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RESEARCH ARTICLE

Comparative Analysis of Types of Liability and Punishments for the Falcification of Medicines in Countries of European Union

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Abstract

The article presents the results of an analysis of modern approaches in determining the types of responsibilities and penalties for falsification of medicines in the EU countries. It is determined that, process of recognition and implementation of norms and requirements of The Medicrime Convention in the states that are members to the Council of Europe continues and dynamically develops. The changes, which were adopted after the signature by the EU countries of The Medicrime Convention in 2011, are analyzed. Determined, that out of all liabilities which exist in jurisprudence in regards to the issue of falsification of medicines, the criminal, administrative and civil liabilities are applied. Current practice exists in all 28 EU states. It was found that in most of the EU countries (10 countries) relatively soft criminal sanctions (from 1 to 3 years of imprisonment) dominate for the falsification of medicines. In addition, there is no consolidated position as to what kinds of offenses for falsification in the pharmaceutical market criminal sanctions should be applied. It is found that the maximum values of penalties for falsification of medicines in the EU countries varies in a wide range of indicators (from 4,3 thousand euro to 1 million euros). Relatively soft criminal sanctions in most EU countries and a wide range of fines for drug fraud contribute to the migration of organized crime in the pharmaceutical business. However, it should be noted that the positive experience of struggling against counterfeiting in the EU has great practical significance for countries with low income and health systems, which are in the stage of reforming.

Keywords: *Falsification of medicines, Punishment for falsification of medicines, Types of liability for falsification of medicines, The Medicrime Convention.*

Introduction

Among the problems in the healthcare and pharmaceutical provision of the population, the illegal turnover of falsified drugs is one of the most important and difficult to resolve at the moment. Illicit trafficking of counterfeit drugs inflicts irreparable damage to public health and the commercial reputation of legal drug manufacturers around the world. A clear definition of "falsified drugs" was provided in 1992 by the World Health Organization (WHO). In accordance with this definition, falsified drug (counterfeit medicine) - is a product that is intentionally and unlawfully provided with false markings regarding its authenticity and (or) the source of origin [1, 2]. In compliance with data provided by international experts, the annual sales of counterfeit medicines on the world pharmaceutical market range from 150 to 200 billion euros or from 163 to 217 billion US dollars per year. This makes falsification of medicines the most profitable of all kinds of illegal activity that is carried out in modern society [3, 4, 5]. Despite the large-scale actions taken by international organizations and pharmaceutical companies to protect their markets from counterfeited products, the illicit trafficking in counterfeit

medicines remains an urgent problem for all countries of the world [5-8]. For instance, only in Germany, about 4 million packets of counterfeit pharmaceutical products were withdrawn from the turnover in the pharmaceutical market in 2015 [4]. Herewith, these efforts still have the results essential for the public health and pharmaceutical business [7, 8].

Thus, according to WHO in national health systems, in which effective mechanisms exist to prevent drug fraud and regulate drug turnover in general, the proportion (%) of falsified drugs is less than 1.0% of the total sales of goods on the pharmaceutical market [4,9-12]. For example, in most countries in Africa, as well as in some countries in Latin America and Asia, WHO identifies areas where the illegal sale of counterfeit medicines amounts to more than 30.0% of sales in the pharmaceutical market [1,13,14]. For other countries in the world, statistics on the amount of illegal sale of counterfeit medicines are striking in the range of their values.

For example, according to some sources, in many countries of the former Soviet Union, the illegal sale of counterfeit medicines amounts to more than 20.0% of the total sales of medicines and pharmacy products in national pharmaceutical markets [15,16]. According to WHO, about 1 million people die each year after taking counterfeit medicines [1,9,12]. At the same time, the damage caused to human health from the use of counterfeit drugs is difficult to measure or calculate. It is clear that these are irreplaceable for any society, loss of health and quality of life of people.

Particular medical and social importance is the illegal turnover of counterfeit drugs, which are used to treat socially important and socially dangerous diseases. For instance, falsification of antimalarial, antitubercular, antiretroviral and antibiotic drugs in countries characterized by a shortage of funds in the health care system leads to enormous losses in both material and non-material spheres of society [16-22]. At the same time, particularly acute this problem is observed in countries with relatively low income and inefficient mechanisms of state regulation of drug trafficking coming through illegal channels for marketing of pharmaceutical products. Unfortunately, such countries include the Republic of Kazakhstan. It should be noted that during the last decade, the Republic of Kazakhstan is making bold steps to build a modern and efficient quality assurance system of pharmaceutical products, which are produced in the country and imported from other countries [23,24].

First of all, when building a national system for quality assurance of pharmaceutical products, it is necessary to make effective use of international experience in the prevention of illicit trafficking in counterfeit medicines, which has been developed over several decades in the countries of the European Union (EU). Of particular interest to the national healthcare system of the Republic of Kazakhstan is the consideration of the types of responsibilities and penalties that exist in the EU countries for illegal operations with counterfeit drugs at various stages of their promotion in the pharmaceutical market. For example, in Kazakhstan only in 2015 there were amendments to the Criminal Code, which provides for imprisonment from 2 to 10 years for handling falsified medicines, medical devices or medical equipment in the pharmaceutical market [25].

