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Counterfeit and Falsified Medicines: Today's Challenges and Smart Solutions

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Abstract

In any democratic country, special attention is paid to health protection, as a result of which, through organisational, financial, economic, and legal institutions, the state ensures and maintains the health protection of the population at the sufficient level. The purpose of the study is to examine the existing problems in the field of providing the population of Ukraine with high-quality medical drugs. The research methodology is a set of cognitive tools and methods, the use of which allowed for obtaining the most objective information about the existing problem processes and phenomena in the field of providing the population of Ukraine with high-quality medicines. Considering the critical state of the health care sector of the population of Ukraine, the study analyses legal regulations that focus on problematic issues in the health care sector of Ukraine. Attention is drawn to the need to provide the population of Ukraine with affordable and high-quality medicines that must meet the best European and international standards. Statistical data on the facts of the detection of counterfeit medicines are presented, and actors on this issue are analysed. It is noted that counterfeit and falsified medicines cause irreparable harm to the health of people all over the world, such illegal actions threaten the economy and security of the state, cause economic and financial damage to manufacturers of medical medicines, undermine their image, and harm the owners of intellectual property rights. It is noted that public relations in the field under study concern legal mechanisms related to unfair competition, which negatively affects the image of the state, and the activities of both Ukrainian and foreign business entities. It is noted that since intellectual property in its nature and content is closely linked to the growth of the economy, there is a need for more effective steps by the state to prevent violations of intellectual property rights. The results of the study, and parts of it, can be useful for both lawyers and government agencies that struggle with unfair competition in the field of medicines

Keywords: protection, unfair competition, state, economy, security

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Introduction

In the modern world, scientific views on public health are investigated from a variety of perspectives, which is manifested in economic, legal, political, social, and other approaches. In the leading countries of the world, the issue of providing citizens with high-quality medicines is given priority attention, since the economic growth of the state depends on the health of citizens. Australia, the Netherlands, the United States, Switzerland, and Japan have a highly effective system of medical standards. These countries have an effective system of bodies designed to ensure the proper state of health of the population. This means that in these and other countries of the world, the efforts of the government are aimed at creating an effective regulatory framework that guarantees the production, release, storage, transportation, and sale of medicines and effective mechanisms for protecting the rights holders of intellectual property objects, the importance of which in the creation of medicines is the primary basis. The issue of protection is explained by the fact that in the context of global development, the process of intellectualisation of the economy is taking place. In the end, this phenomenon affects the economic security of a particular country [1, p. 20].

Notably, some important issues of the studied problem were considered by a number of Ukrainian researchers. In particular, A. Hertz paid attention to contractual obligations in the field of providing medical services [2]. B. Logvynenko conducted a theoretical and practical study of the public administration of the health care sector in Ukraine [3]. O. Strelchenko analysed the activities of public bodies [4]. S. Knysh identified the impact of legal provisions on the state of health care in Ukraine [5; 6]. H. Muliar conducted a study of the essence of the implementation of the right of a person to health care [7] and legal prospects for the implementation of medical reform in Ukraine [8].

In the monographic study, the author of the study in collaboration with N. Volk described the state of legal regulation of pharmaceutical activities and identified ways to improve it [9].

S. Sismondo draws attention to problematic issues of formation and drugs that are insufficiently tested [10], other foreign researchers focus on the consequences of falsified medicines for human health [11].

In these works, researchers mainly focus on the specific features of civil and contractual legal relations, patenting inventions in the field of medicine and biotechnology, providing medical services, protecting consumer rights on the Internet, reforming the health care system, medical relations, guarantees of medical care, administrative responsibility, etc. Therewith, today counterfeit medicines are a threat to the national security of the state. Therefore, the existing problematic issues in the field of medicines should concern not only their owners and consumers, but also the state, its authorised officials, and scientific views on solving the existing problem.

The purpose of the study is to determine the ways of effective legal regulation of providing the population of Ukraine with high-quality medicines based on the conducted investigation.

The researcher had to perform the following main tasks to achieve this goal: identify the legislative principles of health care in Ukraine; characterise the state of activity of public authorities in the field of combating counterfeit and falsified medicines; provide statistics related to counterfeiting, falsification of medicines and their negative impact on the state of health of citizens; determine ways to improve the legal regulation of the field of public relations under study.

