



Legal Responsibility for Illicit Trade in Pharmaceuticals under Conditions of the Covid-19 Pandemic

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Abstract

The aim of this study was to examine the optimal types and measures of legal liability for crimes in the field of illicit trade in pharmaceuticals in the conditions of the COVID-19 pandemic. The research used methods of systematic approach, descriptive analysis, synthesis and prognosis, systematic and formal legal and comparative selection. It has been established that illicit trade in pharmaceuticals is carried out by organized criminal groups and is related to corruption and cybercrime. Also, the article has revealed typical legal flaws, which complicate international cooperation in this field and lead to non-compliance with international standards of criminalization and imposition of sanctions for illegal circulation of counterfeit medicines. All this leads to the conclusion that the illicit trade in pharmaceuticals manifests itself in a series of offenses for which administrative or criminal liability must be foreseen. Equally promising is the development of a model for law enforcement activity that includes criminalization of trade in low-quality, unregistered and counterfeit pharmaceuticals, according to international standards; proportional punishments for natural persons and influence measures for legal persons and compensation for their victims.

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Keywords: counterfeit pharmaceuticals; medical care; illegal markets; legal liability; organized crime.

Responsabilidad Jurídica por Comercio Ilícito de Productos Farmacéuticos en Condiciones de la Pandemia del Covid-19

Resumen

El objetivo de este estudio fue examinar los tipos y medidas óptimos de responsabilidad legal por delitos en el campo del comercio ilícito de productos farmacéuticos en las condiciones de la pandemia COVID-19. La investigación utilizó métodos de enfoque sistemático, análisis descriptivo, síntesis y pronóstico, selección sistemática y legales formales y comparativos. Se ha establecido que el comercio ilícito de productos farmacéuticos es realizado por grupos delictivos organizados y se relaciona con la corrupción y el delito cibernético. También el artículo ha revelado fallas legales típicas, que complican la cooperación internacional en este campo y conducen al incumplimiento de los estándares internacionales de criminalización e imposición de sanciones por la circulación ilegal de medicamentos falsificados. Todo permite concluir que el comercio ilícito de productos farmacéuticos se manifiesta en una serie de delitos por los que debe preverse la responsabilidad administrativa o penal. Igualmente es prometedor el desarrollo de un modelo para la actividad de aplicación de la ley que incluya la criminalización del comercio de productos farmacéuticos de baja calidad, no registrados y falsificados, según los estándares internacionales; castigos proporcionales a las personas físicas y medidas de influencia a las personas jurídicas y la indemnización a las víctimas de estos.

Palabras clave: productos farmacéuticos falsificados; atención médica; mercados ilegales; responsabilidad legal; crimen organizado.

Introduction

Access to health care and effective medicines today is a human right, similar to other rights recognized by the international community. Patient safety is the most important component of the provision of medical care (Shojaei and Salari, 2020) and the main task of health care systems in all countries of the world.

One of the main aspects here is ensuring the authenticity and quality of medicines. The pharmaceutical market is subject to falsification due to the high profitability of the illicit trade in counterfeits. Many experts claim that approximately 10% of medications sold on the legal market, especially in middle- and low-income countries, are falsified. This leads to the inclusion of counterfeit drugs in treatment protocols alongside legal medications.

As a result, there are side effects, diseases spread more rapidly, and the mortality rate increases (Haji *et al.*, 2021). However, the illegal circulation of medicines has an extremely negative impact not only on the health of the population but also on the economic situation. In particular, the growth of the *markets for counterfeit pharmaceuticals* may exceed \$ 16.04 trillion in 2030 with the prospect of increasing to \$ 24.24 trillion in 2040 (Kasting, 2021; Kemp *et al.*, 2021).

In a pandemic, the threat level increases significantly. The experience of combating the COVID-19 around the world showed that criminals quickly identified vulnerabilities in the organization of anti-epidemic measures and organized the receipt of super-profits through illicit trade in pharmaceuticals. The production and distribution of fake pharmaceuticals related to COVID-19 have significantly affected the pharmaceutical market of the vast majority of countries (Europol, 2020c). However, due to the illicit trade in pharmaceuticals, the pandemic has become more destructive to the lives, health, and well-being of the elderly, people with serious concomitant diseases, and persons with low socio-economic status (United Nations, 2020).