Earlier, in the Republic of Kazakhstan, only administrative sanctions were applied for these unlawful acts. All of the above resulted in the goal of our research. The aim of our research was the comparative analysis of the types of liability and penalties, which are prescribed in the EU for illegal operations against counterfeit medicines at all stages of the promotion of these drugs in the pharmaceutical market.

Materials and Methods

The objects of the study were the data of the legislative and regulatory framework that regulates the issues of determining the degree of responsibility and penalties for falsification of medicines in the EU countries.

Numerous reviews and original articles have also been used, presented in various international publications that highlight the problems of drug fraud, and also consider the experience of carrying out measures to prevent such drugs from entering into legal channels of sale in the pharmaceutical market. In light of the recent changes that have occurred in the EU legislation regarding the definition of a measure of responsibility

for counterfeiting medicines, special attention was paid to the analysis of the European Convention «Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health» (herein after *The Medicrime Convention*) [26,27]. The document (2011/62 / EC) was adopted in 2011 as a supplement to Directive 2001/83/EC, which addressed the issue of the threat of drug fraud in Europe [28, 29].

The Council of Europe drafted a convention which constitutes, for the first time, a binding international instrument in the criminal law field on counterfeiting of medical products and similar crimes involving threats to public health [26,29,30]. As it is stated on the official website of The Council of Europe, The Council of Europe has long been concerned about the absence of harmonized international legislation, non-deterrent sanctions that were not proportionate to the harm caused to patients, and the involvement of criminal organizations which operate across borders [26].

The Medic rime Convention is the first international document that obliges all signatories to bring the perpetrators to criminal liability for deliberate falsification of medicines, as well as active pharmaceutical ingredients. It also provides for criminal liability for falsification of excipients used in pharmaceutical production and for the distribution of counterfeit drugs at various stages of the distribution chain in the pharmaceutical market [26, 31, 32]. In addition, analytical reports were analyzed, including the report of The European Commission on the effectiveness of implementing a set of measures related to increasing criminal liability for drug fraud, active pharmaceutical ingredients and excipients [26, 27, 30, 33, 34].

To achieve the goal of our research, the following tasks were set: to analyze existing types of responsibilities and penalties for falsification of medicines that exist in international legal practice; to study the main provisions of the medicrime convention, which deal with the procedure for determining the measure of responsibilities and punishment for the falsification of medicines; to systematize and analyze the data of analytical reports covering the effectiveness of the implementation of standards and requirements of The Medicrime Convention; to classify the EU countries in terms of prison sentences and fines for falsification of medicines; to achieve the goal of our research, the following tasks were set: to determine the most important aspects of the implementation of international medical and legal practice to prevent illicit trafficking in counterfeit drugs in practical health care of the Republic of Kazakhstan.

Traditionally, for the work of organizational and economic areas, which are held in pharmacy, historical, logical, comparative and graphical methods of research were used. In addition, the methods of materialistic dialectics, scientific abstraction, induction and deduction, individual elements of economic and statistical analysis, etc. were used. All statistical calculations were performed using the statistical package Stat Soft. Inc. (2014). STATISTICA version 12.0 and Excel spreadsheet. A p-value <0.05 was considered as statistically significant.

Results and Discussion

As a result of the analysis of existing types of legal responsibility and the degree of punishment for illegal actions with counterfeit drugs that exist in international legal practice, we established the following. In international jurisprudence, depending on the type of offenses, there are nine types of legal liability (Table 1).

Table 1: Characteristics of the types of liability in international legal practice and the definition of the possibilities of their application to illegal actions on falsification of drugs

View responsibility	Characteristics of liability and the possibility of their application to the facts of illegal trafficking in counterfeit drugs
	«+» - Applicable, «–» - Not Applicable
Criminal liability	Arrives for the commission of an act provided for by the criminal law. It is characterized by the most severe sanctions, namely deprivation of liberty and even the death penalty. It is established only by law and is applied exclusively in the courts. The order of its superposition is extremely detailed. This is due to its special repressiveness and the desire of the legislator to prevent the slightest possible errors on the part of offenders.
	«+» - Applicable
Administrative responsibility	Provided for administrative offenses. In comparison with criminal sanctions, administrative sanctions are less stringent. At the same time, their implementation is capable of delivering