Materials and Methods

The methodological basis for the study of counterfeit and falsified medicines is a set of techniques and methods that allowed examining and identifying the current state of providing the population with high-quality medicines. The dialectical method is used to analyse the current state of the regulatory framework and determine ways to improve Ukrainian legislation in the field under study. The historical-legal method is used for a retrospective analysis of today's challenges in the fight against counterfeit medicines. The statistical method helped to summarise empirical data for writing the study. Deduction and induction methods are used to identify legislative access and implementation of the right to health care. The method of doctrinal analysis allowed for analysing the problematic issues related to the counterfeiting and falsification of medicines. Formal legal and forecasting methods allowed for determining ways to overcome counterfeiting and falsification of medicines. The application of the method of legal modelling allowed for identifying ways aimed at improving legislation in the field of health care.

The normative basis for writing the study consists of Ukrainian legislative acts, in particular, the Constitution of Ukraine, the norms of the Customs Economic Procedure and Criminal Codes, and numerous Ukrainian and international regulations.

The study used statistical data, judicial practice and economic and legal journalism, analytical materials and internet resources.

Results and Discussion

Among many problematic issues, public health issues in Ukraine are the cornerstone that is inextricably linked with human life. It is no coincidence that Art. 3 of the Constitution of Ukraine declares that "a person, their life, and health are recognised as the highest social value in Ukraine", and Art. 49 of the Constitution guarantees everyone the right to health protection [12].

This duty of the state also follows under the application, in particular, of the norms of Art. 6, 7, and 8. Fundamentals of the legislation of Ukraine on health care, which provide a list of guarantees of the right to health protection and state protection of these rights [13].

The consolidation of these relations in the Constitution of Ukraine is a direct duty of the state to ensure the human right to life and health through the approval of effective legal provisions aimed at protecting health. However, despite the mandatory consolidation of this norm in the Basic Law of the state, Ukraine still cannot guarantee its citizens the proper state of health care [5, p. 1].

Thus, despite the imperative consolidation in the Constitution of Ukraine and other normative regulations to ensure the realisation of citizens' right to health protection, some researchers and specialists draw attention to the shortcomings of legislation (in particular, in the Constitution of Ukraine), which do not fully ensure citizens' access to high-quality and safe medicines, and the medical reform initiated in 2017 has not yet yielded the desired results, which negatively affects the implementation by citizens of their rights guaranteed by the Constitution and other legislative acts of Ukraine [14, p. 141].

Therewith, recently there have been numerous cases of detection of counterfeit medicines, both at the customs border and pharmacy chains, where law enforcement agencies are increasingly detecting counterfeit and falsified medicines. As a result, the state, owners of medicines, and owners of intellectual property rights suffer financial and image losses. Despite the criminalisation of certain articles of the Criminal Code of Ukraine (Part 2 of Art. 305, part 2 of Art. 321-1, part 2 of Art. 229), they are not yet able to ensure proper health care in the country [15]. Therefore, it is advisable to agree with M. Quet's opinion, that pharmacy employees are actively involved in the illegal sale of counterfeit medicines [16]. As a result, the counterfeiting of medicines and their sale through a network of unscrupulous pharmacy employees negatively affects the health of citizens not only in Ukraine but also in other countries of the world [17].

S. Hodges and E. Garnett also argues that "Over the past few decades, global health research and policy have raised concerns about the growing threat of counterfeit and low-quality medicines" and draws attention to the need for evidence when identifying counterfeit, low-quality, or falsified medicines [18].

Investigating the principles of the actual presence on the Ukrainian pharmaceutical market of counterfeit and counterfeit goods, "white" counterfeit goods and medicines that are a consequence of an imperfect system of turnover control and protection, Yu. Vishar draws attention to the problems of intellectual property law and comes to the conclusion that a negligent attitude to the clarity of the definition of concepts and objects of intellectual property in specialised and special legislation creates opportunities for manipulative regulations, pushing such urgent socio-economic problems as "evergreen patents", availability of medicines, reimbursement of medicines, patent trolling, parallel "grey" import of medicines, preclinical and clinical studies of medicines, etc., into the category of secondary [19, p.256-257].

