Protection of Human Rights in the Context of Combating of Counterfeiting Medicines: Theoretical and Legal Issues of International Cooperations

Filei Yurii Vladimirovich[1], Davidov Pavel Grigorovich[2], Dmytro Yermolenko[3], Koverznieva Hanna[4], Vasyl V. Ilkov[5]

[1]Candidate of Law, Associate Professor, Dean of the Faculty of Law, Institute of Management and Law National University "Zaporizhzhia Polytechnic" (Zaporizhzhia, Ukraine), [2]Candidate of Philosophy, Associate Professor, Department of Language and Humanitarian Disciplines No. 1, Donetsk National Medical University, Doctor of Science (Law), Professor, Civil Law Department, Zaporizhzhya National University, Zaporizhzhia, Ukraine, [4]Ph.D. in Law, Assosiated Professor, Faculty of Business Administration and Law, Department of Law, Kyiv University of Market Relations, Ukraine, [5]Doctor of Science (Law), Professor, Judge of Dnipropetrovsk Regional, Administrative Court

Abstract

The article highlights the problematic issues of implementing of the best international practices in protection of a human and human rights, and counterfeiting medicines in the context of globalization. Every state exists for man, for the protection of universally recognized rights and freedoms. Counterfeiting of medical products and other similar crimes require attention in any country in the world.

Counterfeiting is not an exception in developed countries in Europe, such as the Netherlands, Belgium, Sweden, Switzerland, Finland, Norway, Denmark, and Austria. This problem is global for, both, legal and public administration science. It is widespread throughout the world, and the negative effects of this crime have severe consequences that affect people's lives and health.

Keywords: *Counteraction management, counterfeiting of medicines, globalization, digitization, protection of a human and human rights.*

Introduction

The development of Europe, Asia, North and South America, Africa, Australia and Oceania is currently linked with the implementation of a number of urgent reforms, including the modern transformation of crime-fighting method. The global problem of counterfeiting in medicines is in need of immediate solution worldwide.

When a person dies because of adulteration of medicines or loses health, the consequences are deplorable. Buying medicines from pharmacies, a patient does not always pay attention to their quality. The regulation of this issue at the international level makes it possible to issue responsibility for the above-mentioned crimes in the states and stop it, or at least significantly reduce their number normatively. In the case of purchase of counterfeit medicines, a person may file a lawsuit with the administrative court to protect their rights in the field of public-legal relations in the event of inaction or unlawful decisions by the relevant authorities.

Literature Review: Counterfeit products reach the highest levels in countries with imperfect legal frameworks in the regulation of drug trafficking and lack of efficiency in regulatory oversight of counterfeit drugs. In most countries with developed regulatory framework and market control, such drugs are rarely found[1,2], [p. 29]. Ukrainian scientist Khromykh A.G. conducted an expert survey to determine the main factors affecting the adulteration of medicines by developing a questionnaire with more than 150 experts. Therefore, according to experts, the most important factors influencing the circulation of counterfeit medicines are identified as follows: a developed system of selling medicines

through the global Internet information network and mail that does not allow the control bodies to check their quality; high cost of imported medicines, which makes the sale profitable; etc. These practices and the review of scientific sources have made it possible to identify also the most promising at the present stage of the technology of protection of pharmaceutical products from adulteration[3], namely: their origin through electronic registration.

The World Health Organization estimates that counterfeit drug sales are about $ 200 billion annually, equivalent to 10-15% of the global pharmaceutical market[4]. In Russia, the problem of counterfeiting of medicines, as in most countries of the world, remains urgent and needs to be addressed by amending the legislation.