	tangible consequences for the offender (for example, arrest, disqualification, fines, confiscation of items, deprivation of special rights). This kind of responsibility comes for misdemeanors, which, from the point of view of public danger, border on crimes, including for unlawful actions with falsified drugs and documents.
	«+» - Applicable
Disciplinary responsibility	It is used for violation of official duties. Established in the Labor Code of the country, presented in the rules of internal labor regulations, in the charter of the enterprise, etc. Not as harsh as criminal and administrative, but can significantly detract from the honor and dignity of the employee. They are used for pharmaceutical workers mainly for preventive purposes.
	«–» - Not Applicable
Material liability	It is used to inflict material damage on individuals and legal entities who are in labor relations.
	«–» - Not Applicable
Civil-law	It is used for committing a civil offense, the essence of which is the infliction of property or moral harm to citizens, organizations with whom the offender is not in employment relations. Its application means imposition of the obligation to compensate property and moral damage inflicted on citizens and organizations. Can be applied in parallel with the application of criminal and administrative responsibility.
	«+» - Applicable
Financial responsibility	It is used for committing acts that violate the rules for handling money resources.
	«–» - Not Applicable
Family responsibility	Applies to family misconduct, which has a social resonance in society.
	«–» - Not Applicable
Constitutional responsibility	It is a responsibility for the abolition of regulations that contradict the constitution of the country, etc.
	«–» - Not Applicable
Procedural responsibility	It is used for violation of the order of passing the case in the law enforcement agency, as well as for violation of the rules of justice established by law.
	«–» - Not Applicable

This is criminal, administrative, disciplinary, administrative, material, civil, financial, family, constitutional and procedural [34, 35]. As it can be seen from the data in Table 1 of the nine existing types of responsibility for illegal actions that are associated with the falsification of medicines in international legal practice, only three apply. This is criminal, administrative and civil law. It should be noted that civil liability is applied in parallel with the application of criminal and administrative liability.

Thus, the competent authorities oblige a natural or legal person to remedy in court the material or non-material damage that has been inflicted on citizens due to unlawful actions that have involved the trafficking of falsified drugs or the forgery of documents confirming their quality. It stays clear, that out of all types of legal liability, the criminal one is the most severe. The Medicrime Convention just provides for the expansion of the spectrum of criminal liability for illegal actions associated with the falsification of drugs, active pharmaceutical ingredients and excipients used in the manufacture of drugs [32-34].

As Shown by the Content Analysis, The Medic rime Convention is the First International Criminal Law Instrument to Oblige States Parties to Criminalise

- The manufacturing of counterfeit medical products;
- supplying, offering to supply and trafficking in counterfeit medical products;
- The falsification of documents;
- The unauthorised manufacturing or supplying of medicinal products and the placing on the market of medical devices which do not comply with conformity requirements [26,34,35].

The Convention provides a framework for national and international co-operation across the different sectors of the public administration, measures for coordination at national level, preventive measures for use by public and private sectors and protection of victims and witnesses. Furthermore, it foresees the establishment of a monitoring body to oversee the implementation of the Convention by the States Parties [26,35].

As of 13.04.2018 (the official website of The Council of Europe) We have been analyzed a set of countries that have signed and ratified the Treaty 211 Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health. The results of the conducted analysis are available in Table 2. As we see from the data in Table 2, the process of recognition and enforcement of the standards and

requirements of The Medicrime Convention in the countries that are members of the Council of Europe continues and dynamically develops. It should be noted that The Medicrime Convention can be signed and ratified by all 47 states of the Council of Europe member states and observer states of the Council of Europe and all other countries that have participated in its elaboration. As of 13.04.2018, out of 47 countries that are members of the Council of Europe, only 23 countries have signed this document. Of the countries that signed The Medicrime Convention, 10 countries have ratified this document and have implemented or plan to put it into effect. They are Albania, Armenia, Belgium, France, Hungary, Republic of Moldova, Russian Federation, Spain, Turkey and Ukraine.

Table 2: Countries that have signed, ratified and enforced the medicrime convention

Country	Dates		
	Signings	Ratifications	Putting into operation
Members of the Council of Europe			
Albania	17/12/2015	06/06/2016	01/10/2016
Armenia	20/09/2012	05/02/2016	01/06/2016
Austria	28/10/2011	–	–
Belgium	24/07/2012	01/08/2016	01/11/2016
Bosnia and Herzegovina	04/02/2015	–	–
Croatia	03/09/2015	–	–
Cyprus	28/10/2011	–	–
Denmark	12/01/2012	–	–
Finland	28/10/2011	–	–
France	28/10/2011	21/09/2016	01/01/2017
Germany	28/10/2011	–	–
Hungary	26/09/2013	09/01/2014	01/01/2016
Iceland	28/10/2011	–	–
Italy	28/10/2011	–	–
Luxembourg	22/12/2011	–	–
Liechtenstein	04/11/2011	–	–
Portugal	28/10/2011	–	–
The Republic of Moldova	20/09/2012	14/08/2014	01/01/2016
Russian Federation	28/10/2011	20/03/2018	01/07/2018
Spain	08/10/2012	05/08/2013	01/01/2012
Switzerland	28/10/2011	–	–
Turkey	29/06/2012	21/09/2017	01/01/2018
Ukraine	28/10/2011	20/08/2012	01/01/2016

To the European process to toughen the criminal responsibility for falsification of medicines, as well as the coordination of government action to prevent this illegal activity at the international level and also joined the countries that do not belong to the Council of Europe. This is Israel (28/10/2011), Burkina Faso (16/02/2017), Guinea (10/10/2012) and Morocco (13/02/2012).

