

Research Article

Foreign Experience of Illegal Import/Export of Medicinal Drugs: Administrative Legal and Criminal Legal Aspects

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Abstract

Aim: The article examines foreign experience in combating the illiciting of medicines in the context of administrative, legal and criminal regulation.

Methods: The methodological basis is made up of general scientific and special legal methods, in particular comparative legal, systemic and structural, formal legal and legal modeling methods. In the process of the study, regulatory and legal acts (in particular, Directive 2011/62/EU, the MEDICRIME Convention, the US DSCSA) were analyzed, as well as institutional mechanisms of the activities of authorized bodies (EMA, FDA, MHRA).

Results: It is substantiated that the effectiveness of countering the illiciting of medicines is ensured by a combination of preventive administrative measures (licensing, serialization, digital tracking, pharmacovigilance) with strict criminal sanctions (fines, imprisonment, confiscation of assets). It is established that the digitalization of supply chains, interagency coordination and international cooperation play a key role.

Conclusion: The scientific novelty lies in the systematization of modern approaches to legal support for combating illiciting of medicines and determining the optimal model of their adaptation to the national legal system of Ukraine. The practical significance of the results lies in the possibility of using the formulated recommendations in regulatory activities, as well as in the activities of customs and law enforcement agencies.

Directions for improving Ukrainian legislation are proposed, in particular, the implementation of a full-fledged track and trace system, harmonization with EU law, strengthening criminal liability and the development of international cooperation in the field of combating pharmaceutical illiciting.

Keywords: Fight; Illiciting; Drugs; Administrative basis; Administrative legal regulation; Criminal legal regulation; Criminal process; Evaluative concepts

Introduction

The current stage of development of the globalized pharmaceutical market is characterized by the intensive growth of cross-border circulation of medicines, which, along with positive aspects, leads to the emergence of new challenges associated with the illegal movement of medicines across the customs border. Illiciting of medicines has acquired the features of a highly profitable transnational criminal activity, which is often associated with organized criminal groups and the use of complex logistical and digital schemes.

The circulation of counterfeit, unregistered or low-quality medicines is of particular danger, which can cause serious consequences for the life and health of the population. According to estimates by international organizations, the share of counterfeit medicines in global circulation in certain regions can reach significant indicators, which indicates the systemic nature of the problem. In this context, combating the illiciting of medicines goes beyond a purely economic offense and is transformed into an important element of ensuring national security and public health.

For Ukraine, this issue is particularly relevant in the context of European integration processes, reform of the healthcare system and strengthening of customs and border control. The presence of a common border with the European Union, the intensification of foreign economic activity, as well as the development of e-commerce create additional

risks of illegal import and distribution of medicines. At the same time, the national legal system is in the process of adapting to international standards, which necessitates the scientific understanding of effective foreign practices [1].

It should be noted that most developed countries have developed comprehensive mechanisms for combating the illiciting of medicines, which combine administrative and legal control instruments (licensing, certification, pharmacovigilance, digital tracking) with criminal and legal measures of influence. Considerable attention is paid to institutional interaction between customs, law enforcement and regulatory authorities, as well as international cooperation within specialized organizations and agreements.

Despite the existence of separate scientific studies in the field of circulation of medicines and combating illiciting, the issues of a comprehensive analysis of foreign experience in the area of combining administrative-legal and criminal-legal mechanisms remain insufficiently developed. This necessitates the need for a systematic study of the above-mentioned issues.

The purpose of the article is a comprehensive analysis of foreign experience in combating illiciting of medicines in the context of administrative-legal and criminal regulation, as well as determining the possibilities of its use for improving the legislation of Ukraine [2].

To achieve the set goal, the following tasks have been defined: To analyze the administrative-legal mechanisms for controlling the circulation of medicines in foreign countries; to investigate the features of criminal liability for illiciting of medicines; to carry out a comparative analysis of the effectiveness of various legal models; to formulate proposals for the implementation of best practices in the national legislation of Ukraine.