At the same time, the real volume of illegal circulation of counterfeit medicine can be assessed only partially. Analysis by UN experts showed that some countries did not register the production or distribution of falsified medicines, considering them to be of poor quality. This significantly affected the statistical data (United Nations Office on Drugs and Crime, 2021). However, you can use the law enforcement data. Thus, under the coordination of Interpol, more than 34,000 counterfeit medical products were seized during a global operation only in March 2020 (Interpol, 2020: 2). In October 2020, the *Director-General* of the United Nations Office on Drugs and Crime (UNODC) acknowledged the placing of fake COVID-19 vaccines on the online market as the most serious criminal threat.

EU countries supported the recognition of the fight against the counterfeiting of COVID-19-related medicines as urgent and emphasized the close connection of this illegal activity with international economic and financial crimes, committed by organized criminal structures (Csonka and Salazar, 2021).

The illegal circulation of fraudulent medicines under COVID-19 has highlighted many interrelated law enforcement problems, such as

an increase in the level of cybercrime. Under quarantine restrictions, governments have allowed online sales of medicine and medical supplies, as well as direct delivery to customers, to comply with the transportation conditions (Centre for Applied Research; Konrad-Adenauer-Stiftung E. V. Foundation Office Ukraine, 2020). This led to an increase in social media advertising scams and the creation of special websites that offered counterfeit medicines (United Nations Office on Drugs and Crime, 2021).

Enterprises that wanted to buy consumables and protective equipment became one of the first targets of fraudsters (Europol, 2020b). The number of facts of falsification of documents, used to move counterfeit pharmaceutical products (including incorrect labelling of medicine packages), has increased (Europol, 2020). Offenders are also engaged in illicit trade in legal medications through corruption, weakening of inspections, and system deficiencies that have been exacerbated by COVID-19. Corruption in the health care system is a global problem that creates optimal conditions for illegal withdrawal of state medication (United Nations Office on Drugs and Crime, 2021).

Illicit trade in pharmaceuticals under conditions of the COVID-19 pandemic has significantly affected the level of shadowing of national economies. Organized crime groups have adapted to the opportunities created by the COVID-19 pandemic by exploiting gaps and inconsistencies in the public health and criminal justice systems. They use uncertainty among the public and authorities to create demand for *scarce medicine* and to enter the legal economy (United Nations Office on Drugs and Crime, 2021). They quickly create shell companies to hide their activities which significantly complicates law enforcement activities, because most of such crimes are transnational (Europol, 2020c). In general, the profitability of illicit trade in pharmaceuticals led to the inclusion in this activity of criminal groups that were engaged in the drug business (United Nations Office on Drugs and Crime, 2020).

Thus, under the COVID-19 pandemic, a super-profitable type of transnational organized criminal activity was formed. This determines the mainstreaming of the issues of countering it with measures of legal liability, which allow influencing the behaviour of interested persons (Haji *et al.*, 2021).

The rapid formation of the market for falsified medicines related to the COVID-19 pandemic did not give the authorities enough time to develop proper investigative procedures and subsequent judicial trials of cases. Since such crimes can be transnational and complex, this requires the provision of expert opinions and legal assistance from other countries (United Nations Office on Drugs and Crime, 2021).

Today, the only specialized international document on combating crime in this field is the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (Elliott *et al.*, 2020; Medicrim, 2011). It determines the need to criminalize forgery; intentional acts aimed at the production, sale, offer, and transportation of falsified medical products; and low-quality production of approved drugs (The Council of Europe, 2021).

But to this day, there is no general understanding of the seriousness of the problem. In particular, pharmaceutical companies are trying to independently counter the counterfeiting of medicinal products through the introduction of potential protection measures (Haji *et al.*, 2021). In many countries, regulations do not contain adequate definitions, provide for inadequate penalties, or do not include crimes related to the circulation of falsified medical products as predicates for anti-money laundering. In addition, there is a lack of qualified personnel or technical capabilities to detect low-quality, falsified, or counterfeit medicinal products (United Nations Office on Drugs and Crime, 2021).

All this gives grounds to speak of such negative trends in this field, as a) shift of criminal activity towards the production and delivery of falsified vaccines (United Nations Office on Drugs and Crime, 2021); b) the growth of trade in counterfeit medicines on online platforms (Interpol, 2020; Mackey *et al.*, 2020).

In such conditions, the lack or insufficient development of measures of legal responsibility is extremely unfavourable, as in the future, the world will face new epidemics and pandemics. Therefore, we cannot allow repetition of the situation when the society again will not be ready for stable functioning in the conditions of the crisis (Borysov, 2021).