A number of international acts have been adopted in order to address the problem of counterfeiting of medicines. For example, in Ukraine, the Council of Europe Convention on Counterfeiting of Medical Products and Similar Health-Related Crimes[5] entered into force on 1 January 2016. The Universal Declaration of Human Rights[6], promulgated by the General Assembly of the United Nations on 10 December in 1948; and the Convention for the Protection of Human Rights and Fundamental Freedoms, issued in1950 and its number ETS No. 5[7]; the European Social Charter, issued in 1961, ETS No. 35[8]; the Convention on the Development of the European Pharmacopoeia (1964, ETS No. 50)[9]; and Protocol thereto 1989, ETS No. 134); the Convention on the Protection of Rights and Dignity on the application of biology and medicine; Convention on Human Rights and Biomedicine, issued in 1997, ETS No. 164)[10]; Additional Protocols, issued in 1998 ETS number 168; issued in 2002; ETS number 186, issued in 2005; CETS number 195, issued in 2008; CETS number 203; the Convention on Cybercrime issued in 2001, ETS number 185 are International instruments for governing these issues[11]. Rule makers have duly drawn attention to other relevant international legal instruments and programs. They were paid to those which were conducted by the World Health Organization and included the work of the IMPACT Group, the European Union, and the G8 (since 2014 - G7). Determined to effectively achieve the overall goal of combating crime, which includes counterfeiting of medical products and similar health-threatening crimes, in particular, by fixing new crimes and criminal penalties relating to these crimes[12].

Aims: Studying and generalizing the best international experience in counterfeiting medicines, as well as exploring the problematic issues of its implementation in the context of globalization.

Method

The research material is a modern international regulatory framework governing the fight against counterfeiting of medicinal products, foreign and domestic scientific works of specialists. The system method, structural and functional method, techniques of logical method (analysis, synthesis, deduction and induction), method of legal statistics, legal modeling were used in writing the article.

Results

For example, it is worth noting that Article 165 of the Criminal Code of Poland establishes responsibility for actions such as the manufacture and putting into circulation of harmful substances, foodstuffs or other public goods, as well as pharmaceuticals that do not meet the mandatory requirements, which do not meet the requirement of conditions of quality[13]. Denmark's criminal law, for example, establishes liability for actions such as the sale of medicines that do not meet these goals and may cause harm to health[14]. In the United States, the Food and Drug Administration is the primary body responsible for monitoring compliance with pharmaceutical law. Along with the Food and Drug Administration, as a federal body, each state has its own supervisory authority[15].

For example, in October 2011, pharmaceutical giant subsidiary Glaxo Smith Kline was found guilty of four counts of counterfeit medicines. The lawsuit is also considered a civil suit filed by the Office of Criminal Investigations alleging that Glaxo Smith Kline has accused the Food and Drug Administration Medicaid program of thinking information about low-quality drugs of its own manufacture. The case, in which the Office of Criminal Investigations employees represented the State, resulted in the fine of Glaxo Smith Kline. It was fined $ 140 million in criminal proceedings and $ 600 million in civil proceedings[15;16]. During the unscheduled audit, 18 violations were detected. One of them was critical. Nine were significant. There were eight non-essentials. In view of the presence of a critical disorder, which may lead to the production of substandard medicines and which may harm the health or life of a person, a decision was made to issue an order to remedy the violations

of the License terms. The enterprise is obliged to stop the production of medicines until the critical breach of the License Terms. However, considering the available material and the facts of the case, examining and evaluating the evidence presented in their totality, the court decided to dismiss the claim in its entirety. The court considers that on the day of the court hearing there are no grounds for taking the measures mentioned in the claim. The violation, which were classified as critical ones after an unplanned measure of state supervision (control) with respect to compliance by the entity with the requirements of the Licensed Conditions of Business Activity in the Production of Medicinal Products "Zaporizhzhia Autogeneous Plant" and the Company", was independently eliminated by the defendant. The company[17].

Discussion

Counterfeit drugs cause both social and economic harm to society according to V. Pashkov, A. Soloviov, A. Olefir. Counterfeit and substandard medicines should be distinguished. Although there are recommendations for patients to identify counterfeit drugs, the law is essential in counteracting their circulation. Opposite actions can be carried out at the level of general rules, as well as through specific regulatory requirements. The latter can be divided into economic (setting rules for market participants, how to detect and remove counterfeit medicines) and those, imposing penalties for offenses. In all European Union countries studied, the use of counterfeit medicines is strictly prohibited and administrative liability is envisaged for such actions. At the same time, there is no single approach to criminal liability as defined by national governments[18],[p. 848].