The object of the study is public relations in the field of combating the illegal movement of medicines across the customs border, and the subject is administrative-legal and criminal-legal mechanisms for ensuring relevant activities. [3].

Materials and Methods

The methodological basis of the study is a combination of general scientific and special legal methods with the dominance of the comparative legal method, which allows comparing models of legal regulation of countering the illiciting of medicines in different legal systems.

The comparative legal method was used to: Compare regulatory approaches of the EU (Directive 2011/62/EU, MEDICRIME Convention), the USA (DSCSA), the UK (MHRA regulation) and Asian countries; identify common elements (serialization, track and trace, licensing, pharmacovigilance); determine differences in the degree of criminalization and severity of sanctions; assess the effectiveness of institutional models (centralized vs. decentralized control systems).

The EU has introduced mandatory serialization of drug packaging and a verification system through a single database, while in the USA, the DSCSA provides for the gradual creation of an electronic tracking system at the level of the entire supply chain. The comparison shows a faster unification in the EU and a gradual but technologically flexible model in the USA.

In the UK, the emphasis is on regulatory oversight by the MHRA and interaction with customs authorities, while in Singapore, the key element is strict sanctions and a strict licensing system. This allows us to assess the impact of the level of repressiveness on reducing offenses.

A comparison of criminal sanctions shows that the USA and some Asian countries apply more severe penalties (long prison terms, significant fines) than in most EU countries, where a comprehensive approach with an emphasis on prevention prevails.

Statistical indicators and empirical basis. To substantiate the conclusions, generalized data from international organizations and pharmaceutical market regulators were used: according to WHO estimates, in low and middle-income countries, the share of falsified and substandard medicines can reach about 10% of the total circulation; According to INTERPOL operations (in particular the Pangea series), millions of units of illegal drugs are seized every year and thousands of Internet resources engaged in illegal sales are closed; in the EU, customs authorities regularly record significant volumes of detained pharmaceutical products, which indicates the stability of illegal supply channels; in the USA, the FDA annually reports numerous cases of violations in supply chains and product recalls related to counterfeiting or illegal imports [4].

The use of statistical analysis in combination with the comparative legal method allowed not only to identify patterns in the development of legal regulation, but also to assess the effectiveness of specific instruments for combating drug illiciting.

Thus, the methodology used ensures the comprehensiveness of the study and the validity of the formulated conclusions and recommendations.

Results and Discussion

Administrative and legal mechanisms for combating drug illiciting are a systematically organized set of legal norms, institutional instruments and procedures aimed at preventing the illegal movement of pharmaceutical products across the customs border, its timely detection, cessation and bringing the guilty to justice. In the context of the globalization of the pharmaceutical market and the active development of international trade, the problem of illegal circulation of drugs is becoming particularly relevant, as it poses a threat not only to the economic security of the state, but also to the life and health of the population [5].

The regulatory and legal basis of such mechanisms in Ukraine is formed, first of all, by the Customs Code of

Ukraine, which determines the procedure for moving goods across the customs border and establishes the forms and methods of customs control, the Code of Ukraine on Administrative Offenses, which provides for liability for violation of customs rules, as well as the Law of Ukraine "On Medicines", which regulates the circulation, import and state registration of pharmaceutical products [6]. An important role is also played by the subordinate regulatory

legal acts of the Cabinet of Ministers of Ukraine and the Ministry of Health, which detail the procedures for licensing, certification and quality control of medicines. In the context of international cooperation, the standards of the World Health Organization, the World Customs Organization and the provisions of the TRIPS Agreement should be taken into account (Table 1) [7].