Although at the international and regional levels, authoritative structures are trying to reduce the scale of falsification of medicinal products to protect patient safety (Haji *et al.*, 2021), the issue of legal liability for illicit trade in pharmaceuticals under conditions of the COVID-19 pandemic is gaining relevance.

Taking into account the above, the main problem is to determine the specifics of offenses in the field of illicit trade in pharmaceuticals and adequate measures of legal liability for their commission. It is also considered important to identify the prospects for the development of these measures given the trends in the development of the situation in this field.

Taking the above into consideration, the *purpose of this study* is to examine illicit trade in pharmaceuticals under conditions of the COVID-19 pandemic as an illegal behaviour with the development of appropriate types of legal responsibility for the relevant offenses. The research tasks were the following: identifying the specifics of offenses in the field of illicit

trade in pharmaceuticals under conditions of the COVID-19 pandemic; clarification of the types and measures of legal responsibility for these offenses; determination of the most effective model of combating illicit trade in pharmaceuticals under conditions of the COVID-19 pandemic using legal liability.

1. Methodology and methods

This study was carried out in the following stages: search and selection of literature and data of law enforcement practice; analysis of the material, presented in the selected sources, and evaluation of the results of these studies; identification of the current state and conceptual problems of the grounds and types of legal liability for offenses in the field of illicit trade in pharmaceuticals; determination of the purpose of the article; formulation of conclusions and practical recommendations for the formation of the most effective model of countering illicit trade in pharmaceuticals under conditions of the COVID-19 pandemic.

This study used international legal standards regarding the types of legal liability for illicit trade in pharmaceuticals, and generalization of regional and international law enforcement practice in countering it, including in the context of related offenses. This made it possible to determine the prospects for the development of the most effective model of countering illicit trade in pharmaceuticals under conditions of the COVID-19 pandemic through legal liability.

To achieve the goal, the following methods were used in this study: *the method of the systemic approach* was used to consider illicit trade in pharmaceuticals as a component of the shadow economy, on the one hand, and as the central element of a set of interrelated offenses; *the method of descriptive analysis* was used to determine the types of legal liability for illicit trade in pharmaceuticals under conditions of the COVID-19 pandemic; *the methods of synthesis and forecasting* were used to determine the prospects for the development of the most effective model of countering illicit trade in pharmaceuticals under conditions of the COVID-19 pandemic by means of legal liability; *the method of systematic selection and comparison method* were used to select and compare law enforcement practices countering illicit trade in pharmaceuticals; *the formal-legal method* made it possible to study the peculiarities of illicit trade in pharmaceuticals as a basis for the application of various types of legal liability.

2. Results

The analysis of legal liability for illicit trade in pharmaceuticals under conditions of the COVID-19 pandemic includes the determination of two fundamental aspects: a) the limits of the understanding of offenses related to such trade as grounds for legal liability; b) types of legal liability for these offenses.

It is advisable to take an integrated approach to the definition of offenses that can be included in the concept of “illicit trade in pharmaceuticals”, as it provides for the understanding of both a criminal act and the object for which it was committed. Trade per se means a certain stage of the activity of bringing the medicinal product to the consumer and it is made illegal by the object – the peculiarities of the medicinal product.

The recommendations of the World Health Organization classify medications, including vaccines, as medicinal products and define the following types: a) substandard (low-quality) medicinal products are authorized medicinal products that do not meet quality standards and/or technical conditions; b) unregistered medical products are medical products that have not undergone evaluation and/or approval by a national or regional regulator for the market where they are sold/distributed/used; c) falsified medical products are medical products, the identity, composition or source of which were intentionally distorted (World Health Organization, 2017). Along with this, offenders can carry out illicit trade through legal activities (see Figure 1).

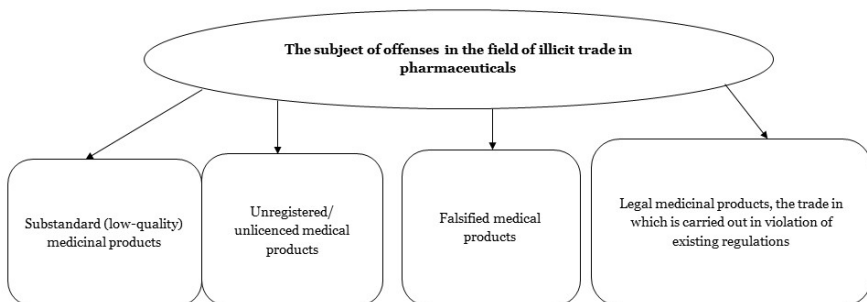


Figure 1: Offenses related to the illicit trade in pharmaceuticals

The trade in falsified medicinal products is the most dangerous offense, which is stipulated by the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health of 2011 (The Council of Europe, 2011).