Today, counterfeit and falsified medicines have flooded the national market. In particular, in 2022 alone, counterfeit medicines will reach 991 billion USD, which threatens the health of consumers [17].

In this context, there is also a demand for urgent state measures to protect the economic interests of the state. "This is also due to changes in the principles of functioning of the economy of the country and the movement of financial flows, the issue of creating and functioning an effective system of economic protection of Ukraine in the state has become extremely important" [19 p. 160]. The same opinion is shared by other Ukrainian researchers that draw attention to the need to implement economic reforms in the state [20].

In the context of the problem under study, to determine what should be understood by "falsified medicine" and "counterfeit goods", specialists, officials of customs and law enforcement agencies, etc., should refer to the norms of the Law of Ukraine "On Medicines" of 04/04/1996 No. 123/96-BP [21] and the Customs Code of Ukraine of 13.03.2012 No. 4495-VI [22]. For the accurate identification of counterfeit medicines that have the packaging, a label, or are marked with a certain logo, the factual establishment of a violation of the rights of copyright holders of intellectual property rights, which can be designated counterfeit and falsified medicines.

The Verkhovna Rada of Ukraine on 10/03/2017 amended the economic procedural code of Ukraine on the establishment and operation of a specialised Supreme Court on intellectual property issues of Ukraine to ensure the rapid and effective protection of intellectual property rights [23]. However, due to the existing problems of the High Qualification Commission of judges, the selection for the positions of judges has not yet been completed.

Ukraine ratified the Council of Europe Convention on counterfeiting medical products and similar crimes that threaten health of 06/07/2012 [24], which entered into force on 01/01/2016 to prevent the threats to health [25].

The Convention, among other things, emphasises the need to protect patented medical products as an object of intellectual property rights.

Following the provisions of the Convention, the Order of the Cabinet of Ministers of Ukraine approved the concept, which should be implemented during 2019-2023 in three stages, each of which provides for the gradual and mandatory introduction of necessary measures related to ensuring the protection of medicines and intellectual property rights [26].

The introduced pilot project, the implementation of which was to be conducted from 09/01/2019 – 12/31/2020 [27], had a substantial number of ambiguous comments both from authorised officials of executive authorities and specialists of the pharmaceutical market, who paid attention to the problems of the unified state system for monitoring the turnover of medicines, as a software product that was to be created by the Ministry of Economic Development and Trade.

By order of the Ministry of economic development and trade "Some Issues of Implementation of the Pilot Project on Labeling with Control (Identification) Signs and Monitoring of Drug Circulation" dated 11/26/2019 No. 433, the state enterprise "State Information Analytics" was designated as responsible for the implementation of this Order [28]. However, not agreeing with the Order of the Ministry of Economic Development and Trade No. 433, SE SIA appealed the order of the Ministry of Economy to the District Administrative Court of Kyiv on 03/16/2021 [29].

Despite the adoption of a number of legislative acts, in particular, through amendments to the Criminal Code of Ukraine, as a result of which the guilty person can receive the maximum criminal penalty in case of falsification of medicines [30], the Law of Ukraine "On the Joint Transit Regime and the Introduction of a National Electronic Transit System" [31], which to some extent should have improved the state of affairs at customs, but it did not fully solve the problematic issues of counterfeiting and falsification of medicines, and the Draft Law No. 5547 "On Medicines" [32], which, according to its authors, should somewhat improve the state of affairs in the field of public relations under study, however, a substantial number of comments to this draft law from the perspective of a number of ministries and departments, and experts doubt that this bill will become law in the near future.

Despite the above-mentioned and other measures taken, the scale of the problem of counterfeiting and falsification of medicines has not been resolved. This is indicated by the statistical data on a substantial number of offences in this area and the financial losses that the state suffers due to the illegal manufacture and distribution of counterfeit medicines [33].

Thus, the existing problematic issues of counterfeiting and falsification of medicines that negatively affect the state of Health and life of citizens, along with the failure of the state in the person of authorized bodies of public power, their officials, "question the entire health care system, methods of activity, and legal influence of the state in this area" [34, p. 5].