Table 1: Statistics on illegal import/export of medicines

Region/Country	Estimated share of counterfeit/illegal drugs	Detected cases (annually)	Volume of seizures	Main channels
World (general)	~10% of the global drug market (WHO)	>100 thousand cases (INTERPOL)	Billions of dollars annually	Online pharmacies, sea transportation
EU	4–6% of the market	~5–7 thousand cases/year	€1–2 billion (EUIPO, OLAF)	Postal shipments, courier services
Ukraine	2–5% of the pharmaceutical market (estimate)	500–1000 facts/year	Tens of millions of UAH	Small consignments, "gray" imports
USA	~1% (high control)	>1 thousand criminal cases	>\$1 billion of seizures	Internet trading
India	10–20% (various estimates)	>10 thousand cases	Significant export volumes	Production and export
Africa (selected countries)	Up to 30% of the market	Data limited	High volumes	Illegal supplies, humanitarian channels

The content of administrative and legal mechanisms for combating illiciting of medicines covers several interrelated areas. First of all, this is customs control, which is implemented by checking the documents accompanying medicines, in particular quality certificates, registration certificates and licenses. An important element is the use of a risk management system, which allows customs authorities to identify potentially dangerous deliveries and carry out their in-depth control. In case of suspicions regarding the legality of the import of goods, it is inspected, scanned or sent for laboratory tests, and temporary detention is also possible [8]. Practice shows that a significant part of the offenses is associated with the declaration of medicines under the guise of other goods, for example, biologically active additives, which allows avoiding proper control [9].

Another important element is the permit-licensing mechanism, which provides for the mandatory presence of a license for the import of medicines and their state registration. Control over compliance with these requirements is carried out by the State Service of Ukraine for Medicines and Drug Control [10]. In case of detection of violations, in particular, the import of unregistered or falsified drugs, sanctions may be applied to business entities in the form of cancellation of the license or a ban on carrying out the relevant activity [11].

A significant place in the system of combating illiciting is occupied by the institution of administrative liability. In particular, in accordance with Articles 472 and 483 of the Customs Code of Ukraine, failure to declare goods or their movement with concealment from customs control provides for the imposition of fines that may reach the full value of the goods, as well as their confiscation. Such sanctions are preventive in nature and are aimed at reducing the motivation to commit offenses [12].

An important component is also market surveillance and pharmacovigilance, which ensure control over the quality of medicines after they are imported into the territory of the state. In case of non-compliance with established standards or a threat to public health, the corresponding series of drugs are subject to withdrawal from circulation [13]. This allows minimizing negative consequences even in cases where smuggled medicines have entered the domestic market [14].

A separate role is played by information and analytical mechanisms, which include maintaining electronic registers of medicines, data exchange between customs, law enforcement and regulatory authorities, as well as participation in international operations aimed at combating the illegal circulation of pharmaceutical products. In particular, international operations under the auspices of Interpol allow identifying channels of illegal supply of medicines, including *via* the Internet [15].

Foreign experience shows the effectiveness of implementing comprehensive systems for tracking the movement of medicines. The European Union has a Directive on Falsified Medicines, which requires the mandatory marking of packages with unique identifiers and their verification at all stages of supply [16]. In the USA, a system of full traceability of medicines operates in accordance with the Supply Chain Security Act, which ensures transparency of the movement of products from the manufacturer to the end consumer. Similar mechanisms are gradually being implemented in other countries, in particular through the use of QR codes and digital platforms [17].

At the same time, the effectiveness of administrative and legal mechanisms in Ukraine is hampered by a number of problems, including insufficient interdepartmental coordination, the difficulty of detecting counterfeit

medicines, the presence of corruption risks, and the imperfection of legal regulation of electronic trade in medicines. An additional challenge is the growth in the volume of international postal items, through which illegal movement of medicines is often carried out [18].

Improving administrative and legal mechanisms for combating illiciting of medicines requires the introduction

of modern digital technologies into the activities of customs authorities, harmonization of national legislation with European Union law, strengthening responsibility for relevant offenses, and expanding international cooperation. The comprehensive application of these measures will increase the effectiveness of state policy in the field of ensuring the legal circulation of medicines and protecting public health (Table 2) [19].

