

REVIEW ARTICLE

Problems of Falsification of Medicinal products in the conditions of the COVID-19 Pandemic: Adaptation of Ukrainian legislation to the norms of the European Union

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ABSTRACT:

The problem of distribution of low-quality medicinal products in Ukraine has become especially relevant against the background of the spread of the COVID-19 pandemic. The challenge to the national medical system became more tangible, as the fight against the virus and quarantine restrictions became heavy psychological blows for patients who sought appropriate treatment in an unofficial way. The purpose of the article is to analyze the problem of falsification of medicines in the conditions of a pandemic and to develop development models against the background of the study of European legislative norms. General scientific methods (synthesis, analysis, induction and deduction) became the main methods for writing the article. The methods of content analysis, systematic review of scientific literature, SMART and FINER principles were also used. The results highlighted one of the most important problems of the distribution of falsified and unlicensed drugs during the spread of COVID-19 - the semi-legal activity of pharmacies that work exclusively in the field of online sales. The requirements for their activities are quite loyal, and the distribution of low-quality or uncertified medicinal products is punished only administratively. The possibility of using European (primarily German) experience to counter the distribution of falsified medicines was discussed. Attention was also drawn to the geopolitical factor in the fight against COVID-19 – the use of the Russian vaccine “SPUTNIK V”, which in the conditions of Russian aggression can be assessed as a hybrid threat. The problematic nature of using this vaccine has been demonstrated, given the secrecy of the mechanism of conducting experiments. Resolutions of the European regulatory bodies allowed Ukrainian doctors not to use this vaccine either. This episode can be considered a positive moment of using European experience to establish medical rules for work in Ukraine. The conclusions note the need to reform Ukrainian legislation, take into account the European experience and harmonize with European regulations on the circulation of medical drugs. Such a step will make it possible to face modern challenges and significantly complicate the entry of counterfeit medicines into Ukraine.

KEYWORDS: COVID-19, Ukraine, falsification of medicines, European development.

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INTRODUCTION:

The problem of the spread of counterfeit drugs in Ukraine has become more acute as a result of the COVID-19 pandemic. This challenge immediately

demonstrated the vulnerability of the legal framework regulating the circulation of medicines. The article aims to analyze the problem of falsification of medicines in the conditions of the pandemic and to develop development models against the background of research on European legislative norms.

In general, the problem of drug adulteration has interested more than one generation of scientists. For example, Janvier, De Spiegeleer, Vanhee, Deconinck¹ investigated biotech drug adulteration and outlined the main dangers and threats of further medical drug counterfeiting. Since the beginning of the widespread COVID-19 pandemic, modern experts have begun to look for basic solutions to this global problem, predicting the possible consequences and threats of the disease. In particular, Corrie, Muzaffar-Ur-Rehman, Kukatil, Manasa, Shirisha² described the main possible causes of COVID-19 spread and outlined the prospects for medical treatment of this disease. These researchers also analyzed the specifics of COVID-19 antifibrotic drugs. According to Baker³, modern antiviral drugs have demonstrated that they are safe and effective against COVID. Specifically, Baker³ claims that Molnupiravir, developed by Merck and Ridgeback Biotherapeutics, and Paxlovid, developed by Pfizer, significantly reduce hospitalizations for people with early-stage COVID-19. Some researchers, such as Dwivedi, Rawat, Ranjan, Agrawal, Misra, Gupta, Kishore, Misra⁴ hope that new weapons to fight COVID (particularly Coronapod) could have a big impact, particularly in parts of the world where vaccines are still not available. At the same time, Wakhlu, Manoj, Bafna, Sahoo, Hazarika⁵ in their study formed key recommendations for pandemic non-proliferation. On the other hand, Jacob⁶ investigated the problem of the future drug against coronavirus, investigated the main features of prevention and treatment of this large-scale disease. At the same time, Pocock⁷ investigated the problem of adulteration of drugs, using false vaccines in Iran as an example. The author also investigated the problem of the non-regulation of certain legislative aspects related to false medicines. On the other hand, Kanozia, Arya⁸ characterized the peculiarities of the spread of false news against the background of the COVID-19 pandemic in Africa and Asia. At the same time, the study by Metil, Reshetnykova⁹,

Which analyzed the current state and key aspects of legislative regulation of COVID-19 drugs in Ukraine, is valuable for this study. Separately, the authors paid notable attention to the study of the implementation of major bans and regulations against the background of coronavirus proliferation in Ukrainian legislation. Based on preliminary studies of Ukrainian scientists, it is possible to form an idea about the main gaps in Ukrainian legislation regarding the detection of

counterfeit drugs and to make basic recommendations to address this situation, using the works of European authors.