It should be noted that Guinea and Burkina Faso not only signed, ratified and already introduced the standards and requirements of The Medicrime Convention into the health care system. In Guinea, the actions of this document were implemented from 01/01/2016 and in Burkina Faso from 01/11/2017. Unfortunately, the Republic of Kazakhstan has not yet joined this European process, connected with the tightening of criminal responsibility for the falsification of medicines, active pharmaceutical ingredients and auxiliary substances used in the manufacture of medicines.

Next, we analyzed data from the analytical reviews and the Council of Europe's Report on the effectiveness of the implementation of the standards and requirements of The Medicrime Convention (2011) in the EU countries [26, 27, 29, 30, 33, 34]. It is established that since the signing of The Medicrime Convention (2011) all 28 EU countries have made changes to national legislation. The purpose of these changes was to strengthen the degree of criminal punishment or to increase the amounts of fines for falsifying drugs.

Herewith, all EU member states, except Finland, Luxembourg and Malta, have introduced additional administrative sanctions in the national legislation for the falsification of medicines, active pharmaceutical ingredients and auxiliary substances used in the manufacture of drugs [27, 29, 35, 36]. All 28 EU countries apply criminal penalties for falsification of medicines at all stages of their promotion in

the pharmaceutical market. In all the other 21 EU countries, falsification in the pharmaceutical market is already illegal and a priori does not require confirmation of material or moral damage to third parties. In the remaining 7 EU countries, civil-law (fines) or administrative sanctions (deprivation of licenses) can be used to falsify medicines. It should be noted that in these countries (Bulgaria, Latvia, Lithuania, Poland, Romania, Finland and Sweden) criminal sanctions still apply, but to certain types of illegal activities related to the falsification of drugs.

It makes since to look closer at addressing this issue. For example, in Bulgaria, criminal sanctions are applied only in the case of the import and export of counterfeit medicines. All other types of unlawful actions for falsifying drugs are considered by government agencies as civil and administrative violations with appropriate sanctions. In Latvia, criminal sanctions are applied only to the production, distribution and retail sale of counterfeit medicines. In Latvia and Romania, operations on the export and import of counterfeit medicines are considered by the competent authorities as civil-law and administrative violations of the current legislation. In countries such as Poland and Sweden, falsification of drugs during export is defined as a civil law violation of the current legislation.

In Lithuania, only operations involving the import of counterfeit medicines fall under the same jurisdiction. In addition, it should be noted that in Latvia, criminal liability is only applied if the use of counterfeit drugs has led to death or caused significant physical harm to the health of citizens. In countries such as Portugal and Estonia, similar sanctions are applied in cases where a potentially falsified drug in its use can cause significant harm to people and the health system as a whole. In countries such as Greece, Romania, Lithuania and Sweden, criminal sanctions are applied if the use of a falsified drug can have dangerous consequences.

For example, due to inadequate concentration of active substance or presence of harmful impurities. As it can observed, in the EU countries, since the signing of The Medicrime Convention (2011), there is still no consolidated and clear position regarding the measure of responsibility for counterfeiting drugs at various stages of their promotion along the commodity distribution chain in the pharmaceutical markets. It is an interesting fact that in other countries of the world the criminal liability for falsification and illegal sale of such products, which caused health damage, which also led to the patient's death, turns into a very strict punishment. For example, in Turkey, the falsification of medicines is punishable by imprisonment for 30 to 50 years, in the United States and India - to life imprisonment, while in China and some countries in the Muslim world - the death of those responsible [1,4,36,37].

As stated previously, in all 28 EU countries to the falsification of medicines in various stages of advancement of the pharmaceutical market, active pharmaceutical ingredients, excipients used in the pharmaceutical industry, criminal penalties are applied. Therefore, below, we were interested to distribute all the countries in the group on conditional terms of imprisonment for these unlawful acts. In general, it should be noted that these illegal actions in EU countries can be deprived of liberty in a very wide range, from 1 to 15 years. By the maximum value of the terms of imprisonment for these actions, all the EU countries we were divided into conditional four groups. By I-st group of countries were classified as статьи, in which the term of imprisonment for falsification and illegal trafficking of drugs, active pharmaceutical ingredients and excipients is between 1 and 3 years.