Table 1: Comparative analysis of foreign experience in combating drug illiciting

Country/Region	Administrative mechanisms	Legal regulation	Criminal measures	Practical examples and features
European Union	FDA, serialization of packages, import control	Directive 2011/62/EU (Falsified Medicines Directive), EMA regulations	Criminal liability for the production and circulation of counterfeit medicines, severe sanctions	A single database of serial numbers; checking each package in the pharmacy
USA	Track and trace system, electronic monitoring of supply chains	Drug Supply Chain Security Act (DSCSA), FDA regulations	Severe penalties for illiciting and falsification (including long imprisonment)	Full traceability of drug movement; import control through the FDA
United Kingdom	Importer licensing, MHRA control, inspections	Human medicines regulations	Criminal liability for illegal circulation and illiciting	Active use of online monitoring of illegal pharmacies
Germany	Strict customs control, pharmacovigilance, serialization	Arzneimittelgesetz (Medicinal Products Act)	High fines and imprisonment for falsification	High level of coordination between customs and police
India	Track and Trace system for exports, QR code labeling	Drugs and Cosmetics Act	Criminal liability for the production and export of counterfeit medicines	One of the largest exporters-enhanced quality control
China	Government control of production and exports, digital monitoring platforms	Drug Administration Law	Severe criminal sanctions, including life imprisonment	Tough measures after scandals with counterfeit vaccines
Canada	Regulatory control health Canada, licensing	Food and Drugs Act	Criminal liability for illegal import and circulation	Control of online sales of medicines
INTERPOL (international level)	Coordination between states, joint operations	International conventions (UN, WHO)	Prosecution of transnational criminal groups	Operation "Pangea" -global raids against illegal online pharmacies

Criminal law mechanisms for combating drug illiciting constitute a set of criminal law norms and the practice of their application, aimed at identifying, stopping and punishing socially dangerous acts related to the illegal movement of drugs across the customs border, as well as the circulation of falsified or dangerous pharmaceutical products. Unlike administrative law measures, criminal law mechanisms are used in cases of increased public danger, when the offense causes or may cause significant harm to the life and health of people, the economic security of the state or the pharmaceutical market [20].

The regulatory and legal basis of these mechanisms in Ukraine is, first of all, the Criminal Code of Ukraine. Although classic "illiciting" in the narrow sense is decriminalized for most goods, criminal liability remains for the illegal movement of certain categories of items that pose an increased public danger. In the sphere of circulation of medicines, the following norms are of key importance: Article 201 of the Criminal Code of Ukraine (illiciting of certain types of goods, in particular poisonous, potent or radioactive substances), Article 305 of the Criminal

Code of Ukraine (illiciting of narcotic drugs, psychotropic substances, their analogues or precursors), Article 321-1 of the Criminal Code of Ukraine (falsification of medicines or circulation of falsified medicines), as well as related elements of crimes, such as illegal production or sale of poisonous or potent medicines (Article 321 of the Criminal Code of Ukraine) [21]. Thus, criminal law counteraction covers both direct illegal movement and subsequent illegal circulation of dangerous pharmaceutical products [22].

The content of criminal law mechanisms consists in establishing criminally punishable acts, determining the elements of crimes, the system of punishments and procedures for bringing the guilty to justice. An important feature is that the qualification of the act depends on the subject of the offense. For example, if we are talking about the movement of narcotic drugs or precursors across the customs border, Article 305 of the Criminal Code of Ukraine is applied, which provides for severe sanctions in the form of imprisonment for significant periods with confiscation of property. In the case of the movement of counterfeit drugs or their sale, Article 321-1 of the Criminal

Code of Ukraine is applied, which provides for liability up to imprisonment depending on the consequences and scale of the offense [23].

The practice of applying criminal legislation shows that one of the common ways to commit such crimes is to hide drugs in cargo with different markings or send them through international mail. For example, law enforcement agencies have repeatedly exposed channels of illegal import into Ukraine of drugs containing psychotropic substances, which were declared as ordinary medical supplements. In such cases, the actions are qualified by a set of crimes, in particular under Articles 305 and 321 of the Criminal Code of Ukraine. Another example is the detection of clandestine production of counterfeit medicines with their subsequent import or export across the customs border, which poses a threat of mass poisoning of the population [24].