MATERIALS AND METHODS:

This work refers to non-empirical (the use of data from previous researchers, work with literature, systematic reviews), fundamental (obtaining new results that expand the boundaries of knowledge of researchers) and applied (the results are implemented in practice) research. Consequently, the work used general scientific methods of research: synthesis, analysis, induction, and deduction. Based on content analysis it was possible to systematically study the sources of written and visual information posted on the Internet. In developing the research problem, a systematic literature review was carried out.

At the same time, the goal and objectives of this research corresponds to the principle of SMART, i.e., the legislative aspect of the regulation of drug counterfeiting is quite realistic to implement in the Ukrainian realities), T (Timely) - the results can be achieved in a certain time interval).

According to the FINER principle, the subject of research (analysis of possibilities of adaptation of Ukrainian legislation to norms and requirements of modern European law in the sphere of counteraction to falsification of medicines from COVID-19 is F (Feasible) - feasible, I (Interesting) - interesting for researcher and other scientists, N (Novel) - new (research is relevant both for Ukrainian medicine and law), E and R (Ethical and Relevant) - research results are ethical and grounded.

Separately, the work is built on the observed and expert assessment of the authors of the article.

RESULT:

Illegal online pharmacies and their activities amid the COVID-19 pandemic:

Internet sales of medicines, when compared to sales in regular pharmacies, have much deeper risks. First of all, we are talking about the frequency of sales and purchases of unregistered drugs by persons who do not have the necessary licenses, so that drugs without proper documents, low-quality, unregistered drugs, etc. can come to the market. The development of illegal sales of medicines through the Web is widespread during the COVID-19 pandemic, especially during quarantine restrictions and due to psychological panic when citizens are confronted with the disease on a large scale.^{2,5} Distance sales of drugs were legalized in 2020, but the formation of a proper legislative framework for such a process has not occurred. For this reason, online

pharmacy sites began to appear quite actively, but these initiatives led to the spread of a black market in drugs, as sales began to be carried out by persons and institutions without the appropriate license.^{1,10} They began to offer smuggled, unregistered Ukraine, low-quality, and sometimes counterfeit medicines.^{11,12}

This can be confirmed by content analysis of websites of Internet pharmacies that do not belong to the well-known and certified Ukraine stationary pharmacy networks. Based on this, it is easy to see that some drugs are of dubious origin and imported illegally.^{8,9} In particular, these are medicinal products registered in other countries (including EU member states) and sold in Ukraine in certified secondary packaging with obligatory instructions in the Ukrainian language through official representatives with licenses for the wholesale trade of imported medicines.

The use of content-analysis and comparison method allowed us to summarize the most common types of fraudulent sales of COVID-19 drugs through online pharmacies (See Table 1.).

Usually, such websites of pharmacies do not provide information about the availability of licenses for the wholesale or retail sale of medicines. Some sites openly inform potential customers that the products offered are imported into Ukraine unofficially from third countries.¹ A noticeable characteristic of such shady online pharmacies is the closed nature of any contacts, in particular, the lack of information about the physical location, landline phone numbers, etc. Communication with customers is proposed to be done exclusively through mobile numbers or using the feedback capabilities of the sites themselves.

Confronting such challenges, especially against the backdrop of the pandemic, has encountered a number of obstacles. Current Ukrainian legislation generally meets the standards adopted in the European Union governing the possibility of e-commerce in retail medicines. For example, we are talking about the regulatory standards of Directive 2011/62/EC of the European Parliament and Council of June 8, 2011.⁹ At the same time, this does not allow solving the problem completely, because Ukrainian legislators have not yet prepared the appropriate procedural solutions, i.e., the functioning of online retail sales of medicines is not in doubt, but the quality control of online pharmacies, mechanisms to combat abuses are not developed perfectly.^{12,13}

This situation arose due to the humanization of criminal legislation, in particular in the field of economic activity, which took place in accordance with the Law of Ukraine of November 15, 2011 (Law of Ukraine №

4025-IV).⁹ The mentioned legislative document decriminalized the acts of carrying out any economic activity (however, also concerning Internet sales)⁴, which was performed without obtaining an appropriate license. Also, the smuggling of certain groups of goods was taken out of the scope of criminal liability, the list also included medicines. As a result, illegal import to the territory of Ukraine of medicines and other medicinal products (except for narcotic and psychotropic varieties, falsified medicines) even for distribution, illegal sale of medicines by persons or institutions without necessary licenses, or other approvals belonging to administrative offenses.