Illicit trade in pharmaceuticals is often equated with other crimes, as it is a complex, sometimes long-term action, combined with other types of activities. However, for the correct assignment of legal liability, offenses must be differentiated (see Figure 2).

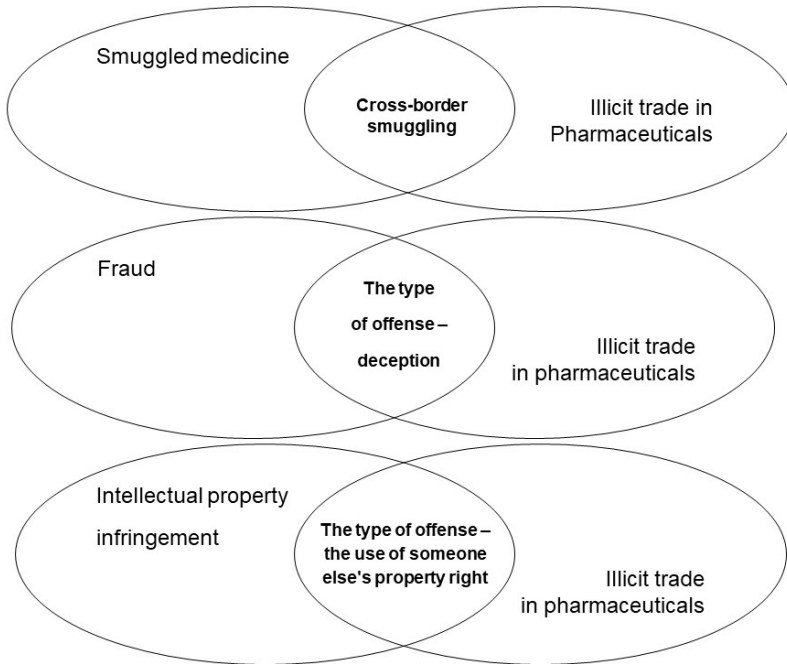


Figure 2: The ratio of offenses in the field of illicit trade in pharmaceuticals and related offenses (European Union Agency for Criminal Justice Cooperation, 2021: 21; Europol, 2020a: 3; Europol, 2020c: 8; Haji et al., 2021: 8; United Nations Office on Drugs and Crime, 2021: 13, 19).

As already mentioned, the illicit trade in pharmaceuticals is part of the shadow activities carried out by organized criminal groups. This is due to the complexity of processes in the pharmaceutical industry. However, the logistics sphere faces the greatest difficulties in the conditions of the pandemic. Quarantine hurt the organization of activities of pharmaceutical companies, which had to respond promptly to a sharp increase in demand for certain types of goods. In addition, quarantine restrictions adversely affected the global supply chains of medications (Davymuka *et al.*, 2020).

The wide availability of pharmacies has shown that they are the first point of the patient's contact with the entire healthcare system (Miszewska

et al., 2022). As a result, there is a situation where inefficient management of supply chains from manufacturers to distributors allowed criminals to use a legal network of pharmacies (Haji *et al.*, 2021). Accordingly, various types of economic chains were formed depending on the capabilities of organized criminal groups (see Figure 3).

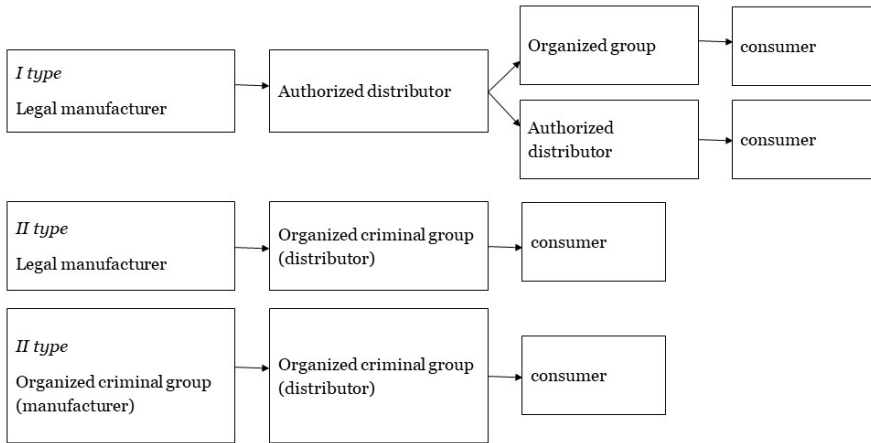


Figure 3: Economic chains involving organized criminal groups in the field of illicit trade in pharmaceuticals (Europol, 2020c: 9)