Being studied the regulatory framework and the work of international scientists; it is fair to point out that the leading countries in the development of the digital economy are Great Britain, Japan, Singapore, New Zealand, Estonia, United Arab Emirates, Israel and more.

It is important to give a theoretical characterization of the term "digitization", which comes from the English "digitalization" and in translation means "digitization", "digitization", or "digitization". At the same time, nowadays domestic scientists are increasingly using this term, based on the requirements of practical transcription, and therefore the terms "digitization" or "digitization" have become widespread. This approach has several advantages, since the term "digitization", by the right remark of K. Lapina-Kratasyuk, covers a wider range of meanings than its synonym "digitization". This is due to the fact that it is in European and American research traditions that the effects of the transition from analogue to digital type of information encoding have been studied not only as technological but also as social, cultural, and anthropological processes[19]. According to K.O. Kuprina and D.L. Khazanova, digitization is theway of bringing any kind of information into digital form[19; 20]; with. [259]. The Polish Government[21] adopted the Digital Government for 2014-2020. Digitization in the country is developing quite actively. Special Ministry of Digitization or Digitization - Ministerstwo Cyfryzacji is engaged in the introduction of new technologies.

Having conducted research of scientific sources, it is right to emphasize that scientists Vasylieva T. A., Lieonov S. V., Rubanov P. M., Vasilyeva TA, note that the digitization of the economy is considered to be a fundamental factor of economic growth, innovation and competitive environment, job creation and social progress in general[22; 23]. In Russia, there is a law on the circulation of medicines, in which the terminology has been successfully developed, for example, the concept of pharmaceutical activity, etc.[24], which, for example, is absent in the Law of Ukraine on Medicines, is enshrined. Pursuant to Article 9 of the Law, medicinal products are allowed to be used in Ukraine after their state registration, except in cases provided for by the Law. Registered by the competent authority of the United States of America, Switzerland, Japan, Australia, Canada, a medicinal product registered by a competent authority of the European Union under a centralized procedure for use in the territories of those countries or Member States of the European Union, only materials on method of quality control of medicinal product are added. Materials of the registration dossier and samples of the packaging of a medicinal product, labeled in a language for the labeling of medicinal products, instructions for the use of a medicinal product in a language must be in accordance with the requirements of this Law; document confirming payment of the registration fee are added too[12]. This makes it possible to regulate this issue legally and avoid crimes in Ukraine, since the person, his life and health, according to Article 3 of the Constitution of Ukraine, is of the highest legal value[25].

The problem of counterfeiting of medical products and other similar crimes require attention in every state, because the negative consequences of this crime have

serious consequences that affect the lives and health of people. The introduction of positive foreign experience makes it possible to legally secure the responsibility for the aforementioned crime in international countries and stop it.

Conclusion

Because of the conducted research, we propose strengthening of legal responsibility for falsification of medicines in the countries of the world, the legislation of which provides insufficiently severe criminal penalties or even administrative liability. We believe that the manufacture and trade (both domestic and export) of counterfeit medicines should be a particularly serious crime, for which criminal liability in the form of imprisonment for 15-20 years with confiscation of property should be provided. The rights of individuals should be protected by an administrative court in the sphere of public-legal relations when appealing against decisions, actions (inaction) of state bodies.