In addition, the issue of the improper legal protection of both medical and pharmaceutical inventions remains problematic [35, p. 421]. The above applies to

an invention, as an object of intellectual property rights that can be granted legal protection, such an invention must be suitable for industrial use in the medical or pharmaceutical industries and meet the conditions of legal protection in accordance with the law. This may apply to: methods of treatment and diagnosis (except for the substances/compositions that are used in this case [36].

The above should be considered when creating new ways to treat and diagnose people.

Conclusions

Thus, considering the above, it can be concluded that today the state of providing the population of Ukraine with high-quality medicines requires the state, public administration bodies, and their officials to take the necessary measures aimed to ensure the right of a person guaranteed by the Constitution and other legislative acts of Ukraine to proper health care and to high-quality and safe medical care at the national level. High-quality and sufficient medicines should contribute to the health care system, but the existing problems of counterfeiting and falsification of medicines does not only prevent citizens from exercising their constitutional right to health protection. The lack of effective mechanisms and ways to solve counterfeiting and falsification of medicines threatens the national security of the state.

To overcome the existing problem, the Parliament needs to respond more effectively and adequately to the state of legislative support for such an important field of public relations. Considering the challenges facing society, it is necessary to improve the work of health management bodies. The state needs to take a more comprehensive approach to the mechanism of introducing a moratorium on advertising medicines and medical devices on TV, radio programmes, and mass media, especially when such advertising concerns the elderly, who are the largest consumers of medicines.

For the purpose of early detection of counterfeit medicines at the customs border of Ukraine, it is necessary to introduce the "Raman spectroscopy" method, which can be used to prevent offences related to medicines.

In the fight against counterfeiting and falsification of medicines, it is necessary to pay attention to the European system of 2D coding of medicines, the use of which should be initiated in Ukraine.

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Контрафактні та фальсифіковані лікарські засоби: сьогоднішні виклики й розумні рішення

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Анотація

У будь-якій демократичній країні охороні здоров'ю приділяється питома увага, унаслідок чого шляхом організаційних, фінансових, економічних та правових інститутів держава забезпечує і підтримує на належному рівні стан охорони здоров'я населення. Метою дослідження є вивчення наявних проблем у сфері забезпечення населення України якісними медичними лікарськими засобами. Методологія дослідження – сукупність пізнавальних засобів та методів, використання яких дало змогу отримати максимально об'єктивну інформацію про наявні проблемні процеси і явища у сфері забезпечення населення України якісними лікарськими засобами. Зважаючи на критичний стан у сфері охорони здоров'я населення України, у статті проаналізовано нормативно правові акти, в яких акцентована увага на проблемних питаннях у сфері охорони здоров'я України. Звернено увагу на необхідність забезпечити населення України доступними та якісними лікарськими засобами, які повинні відповідати кращим європейським і світовим стандартам. Наведено статистичні дані про факти виявленням контрафактних лікарських засобів, а також проаналізовано акторські щодо вказаної проблематики. Наголошено, що контрафактні та фальсифіковані лікарські засоби завдають непоправної шкоди здоров'ю людей у всьому світі, такі незаконні дії загрожують економіці й безпеці держави, завдають економічних та фінансових збитків виробникам медичних лікарських засобів, підривають їхній імідж, наносять шкоду власникам об'єктів права інтелектуальної власності. Звернено увагу, що суспільні відносини у дослідженій сфері торкаються правових механізмів пов'язаних із недобросовісною конкуренцією, що негативно впливає на імідж держави, діяльність як українських, так і зарубіжних суб'єктів підприємницької діяльності. Зауважено, що, оскільки інтелектуальна власність за своїм характером і змістом тісно пов'язана зі зростанням економіки, існує потреба в більш дієвих кроках держави щодо запобігання порушень прав інтелектуальної власності. Результати роботи, а також її частини можуть бути корисними як для юристів, так і для державних органів, що борються з проявами недобросовісної конкуренції у сфері лікарських засобів

Ключові слова: захист, недобросовісна конкуренція, держава, економіка, безпека