The second group of countries formed those in which for similar actions, the deprivation of liberty from 4 to 6 years is foreseen, in the third from 7 to 9 years, and in IV – more than 9 years of imprisonment. The results of the analysis of the maximum periods of imprisonment for the falsification and illegal turnover of these drugs in the EU countries are presented in Figure 1. As we can see from the data in Figure 1, the maximum number of EU countries applies relatively mild criminal sanctions for the falsification of pharmaceutical products on the market. Thus, in the I-th group of countries (where the maximum sentence is from 1 to 3) included 10 countries, and in the II-th (4 to 6 years) – 7 countries, III-w (of 5 to 7 years) – 5 countries, and in the 4th – 6 EU countries.

Thus, we can draw such a conclusion. A significant majority of EU countries (I-st and II-nd group, in total 17 countries) use a term of imprisonment from 1 year to 7 years as punishment for falsification of pharmaceutical products. At the same time, in 10 countries the minimum values of terms of imprisonment are stipulated, that makes from 1 to 3 years. This allows us to state that the EU countries are dominated by a relatively soft legal regime to determine the degree of criminal punishment for falsification of medicines that have the most important social and medical-pharmaceutical significance.

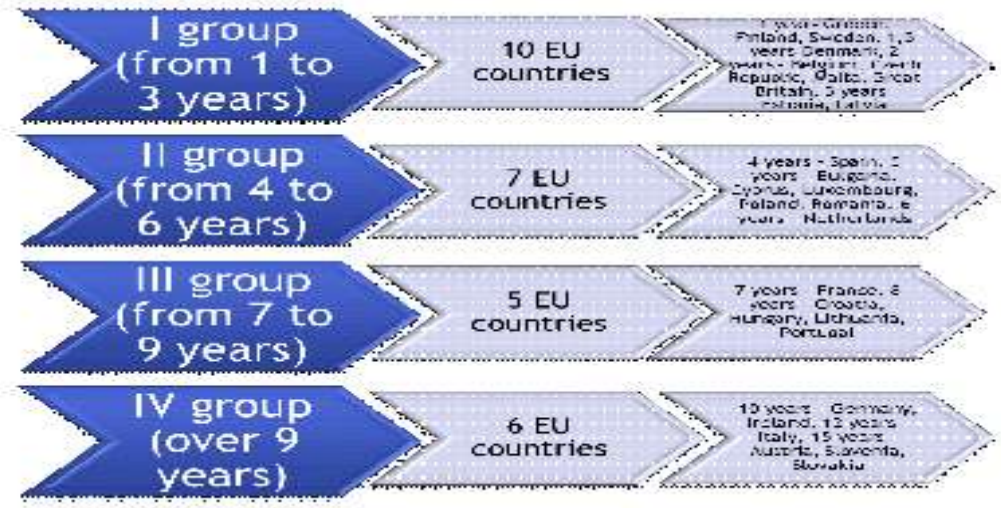

Figure 1: Classification of countries by the maximum value of terms of imprisonment for unlawful actions connected with falsification of drugs

Wherein, in countries such as Germany, Ireland and Italy for similar actions, imprisonment from 10 to 12 years is envisaged. In Austria, Slovenia and Slovakia, actions to falsify medicines and illicit trafficking are punishable by a maximum term of imprisonment among EU countries in the form of 15 years. It is interesting that in Norway, which is not part of the EU, the maximum prison term for these illegal actions on the pharmaceutical market is no more than 4 months [1, 4].

In addition to deprivation of liberty, the use of administrative and civil sanctions is an important lever for influencing illegal actions to falsify medicines. All EU countries for the illegal actions on counterfeiting the medicines at different stages of their promotion of goods-transfer apply penalty sanctions. In countries such as Denmark, Hungary, Poland, Sweden, Finland, there is no clear size of the maximum fine for illegal actions to falsify pharmaceutical products. In the UK, the amount of such fines is not limited by legislation.

Thus, all the EU countries in terms of the maximum penalty for these illegal actions were divided into three groups. When distributing countries, we used unequal intervals of values. In the event that the national currency is used in the country, the values of fines were transferred at the official exchange rate in euros. Thus, in the first group of the country included those EU countries in which the maximum value of fines for the falsification of medicines does not exceed the value of 100 thousand euros.

The second group of countries was formed by those states in which the maximum values of fines ranged from 100 thousand to 500 euros. In the third group, the maximum fines were from 500 thousand and more. The lists of classified countries are presented in Table 3. Analyzing the data of Table 3, it can be concluded that the amount of fines, as well as the terms of imprisonment for falsifying pharmaceutical products, fluctuated over a wide range of values.

The minimum value of fines is observed in Lithuania (4,3 thousand euros), and the maximum value was typical for Spain. So, in Spain for falsification of medicines, the maximum value of a fine of 1 million euros is foreseen. The largest group was the first group of countries with a range of maximum penalties of up to 100 thousand euros.