The above provides an opportunity to talk about the types of legal liability for offenses in the field of illicit trade in pharmaceuticals under conditions of the COVID-19 pandemic. Considering different dangerousness of these offenses depending on the subject of trade, it is possible to agree with the establishment of administrative liability in the case of illicit trade in legal medications. However, in other cases, criminal liability should be established.

Complex organized criminal groups often use corporate structures to hide persons involved in falsified medical product-related crimes. Therefore, it is necessary to introduce the responsibility of legal entities (United Nations Office on Drugs and Crime, 2019). Both natural persons (direct actors) and legal entities shall be subject to criminal liability. A general approach to legal liability measures can be seen in Figure 4.

When determining the amount of the fine, it should be taken into account that falsified medical product-related crimes are an extremely profitable business for criminals. When setting sanctions and imposing punishment, the cost of medical products that were related to the crime, the benefit received by the criminal, and the potential harm to public health should be

considered (United Nations Office on Drugs and Crime, 2019). Therefore, fines shall be significant both for natural and legal persons, as in this case, they will not perform the deterrent function. However, the number of fines for committing crimes should be significantly higher than for committing administrative offenses.

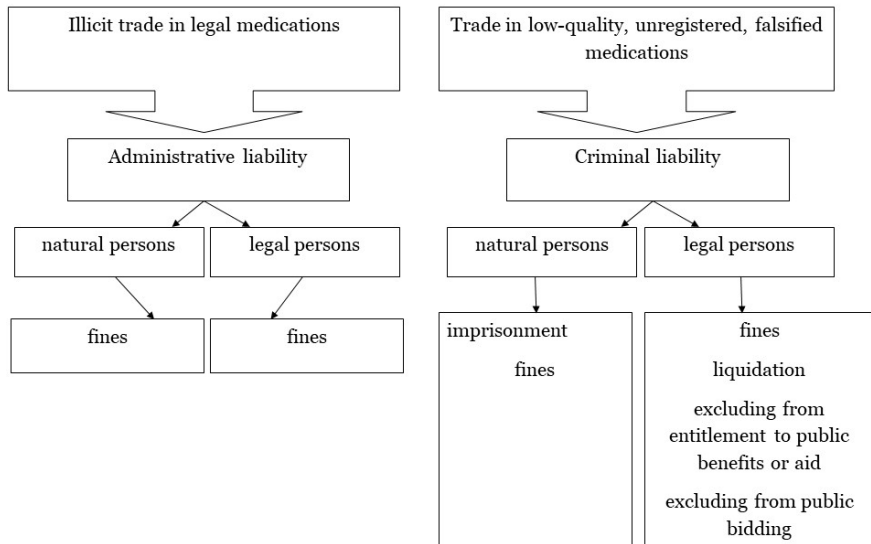


Figure 4: Legal responsibility for falsified medical product-related crimes (United Nations Office on Drugs and Crime, 2019: 42)

In addition, victims of crimes should be compensated for the damage caused by the illicit trade in pharmaceuticals.

Considering the above, there are some reasons to talk about the expediency of developing a model of legal liability for illicit trade in pharmaceuticals under conditions of the COVID-19 pandemic. Given the transnational nature of this activity, it is reasonable to focus on a general international approach to the system of combating low-quality and falsified medical products, in particular, Guide to *Good Legislative Practices on Combating Falsified Medical Product-Related Crime* (United Nations Office on Drugs and Crime, 2021).

This model may include such blocks as definition of Illicit trade in pharmaceuticals-related offenses; establishment of legal responsibility depending on the severity of offenses, but with mandatory criminalization of trade in substandard (low-quality), unregistered, and falsified medicinal products; establishment of proportional punishments for natural persons

and measures of influence on legal entities; compensation to victims of crimes.

3. Discussion

A conceptual vision of the grounds and measures of legal liability for illicit trade in pharmaceuticals under conditions of the COVID-19 pandemic is a component of a complex problem, consisting of security, economic, social, management, and law enforcement issues. This determines the diversity of scientific research and practical activities.