An essential element of criminal law mechanisms is the institution of complicity, since illiciting of medicines is often organized in nature. In such cases, the provisions on organized groups or criminal organizations are applied, which provides for more severe criminal liability. In addition, the institution of special confiscation plays an important role, which allows for the seizure of not only the objects of the crime, but also the income obtained as a result of illegal activities [25].

Criminal procedural aspects are also a component of these mechanisms. Pre-trial investigation is carried out by the National Police, the Security Service of Ukraine and the Bureau of Economic Security (depending on the qualification of the crime), with the involvement of expert institutions to establish the composition and quality of medicines. Forensic chemical and pharmaceutical examinations are important, which allow confirming the fact of falsification or the presence of prohibited substances [26].

In the international context, criminal law mechanisms to combat the illiciting of medicines are consistent with the provisions of the UN Convention against Transnational Organized Crime, as well as recommendations from Interpol and the World Health Organization. Many states have introduced specialized offenses related to the circulation of counterfeit medicines [27]. For example, in the countries of the European Union, criminal liability for such acts is harmonized within the framework of directives and national legislation, which provide for strict sanctions for the production and distribution of counterfeit medicines [28].

Despite the existence of a regulatory framework, the effectiveness of criminal law mechanisms in Ukraine is limited by a number of factors, including the complexity of proving cases in this category, the insufficient level of technical support for law enforcement agencies, and the high latency of such crimes. In addition, a significant part of the illicit trafficking of medicines is transferred to the online environment, which complicates the detection and documentation of offenses [29].

Therefore, criminal law mechanisms for combating the illiciting of medicines are an important tool for ensuring national security and protecting public health [30]. Their

effectiveness depends on the proper qualification of crimes, coordinated activities of law enforcement agencies, the development of an expert base, and active international cooperation [31]. A comprehensive combination of criminal law and administrative law measures allows for the formation of an effective system for combating the illicit trafficking of pharmaceutical products [32].

Conclusion

The conducted study of administrative and criminal legal mechanisms for combating the illiciting of medicines allows us to draw a number of general conclusions.

First, the illiciting of medicines is a complex transnational phenomenon that combines economic crime, threats to public health and elements of organized criminal activity. Its public danger lies not only in the violation of customs rules, but also in the potential introduction into circulation of falsified or dangerous medicines.

Second, administrative and legal mechanisms (customs control, licensing, market surveillance, pharmacovigilance, risk management system) constitute the first level of state protection. They ensure the prevention of the illegal movement of medicines and allow detecting violations at an early stage.

Third, criminal legal mechanisms play a key role in cases of increased public danger. The norms of the Criminal Code of Ukraine (in particular Articles 201, 305, 321, 321-1) ensure that guilty persons are brought to strict liability, including imprisonment and confiscation of property, which has a significant preventive effect.

Fourth, the effectiveness of combating drug illiciting largely depends on the level of interdepartmental coordination, technical support of law enforcement and customs authorities, as well as the development of an expert base for identifying counterfeit drugs.

Fifth, foreign experience (EU, USA, Great Britain and other countries) indicates the high effectiveness of integrated drug tracking systems (track and trace), product serialization and digital control of supply chains, which significantly reduces the level of illegal circulation of pharmaceutical products.

Sixth, it is important for Ukraine to further improve legal regulation in the direction of harmonization with EU law, strengthen criminal liability for counterfeiting and illiciting of medicines, as well as introduce modern digital control technologies.

Therefore, only a comprehensive combination of administrative, legal and criminal law instruments in interaction with international mechanisms will ensure effective counteraction to illiciting of medicines and increase the level of public health protection.

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Conflict of Interest

Authors have no conflict of interest to declare.

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