However, in the first place, it is necessary to create the appropriate conditions for the effective fight against counterfeit medicines at the international level. This requires the use of innovative digital technologies already in use in the leading countries of the world, including the European Union. It is necessary to create in each country a unified electronic system for the identification of goods, including medicines that would be publicly available on the Internet for everyone, including every consumer of medicines. When buying these products from their smartphone, they will be able to open the program, take an electronic ID photo, and verify the authenticity of the medicinal product, obtain information about the manufacturer, date and place of manufacture, etc. Such programs should also be used by business entities to prevent counterfeiting. At the same time, both the persons who manufactured the product and the guilty officials of the economic entities that sell them must be prosecuted. Legal entities and entrepreneurs must be subject to considerable administrative liability - € 100,000, such as in Spain.

A significant aspect of the problem of drug identification is its global, international level. The worldwide locomotive of digitization in counterfeiting of counterfeit medicines should be the World Health Organization, which is already taking care of these problems. To counteract the counterfeiting of medicines globally, it is necessary to develop an international program coordinated by WHO. Authoritative intergovernmental associations, such as the European Union, the Eurasian Economic Union and other trans-state entities, should be involved in the development and implementation of this program. At the national level, such work should be undertaken by relevant health ministries through the creation of appropriate structures of their own subordination or through interaction with national digitization bodies. In the positive experience of Poland, it is appropriate to create special ministries (or other authorities) that would develop modern technologies.

In the future, a global database of certified medicinal products should be created for use of any citizen of any country in the world in the age of the pharmaceutical market globalization. And also give access to such a court system.

Thus, the implementation of the proposed approach will significantly reduce the number of counterfeit drugs in the world, as the inevitability of criminal punishment for such crimes will become evident.

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References

1. Barmina. A. Anti-counterfeiting: US specialists share their experience with Ukrainian colleagues. Public Morion [Internet]. Aptekaua Online. 2011.
2. M. MS. Criminal liability for counterfeiting of medicinal products or trafficking of falsified medicine in Ukraine. National Academy of Internal Affairs. 2017;: p. 223.
3. A.H. K. Topical aspects of protection of integrated pharmaceutical logistic chains from falsified pharmaceutical products. Ukrainian medical almanac. 2013; 16(2): p. 151-154.
4. Organization. WH. Growing threat from counterfeit medicines. Bulletin of the World Health Organization.
5. Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes against

Health, Ukraine's ratification from 07.06.2012 № 4908-VI. Verkhovna Rada of Ukraine.

6. Universal Declaration of Human Rights from 10.12.1948. Verkhovna Rada of Ukraine.
7. Convention for the Protection of Human Rights and Fundamental Freedoms from 04.11.1950. erkhovna Rada of Ukraine.
8. European Social Charter (ETS N 35) from 03.05.1996. Verkhovna Rada of Ukraine.
9. Convention for the Development of a European pharmacopia from 16.10.2012. Verkhovna Rada of Ukraine.
10. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine from 25.01.2005. Verkhovna Rada of Ukraine.
11. Convention on Cybercrime from 07.09.2005. Verkhovna Rada of Ukraine.
12. About Medicines: Law of Ukraine from 04.04.1996. № 123/96-BP. Verkhovna Rada of Ukraine.
13. The Criminal Code of the Republic of Poland from 06.06.1997.
14. S.S. Belyaev SSBNK. Criminal Code of Denmark. Scientific editing and preface of S.S. Belyaev, candidate of Law Sciences (Mr. M.V. Lomonosova MSU); translated from Danish and English candidate of Law Sciences S.S. Publishing house,Law Center Press. 2001;: p. 230.
15. N. AO. International Experience in the Fight against Drug Offences, based on the example of the Russian and United States State Drug Control Authorities. European Perspectives. 2012; 2(1): p. 108-113.
16. U.S. Food and Drug Administrations.
17. Decision of the Zaporizhian district court (introduction and output) from 2018.11.26 Case № 808/708/18, Zaporozhye.
18. Pashkov V. SA,OA. egal aspects of counteracting the trafficking of falsified medicines in the European Union. Wiadomości Lekarskie. 2017; 4: p. 843-849.
19. B.S. T. Digitation and digitalization in the context of virtualization. Innovation system and information technology in modern science. Kharkiv. Pravo. 2017;: p. 180-184.