Table 3: Maximum values of fines for falsification of medicines in EU countries

Group of EU countries (interval of values, thousand euros)			
EU country	Max fine (euro)	EU country	**Max fine (euro)**
Group I (up to 100 thousand euros)			
Lithuania	4,3	Germany	25,0
Romania	6,5	Slovenia	25,0
Latvia	14,0	Bulgaria	25,5
Italy	15,6	Estonia	32,0
Luxembourg	20,0	Austria	50,0
Croatia	20,0	Cyprus	85,5
Group II (from 100 thousand up to 500 euro)			
Malta	116,469	Belgium	240,0
Slovakia	120,0	Ireland	300,0
Portugal	180,0	Netherlands	450,0
Greece	200,0	–	–
Group III (from 500 thousand and above)			
France	750,0	Spain	1000,0
Czech Republic	775,0	–	–

At the same time, it should be noted that within the very first group, the maximum size of fines varied over a wide range of values from 4,300 euros (Lithuania) to 85,500 euros (Cyprus). The second group of countries (the maximum value of the fine from 100 thousand to 500 thousand euros) was already 7 countries. Within this group, the maximum value of the penalty varied from in the range of 116469 euros (Malta) to 450,000 euros (the Netherlands). And the last third group, which was characterized by the maximum values of fines from 500,000 euros and above, consisted of three countries (France, Czech Republic and Spain). When comparing the data of Table 2 and Table 3, it is possible to draw such a conclusion. Countries with the highest fines for drug fraud (France, Czech Republic, and Spain) were represented in groups of countries that had the shortest prison terms for these illegal activities in the pharmaceutical market. Thus, the Czech Republic was represented in the group of countries where the maximum term of imprisonment was from 1 to 3 years (group I), and Spain in the group of countries with imprisonment terms of 4 to 6 years (group II). And only France was represented in the group of countries (group III), with relatively high values of prison terms (from 7 to 9 years) for falsifying medicines. At the same time, the countries with the maximum time limits for imprisonment (15 years - Austria, Slovakia, Slovenia) are represented by fines in the first (Slovenia, Austria) and the second (Slovakia) analysis groups. Thus, it can be stated that in the EU countries there is a dual approach in determining the type of liability or the amount of penalties for falsifying medicines. If the country has high penalties for falsifying medicines, then the terms of deprivation of liberty are relatively mild and vice versa. In general, it would be appropriate to note the following. The presence of a significant range in the maximum fines for falsification of medicines in various EU countries can lead to the migration of organized crime in the pharmaceutical sector of the economy from one country to another. In addition, the variety of approaches of identifying the types of activities to which sanctions for falsification, which exists in different EU countries, can influence the development of this process. Not the least role in this direction is also played by a significant spread of the measure of the penalty (terms of imprisonment, the size of fines) for falsification of medicines, active pharmaceutical ingredients and auxiliary substances in the EU countries. Setting out the results of the conducted studies, as well as the data of the specialized literature, it should be noted that one of the main directions for improving the state system for ensuring the quality of medicines in the Republic of Kazakhstan should be active cooperation with international organizations and the development of a set of documents that meet the requirements of The Medicrime Convention (2011). In addition, an important place in the implementation of a set of measures to prevent counterfeit drugs should take the definition of the form of responsibility and prison terms for falsifying drugs, as well as active pharmaceutical ingredients and excipients used in pharmaceutical manufacture. In this respect, it is necessary to develop a consolidated position that, on the one hand, would take into account the advanced European experience, and on the other hand, would meet the level of social responsibility of the

pharmaceutical business to the state and society as a whole.

Conclusion

Falsification of medicines is a multifaceted problem that affects all practical spheres of modern society. Present days, in most countries, the problem of drug fraud is not considered to be exclusively a medical and economic issue. Today, many drug manufacturers spend collateral on protecting their drugs from falsification [14,39, 40]. The development of modern technologies for the protection of drugs against their falsification is one of the most important directions in the development of the pharmaceutical business [41,42].

International organizations pay attention not only to the development and implementation of modern anti-counterfeit technologies, as well as to the modification of the definition of "falsified drug" [43]. This once again underscores the importance and urgency of the problem of drug fraud on a global scale. Leaves no public concern is also the fact that the illegal acts related to counterfeiting and illegal trafficking of these drugs affect the social and ethical aspects of the functioning of society [44].

Strengthening the criminal component in the falsification of drugs, as well as the formation of international illegal channels for the sale of these drugs determines the need to develop a comprehensive program to counter the falsification of pharmaceutical products. The most important component of such measures is to increase the level of responsibility for these illegal actions. Since the signing of The Medicrime Convention (2011) in the legislation of all EU countries, serious changes have taken place in the direction to strengthen criminal penalties for the falsification of drugs and their illicit trafficking. Of course, all this influenced the development of modern approaches to the construction of national systems for ensuring the quality of medicines in low-income countries, as well as in those countries in which there are significant structural changes in the pharmaceutical supply system of the population [45]. Such countries of the post-Soviet space include Ukraine and the Republic of Kazakhstan. The active development of the pharmaceutical markets of these countries, as well as the processes of reforming the quality assurance systems of medicines that take place in these countries, necessitate the systematic use of the experience of the European countries in the chosen topic [23,24,45-49].