The COVID-19 pandemic has shown the need for a prepared, highly integrated health care system that effectively responds to emergencies (Miszewska *et al.*, 2022). In this regard, we could see the growing importance of the pharmaceutical sector of the economy – the production of drugs and vaccines (Borysov, 2021), the acceleration of trade, and the transfer of materials, means, and equipment to ensure the effectiveness and availability of the treatment of COVID-19 and overcoming its consequences (United Nations, 2020). Since the start of the pandemic, this economic direction has become the leader in the growth of business activity (Centre for Applied Research; Konrad-Adenauer-Stiftung E. V. Foundation Office Ukraine, 2020). However, in addition to the development of the health care sector, it should also be asked, how the COVID-19 pandemic affects the perpetration of offenses, as it will determine the development of strategies for crime prevention (Borysov, 2021).

In general, experts pay more attention to the circulation of falsified medicinal products as the most dangerous phenomenon, as the appearance of falsified medicines indicates significant changes in organized crime (United Nations Office on Drugs and Crime, 2021). However, this does not change the concept of organized criminal activity as a component of the shadow economy, which is characterized by the development according to general economic laws, as the main factor was the demand for scarce medicine and public pressure on health care systems. In the conditions of logistical complications, this became an impetus for the production and sale of substandard (low-quality) and falsified medical products with insufficient control and inspections (Interpol, 2022; United Nations Office on Drugs and Crime, 2021).

Based on the studies of messages on social networks Instagram and Twitter (Mackey *et al.*, 2020), it was found that the development of Internet technologies, including online marketing, had a strong impact on the illicit market in fake medicines. At the same time, we established a direct dependence of public interest in social networks on the introduction of COVID-19-related restrictions (Europol, 2020c).

In this context, it must be emphasized that there is an inconsistency of normative prescriptions regarding *falsified medical product-related crimes* and legal liability for them. The insufficiency and/or inconsistency of the legal framework for the prevention, detection, and punishment of offenders, engaged in the production or sale of falsified medical products, became evident precisely during the conditions of the pandemic.

On the one hand, the relevant offenses are not considered serious, therefore administrative responsibility is established for their commission (United Nations Office on Drugs and Crime, 2021). There is also an opinion on the expediency of economic measures prevalence (Gruszczynski, 2020). There are proposals not to consider the use of medicines that have not yet been officially approved as an offense (Shojaei and Salari, 2020). On the other hand, it is proposed to establish legal liability for the impact of medicinal products on potential consumers (Freckelton, 2020).

At the same time, the experts point to the comprehensiveness of the issues, related to the illicit trade in pharmaceuticals, that need to be resolved. These include a) cybercrimes, the detection of which is complicated by the corporate policy (Button, 2020) and technological features (Fiorella *et al.*, 2021); b) corruption offenses (García, 2019; Gorazd, 2021); c) falsification of documents (Europol, 2020c). The strengthening of the cumulative effect of the mutual influence of the markets of drugs and counterfeit medicines was also rightly noted (Kasting, 2021).

Thus, one can say that the crimes of organized criminal structures have numerous destructive consequences, which cause certain difficulties for the adaptation of the law enforcement system and maintenance of public support (Ross, 2017). The main role in this aspect is played by society's perception of the risk to the health of the population (Sargeant *et al.*, 2022). In general, these considerations can be used as a basis for defining a system of regulatory and institutional tools for combating illicit trade in pharmaceuticals under conditions of the COVID-19 pandemic.

Conclusions

The conducted research allows us to draw many conclusions regarding the specifics of offenses in the field of illicit trade in pharmaceuticals under conditions of the COVID-19 pandemic and measures of legal liability for their commission.

It has been established that the illicit trade in pharmaceuticals is a type of shadow economy that manifests itself in offenses of various degrees of severity, which are committed by organized criminal groups. The latter can use legal mechanisms and legal entities. However, without establishing legal liability, it is impossible to effectively combat such offenses.

It was proposed to develop such a model of law enforcement activities, which is focused on criminalizing the trade in substandard (low-quality), unregistered and falsified medicinal products under international standards; establishing of proportional punishments for individuals and measures of influence on legal entities; compensation for victims of crimes. Such a model should ensure the coordination of efforts of law enforcement agencies at the regional and international levels.

This study opens prospects for the development of safety standards in the field of health care and improving the effectiveness of law enforcement activities in the fight against the illegal circulation of medicinal products. A separate promising direction is the development of legal support for international cooperation to counter transnational organized crime to prevent its influence on pharmaceutical product markets and cyberspace security.

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