Table 1: Content analysis of the main risks of the distribution of counterfeit drugs

Risk category	Description
The use of other secondary packaging, which in its external attributes differs from the official and approved form, is evidence of illegal intervention, that is, it expresses illegal pharmacological activity.	The appearance of drugs sold on the websites of official realtors and black online pharmacies is different. One recent example is the drug PAXLOVID, which was certified in the European states and the United States at the end of 2021 - beginning of 2022. In Ukraine, it was approved for clinical use later and in specialized packaging, while in e-pharmacies it was already available from the beginning of 2022. Apparently, drugs that were illegally imported from Europe were used for sale.
Drugs whose efficacy against the SARS-CoV-2 virus caused by COVID-19 has not been proven.	In the Ukrainian segment of the Internet, the anti-rheumatic drug "CHLOROQUINUM" was actively offered as an effective treatment. The mentioned drug is designed for the treatment and prevention of malaria, but the effectiveness against COVID-19 is not confirmed (in general, the effectiveness of antimalarial drugs is rather problematic). Due to the fact that this drug was sold legally in Ukraine, while the certified effective drug was in short supply, online sales were growing, while in regular pharmacies it was sold only by prescription.
Sale of drugs intended for free distribution.	In February 2022, a scandal broke out related to active sales of MOLNUPIRAVIR, an effective drug against the delta strain, in online pharmacies. The Ministry of Health of Ukraine intervened in the situation. The officials in charge pointed out that this drug was not intended for sale in pharmacies, since all the pills received would be provided free of charge with a prescription (in accordance with the established state program). The drugs sold on the Web turned out to be either illegally imported into Ukraine or counterfeit. The perpetrators believed that illegal and false drugs under the brand name of a well-known drug would quickly find a buyer.

Compiled by the authors of the article based on content analysis of Internet pharmacies during the second half of 2021 - early 2022.

Decriminalization of such types of activity made it impossible to organize full-fledged investigative actions against persons violating Ukrainian legislation. The amounts of fines for the use of Internet sites to sell unregistered medicines are quite moderate. The problem of resumption of criminal punishment for the sale or transportation of contraband drugs, illegal sale of medicines is a topic for scientific discussion with the involvement of lawyers and criminologists.^{4,13} However, the rapid development of unregistered Internet pharmacies against the backdrop of the COVID-19 pandemic brings this issue to the fore since the consequences of a negligent attitude toward regulatory obligations can be extremely threatening. Even decriminalization of such crimes may be acceptable, given the European experience in establishing liability for such actions.¹² For example, a sufficiently flexible system of international cooperation to combat the illicit trafficking of medicines is provided for in the Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes Endangering Public Health, adopted on 28 October 2011.^{5,7,14} This document applies primarily to crimes related to the counterfeiting of medicines, but in the realities of Ukraine based on this act can be formed effective mechanisms to combat counterfeiting and illegal distribution of medicines.

COVID-19 vaccination: a geopolitical challenge and forgery:

The COVID-19 pandemic also demonstrated the political overtones of opposition to vaccination.⁷ In particular, since 2014, the Kremlin regime has been perceived in Ukraine as an occupying power. That year, the Russians seized and annexed the Crimean peninsula; in eastern Ukraine, they supported pro-Russian separatists, who with their help established control over part of the regions. The anti-terrorist operation of the Ukrainian Armed Forces gradually turned into military action using artillery, heavy equipment, and aviation. Armed support from the Kremlin regime allowed the separatists to hold on to part of the territories, where the conflict continued in a somewhat frozen phase until February 2022, when Russian forces began open aggression against Ukraine. Official Moscow, however, made unsuccessful attempts to establish a dialogue with the Ukrainian elite. Such attempts intensified after the pandemic and quarantine regime.^{10,15,23} The search for a vaccine and clinical development was perceived as a response of the international community to a global challenge, the Kremlin regime decided to take advantage of this medical trend and announced successful clinical trials of the vaccine under the brand name "SPUTNIK V". The Ukrainian side was one of the first to be offered the production of this product, which, it should be noted, was perceived by many physicians as a quite positive step, although the political subtext of this decision was

obvious to many.