It is in the countries that emerged in the post-Soviet space that both destructive and constructive trends are observed in the development of both pharmaceutical markets and state systems for ensuring the quality of medicines. As is known, despite the political and financial crisis, such states of the post-Soviet space as Ukraine and the Republic of Kazakhstan allocate considerable resources for the acquisition of relatively cheap and effective medicines for the implementation of state programs for socially unprotected strata of the population [24, 45]. Therefore, the use of positive experience in combating the falsification of pharmaceutical products at all stages of the commodity distribution chain in the EU countries is socially significant and important from the state point of view.

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Conflict of Interest

The authors declare that they have no conflict of interest to disclose.

Contributing Authors

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References

1. The Criminal Code of the Republic of Kazakhstan (with changes and additions as of 01.01.2018).Available at: https://online.zakon.kz/Document/?doc_id=31575252
2. Tulegenova AR, Dilbarhanova Zh R, Sokurenko IA (2018) Analysis of the results of a survey of pharmaceutical workers on the problem of the falsification of drugs and their illicit trafficking in the pharmaceutical market of the Republic of Kazakhstan. Management, Economics and Quality Assurance in Pharmacy,1(53):63-71.
3. Panfilova H, Bogdan N, Gala L, Simonian L, Tsurikova O (2018) Analysis of Ukrainian pharmaceutical market retail segment development. Journal of Global Pharma Technology, 10(3):191-9.
4. Ubaidilla Datkhayev, Alma Shopabaeva, Kairat Zhakipbekov, Clara Shertaeva, Galiya Umurzakhova,

Arman Sultanbekov, Roza Yerzhanova, Aigerim Tulegenova (2016) Determination of Seasonal Demand for Pharmaceutical Staff. International Journal of Pharmaceutical Sciences Review and Research, 36(2):18:105-11.

5. Council of Europe Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes Involving Threats to Public Health (2011) Available at: http://conventions.coe.int/Treaty/EN/Treaties/Html/211.htm
6. Behner P, Marie-Lyn Hecht, Fabian Wahl (2017) Fighting counterfeit pharmaceuticals: New defences for an underestimated – and growing – menace, PWC Strategy., 1-24
7. Falsification of medicines in the EU: the report of the European Commission has been published. Available at: https://www.apteka.ua/article/444750
8. Amir Attaran (2015) Stopping Murder by M Council of Europe Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes Am J Trop Med Hyg.,92(6): 127-32.
9. Hamilton WL, Doyle C, Halli well-Ewen M, Lambert G (2016) Public health interventions to protect against falsified medicines: a systematic review of international, national and local policies. Public health interventions to protect against falsified medicines: a systematic review of international, national and local policies. Health Policy Plan., 31(10):1448-66.
10. Fayzrakhmanov NF (2015) Fighting trafficking of falsified and substandard medicinal products in Russia, 27(1):37-40.
11. Erwin A. Blackstone, Joseph P, Fuhr, Steve Pociask (2014) the Health and Economic Effects of Counterfeit Drug. Am Health Drug Benefits 7(4):216-24.
12. Sugita M, Miyakawa M (2010) Economic analysis of use of counterfeit drugs: health impairment risk of counterfeit phosphodiesterase type 5 inhibitor taken as an example. Environ Health Prev. Med.15(4):244-51.
13. Fake pharmaceuticals (2012) bad medicine: the world's drug supply is global. Governments have failed to keep up. Economist. October 13, Available at: www.economist.com/node/21564546.
14. Liang BA (2006) Fade to black: importation and counterfeit drugs. Am J Law Med.,32:279-323.
15. Coustasse A, Arvidson C, Rutsohn P (2010) Pharmaceutical counterfeiting and the RFID technology intervention. J. Hosp. Mark Public Relations. 20:100-15.
16. World Health Organization (2009) Counterfeit medicines Key facts Available at: http://www.who.int/medicines/services/counterfeit/CfeitsFact SheetJuly09.pdf.
17. Golocorbin Kon S, Mikov M (2011) Counterfeit drugs as a global threat to health. Med Pregl. 64(5-6):285-90.
18. Barbereau S (2006) Counterfeit medicines: a growing threat Med Trop (Mars)., 66(6):529-32.
19. Dipika Bansal, Swathi Malla, Kapil Gudala, Pramil Tiwari (2013) Anti-Counterfeit Technologies: A Pharmaceutical Industry Perspective. Sci Pharm., 81(1):1-13.
20. Wertheimer AI, Norris J (2009) Safeguarding against substandard/counterfeit drugs: mitigating a macroeconomic pandemic. Res Social Adm Pharm.; 5:4-16. Available at: http://dx.doi.org/10.1016/j.sapharm.2008.05.002.
21. World Health Organization Counterfeit medical products: Report by the secretariat. Available at: http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_23-en.pdf.
22. International Policy Network Counterfeit medicines in less developed countries: Problems and solutions. Available at: http://counterfeiting.unicri.it/docs/Ctf%20medicines%20in%20less%20developed%20countries.pdf.
23. International Medical Products Anti-Counterfeiting Taskforce IMPACT brochure. Available at: http://www.who.int/impact/FinalBrochureWHA2008a.pdf.
24. National Council for Prescription Drug Programs Drug pedigree in healthcare background. Available at: http://www.ncpdp.org/members/wg17/201001227%20NCPDP%20%20Drug%20Pedigree-Background_v1.pdf.
25. Pharmaceutical Technology Europe Improving packaging security. 2011. May 2. Available at: http://pharmtech.findpharma.com/pharmtech/article/articleDetail.jsp?id=718108.
26. Elisabeth L, Alejandro R, Louis AL, Caroline K (2011) Technological strategies to deal with counterfeit medicines: the European and North-American perspectives. Int J Ed Inf Technol. 5:275-284. Available at: http://www.naun.org/journals/educationinformation/19-1164.pdf.
27. Pashkov V, Soloviov A, Olefir A (2017) Legal aspects of counteracting the trafficking of falsified medicines in the European Union.; Wiad Lek.,70 (4):843-49.
28. Merks P, Swieczkowski D, Byliniak M, Drozd M, Krupa K, Jaguszewski M, Brindley DA, Naughton BD (2018) The European Falsified Medicines Directive in Poland: background, implementation and potential recommendations for pharmacists. Eur J Hosp Pharm Sci Pract., 25(1):10-15.
29. Susanne Keitel (2012) The MEDICRIME Convention: criminalising the falsification of medicines and similar crimes Generics and Biosimilars Initiative Journal (Ga BI Journal).,1(3-4):138-41
30. Tariq Almuzaini, Imti Choonara, Helen Sammons (2013) Substandard and counterfeit medicines: a systematic review of the literatureю BMJ Open.; 3(8): e002923.
31. Mackey TK, Liang BA. (2011) the global counterfeit drug trade: patient safety and public health risks. J Pharm Sci., 100:4571-9.
32. The Institute of Medicine (IOM) (2013) Countering the Problem of Falsified and Substandard Drugs report Available at:

