary to reanimate this project, to increase the number of counterfeit drugs in circulation. Therefore, it is advisable to consider the possibility of implementing a project on the labeling of drugs entering

the Ukrainian market in order to increase the effectiveness of activities to identify counterfeit drugs and fight corruption in the consumption of drugs purchased for public funds [8, p. 71].

In addition, we believe that the practice of conducting scheduled inspections of drugs circulation should be reviewed, by canceling the warnings of the subject of the inspection on the exact date of the inspection [8, p. 70].

The mechanism of planned quality checks of drugs in circulation is not very effective [8, p. 67]: the supervising authority should warn about the scheduled inspection in advance – 10 days in advance. In this case, it is almost impossible to detect counterfeit, because unscrupulous business entities have the opportunity to hide all problematic drugs.

In practice, it is advisable to ensure that inspections of business entities are carried out, depending on the degree of risk that they carry out business activities in the production and circulation of medicines (based on an assessment of compliance with the requirements of good practice).

Conclusion

Based on the study and synthesis of relevant law enforcement practices in relation to crimes committed in the sphere of production and circulation of medicines, it is necessary to develop and introduce new methods of exposing and investigating these criminal offenses, for which you need to have a clear idea of the types and typical ways of their perpetration; develop a set of economic, legal and criminological measures to identify ways to combat these criminal acts and other offenses; to study, analyze and summarize the regulatory framework governing the process of manufacturing, importing and trading in medicinal products, as well as to study the criminogenic determinants that contribute to the commission of crimes in the pharmaceutical market.

Important is the cooperation of the Department of economic analysis and economic analysis of national industrial establishments with the State Service, the employees of which are authorized to control the observance of licensing conditions for economic activities in the production and circulation of medicines by business entities. Specialists of this service can not only provide information on identified offenses in this area, but also be part of the investigative and operational team in the implementation of investigative (investigative) actions to identify violations in the pharmaceutical industry about the treatment of drugs.

Only under the condition of well-coordinated cooperation between government regulatory, regulatory, law enforcement agencies and drug manufacturers can the flow of fakes and the distribution of counterfeit drugs on the pharmaceutical market of Ukraine be stopped.

References:

1. Farmatsevtychnyi rynok Ukrayny v 2017 rotsi zris na 20%: doslidzhennia. URL: https://ua.censor.net.ua/news/3063203/farmatsevtychnyyi_rynek_ukrayiny_v_2017_rotsi_zris_na_20_doslidjenna
2. Kovinko O., Stakhova A., Vovk A. Farmatsevtychnyi rynok Ukrayny yak rushiyny vazhil rozvytku ekonomiky. Naukovy visnyk Uzhhorodskoho natsionalnogo universytetu. 2017. Vyp. 11. S. 56–59.
3. Pro zatverdzhennia zvitu pro rezultaty audytu efektyvnosti ta obgruntovanosti zastosuvannia podatkovykh pilh z podatku na dodanu vartist za operatsiiamy z postachannia ta vvezennia na mytnu terytoriui Ukrayny likarskykh zasobiv i medychnykh vyrobiv: rishennia Rakhunkovoї palaty vid 6 bereznia 2018 roku № 4–6. URL: http://www.ac-rada.gov.ua/doccatalog/document/16756087/Zvit_4-6_2018.pdf?subportal=main.
4. Falsyfikovani liky v Ukrayni: problemy i shliakhy vyrishennia (interviu z nachalnykom Derzhliksluzhby u Rivnenskii oblasti Lebedem S.). URL: <http://fp.com.ua/articles/falsifikovani-liki-v-ukrayini-problemi-i-shlyahi-virishennya>.
5. Do vidoma spozhyvachiv likarskykh zasobiv. Derzhavna sluzhba Ukrayny z likarskykh zasobiv ta kontroliu za narkotykami. URL: <http://www.diklz.gov.ua/control/main/uk/publish/article/1107377>
6. Opryliudneno ofitsiinu informatsiui shchodo kilkosti falsyfikovanykh likiv v aptekakh. APAU. URL: <http://apau.org.ua/2018/02/27/%D0%BE%D0%BF%D1%80%D0%B%D0>
7. Falsyfikovani liky: yak borotysia z tinniu? URL: <http://www.vz.kiev.ua/falsifikovani-liki-yak-borotysa-z-tinnyu>.
8. Rehuliuvannia rynku likarskykh zasobiv v Ukrayni: problemy ta rishennia: proekt zvitu Analitychnoho tsentru “Nova sotsialna ta ekonomiczna polityka”. URL: http://newsep.com.ua/media/news/816/files/%D0%9F%D0%A0%D0%9E%D0%95%D0%9A%D0%A2_%D0%97%D0%92%D0%86%D0%A2%D0%A3_2016_.PDF
9. Forma № 6 “Zvit pro kikist osib, zasudzhenykh, vypravdanykh, spravy shchodo yakykh zakryto, neosudnykh, do yakykh zastosovano prymusovi zakhody medychnoho kharakteru ta vydy kryminalnogo pokarannia”. Sudova statystyka: zvitnist za danymi Derzhavnoi sudovoї administratsii Ukrayny. URL: https://court.gov.ua/inshe/sudova_statystyka
10. Horbachova I. Deiaki aspeky penalizatsii falsyfikatsii likarskykh zasobiv za KK Ukrayny. Porivniaanoanalytichne pravo. 2016. № 6. S. 228–231.
11. Falsyfiksii likarskykh zasobiv. Zahroza zhyttiu i zdoroviu liudyn ta kryminalna vidpovidalnist. URL: <http://region.diklz.gov.ua/control/zhy/uk/publish/article/388101;jsessionid=819719C98026254C5738E6CC6CD55DCD>