In the Ukrainian press and scientific publications, publications began to appear, accusing the leadership of the European Union of futile procrastination, which led to the spread of the disease and an increase in the incidence of disease.^{16,17} Geopolitics were declared to be the main reason - it seemed that European politicians were artificially limiting the influence of Russian medical science and interfering with vaccination by pointing out the effectiveness of other vaccine manufacturers.¹⁶ Officially quoted were materials from the British scientific journal *The Lancet*, which referred to clinical trials of SPUTNIK V. The efficacy of this Russian vaccine was estimated at 91.6%, which was a very high figure. In particular, SPUTNIK V was believed to be a vector vaccine based on the technology of using the adhesion bill of the SARS-CoV-2 virus, which was placed in specially created and harmless adenoviruses Ad26 and Ad5. Similar technology was used in other vaccines, which demonstrated not-so-high efficiency. Thus, the Russian vaccine became by that time the third known drug that overcame the 90% positive rate. Proponents, including those in Ukraine, considered SPUTNIK V an attractive option for use in poor countries because its cost was quite low, and it was easy and convenient to transport since the vaccine did not require freezing during storage.¹⁷ Official Kyiv's refusal to use SPUTNIK V was perceived ambiguously because the vaccine had several advantages Ukraine needed. At the same time, as time has shown, this step was justified, since the proposed inexpensive and "high-quality" vaccine turned out to be an element of the Kremlin regime's hybrid warfare.

In the fall of 2020, the editors of *The Lancet* were approached by a group of medical researchers who were interested in the details of the trials conducted by the Russians and the medical data used. The editors of the scientific journal refused to provide any comments or allow the researchers access to the information.^{3,16} Further suspicions were raised by the scientists after analyzing the suspicious and unlikely coincidences among the indicators of the different groups of people who had participated in the trials. An uncertain dating situation also attracted attention: not even ten days elapsed between the submission of the article to the journal and the completion of the experiments. It was almost impossible to prepare such a detailed article in such a short period of time. Therefore, the independent expert group became suspicious that the numerical results were written into the experiment in advance, while the entire experiment and clinical trials were adjusted to these figures. Formal responses from the Russian side reinforced suspicions of falsification of SPUTNIK V efficacy, while the original clinical

protocols were not available. In practice, the capabilities of the Russian vaccine were also far from ideal. Therefore, the European Medicines Agency refused to certify the Russian vaccine. Similarly, the World Health Organization put SPUTNIK V on the list of drugs unlikely to be used in the COVID-19 outbreak. The vaccine has been rejected in India and many other countries.^{8,11,24} It is possible that the vaccine's performance was falsified from the beginning, i.e., it was used as a tool of hybrid warfare.^{15,19,20} The recommendations of the European Union countries were taken into account by the Ukrainian government, which refused to use the dubious vaccine²⁵.

DISCUSSION:

To confront the problems of counterfeiting, it is proposed to refer to the experience of European countries. One of the most exemplary models for regulating the circulation of medical drugs is the German model. The main issues of providing the population with drugs are regulated by a group of laws dedicated to the circulation of medicines. In particular, for the manufacture and subsequent distribution of a drug, it is necessary to obtain a special permit, which controls the quality indicators, safety, and efficacy of use.^{5,8,9} Usually, manufacturers are not refused this permission. Refusal occurs only in cases of absence of specialists of appropriate level in production (persons with necessary pharmaceutical licenses or higher education diplomas on appropriate specialties). Persons with criminal convictions, alcohol or drug addictions are also not allowed into production. The main focus is also centered around technical requirements^{9,15}: the availability of the necessary facilities needed to manufacture, store and test medical drugs, the availability of technical upgrades, that is, manufacturers are required to keep up with modern technological solutions and implement them in their own production. The legal system also regulates the circulation of online sales of drugs, with criminal penalties for smuggling drugs not registered in Germany.

For the Ukrainian reality, such a practice would be useful. We should agree with Janvier, De Spiegeleer, Vanhee, Deconinck¹, that the fight against substandard drugs should become the main vector of healthcare in the XXI century. The German legal framework is closely integrated with the pan-European trade rules. In connection with integration European intentions of the Ukrainian government to borrow German rules for the manufacturing and sale of pharmaceutical drugs.

Pocock⁷ noted the danger of the spread of fake vaccines from COVID-19. As shown in the article, the Ukrainian medical market was also faced with the possible spread of substandard or questionable drugs, which may have

been imposed for geopolitical reasons. The German experience of a joint all-European solution to global problems should be useful for Ukraine, whose managers are prone to use rash decisions, reacting to the situation, but poorly aware of the consequences of such a reaction.

In Germany and Ukraine, quite a few drugs containing some active substances are sold only with a prescription. However, on the European pharmacy market in the cohort of prescription drugs considerably more drugs, including all antibiotics or any other drugs that can be harmful if abused, that is, even when used as prescribed. We should note that since December 2021 the European experience, according to which antibiotics are sold with a doctor's prescription, began to be applied in Ukraine.^{8,16} However, this rule does not apply to Internet sales, because the Ukrainian legislation makes it almost impossible to control the circulation of drugs that are sold online by pharmacies. On the other hand, many drugs in Ukraine are still sold without a prescription. For example, popular for COVID-19 medicines against high body temperature, in which the total amount of paracetamol in a package is more than 10 grams. In Germany, such drugs are also prescription, and their sale is carried out exclusively in regular pharmacies.

Pharmacists in the Federal Republic of Germany are regulated by the Pharmacy Act.⁴ This law also applies to online sales. In addition, according to German law, only appropriately licensed persons can formally engage in the practice of pharmacy. These same individuals are automatically included in the self-governing Chamber of Pharmaceuticals, which has its own mechanisms for monitoring its members, investigating violations of the rules. A positive aspect of the German experience is the formation and implementation of a flexible health insurance system. Without health insurance, it is almost impossible to obtain appropriate care. The reimbursement of medical drugs under insurance is possible only in cases where the drugs are prescribed. Some exceptions also apply to medications that have an additional non-essential benefit (e.g., for the common cold). The insurance system confirmed its reliability during the COVID-19 pandemic, when vaccination, treatment, purchase of necessary drugs were compensated by insurance payments.

At the same time, in Ukraine the existence of such a system may encounter additional difficulties, primarily financial.^{9,21,22} The level of earnings of the Ukrainian population is low, and the real insurance agreements are concluded by wealthier individuals. The majority of the population is provided with free medical care, financed primarily from the state budget. The damage from such a system has been rightly criticized. During the pandemic, it demonstrated all its flaws when the influx

of patients placed the brunt of the costs on the patients. The use of European (first of all, German) experience in organizing the work of medical and pharmaceutical institutions would allow the Ukrainian side to significantly improve the sphere of healthcare and harmonize it with the current state of medicine in the European Union.

CONCLUSION:

So, the COVID-19 pandemic demonstrated the crisis in Ukraine regarding the regulation of drug circulation. As a result of previously adopted bills, trade-in medicines via the Internet has become a separate industry, the management of which is difficult because of the softened attitude to offenders. The sale and importation of dubious or unregistered in Ukraine drugs is punishable only by an administrative offense, not criminal liability. For this reason, black pharmacy websites on the Internet were actively building an audience, because they sold medicines without proper licenses during a pandemic when the demand for them is growing. They often sold contraband, unregistered, and sometimes counterfeit drugs. The use of European experience in regulating the legal framework will gradually overcome such destructive phenomena.

Also, the use of European solutions will avoid the use of even questionable vaccines, in particular, the Russian "SPUTNIK V". The use of decisions of the European Medicines Agency is an important example of the use of reasonable decisions of European international organizations and commissions by Ukrainian officials. At the same time, we consider particularly effective the use of German experience in the implementation and development of pharmaceutical products. The analyzed German legislative framework allows the use of these developments to improve the Ukrainian health system in terms of controlling the circulation of medicines and anti-counterfeit drugs used to combat COVID-19.

CONFLICT OF INTEREST:

The authors have no conflicts of interest regarding this investigation.

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