http://www.iom.edu/Reports/2013/Countering-the-Problem-of-Falsified-and-Substandard-Drugs.aspx.

33. Sabartova J, Nathanson E, Polishchuk O (2011) Survey of the quality of anti-tuberculosis medicines circulating in selected newly independent states of the former Soviet Union. Geneva: World Health Organization,. WHO/EMP/QSM/2011.2. Available at: http://apps.who.int/medicinedocs/documents/s19053en/s19053en.pdf.
34. Wertheimer AI, Norris J (2009) Safeguarding against substandard/counterfeit drugs: mitigating a macroeconomic pandemic. Res Social Adm Pharm.,5:4-16
35. Interpol Pharmaceutical Crime (2012) COM/FS/2012–01/DCO-04. Available at: http://www.interpol.int/content/download/3902/37957/version/17/file/Factsheets_EN_jun2012_DCO04.pdf.
36. Urszula WŁodarczak, Damian Swieczkowski, Urszula Religioni, Milosz Jaguszewski, Jerzy Krysinski, Piotr Merks (2017) Awareness of the implementation of the Falsified Medicines Directive among pharmaceutical companies' professionals in the European Economic Area. Pharm Pract (Granada).15(4):1031. Published online 2017
37. WHO Substandard and Falsified (SF) Medical Products. Available at: http://www.who.int/medicines/regulation/ssffc/en/
38. Kaur H, Clarke S, Lalani M, Phanouvong S, Guérin P, McLoughlin A, Wilson BK, Deats M, Plançon A, Hopkins H, Miranda D, Schellenberg D (2016) Fake anti-malarials: start with the facts. Malar J.,15:86
39. Intellectual Property Watch (2017) [accessed on 23 August];WHO Group Suggests New Name For Falsified Medicines, Dropping 'Counterfeit' Available at: https://www.ip-watch.org/2016/11/28/group-suggests-new-name-falsified-medicines-dropping-counterfeit/
40. Hamilton WL, Doyle C, Halliwell-Ewen M, Lambert G (2016) Public health interventions to protect against falsified medicines: a systematic review of international, national and local policies. Health Policy Plan. 31(10):1448-1466.
41. European Medicines Agency (2017) [Accessed on 23 August]; Falsified medicines. Available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000186.jsp.
42. Nayyar GM, Attaran A, Clark JP, Culzoni MJ et al (2015) Responding to the pandemic of falsified medicines. Am J Trop Med Hyg.,92 (6):113-18.
43. Pharmaceutical crime. A major threat to public health. Available at: https://www.interpol.int/Crime-areas/Pharmaceutical-crime/Pharmaceutical-crime.
44. Price R (2016) EU: Falsified medicines directive "Delegated act" accepted by European parliament. Eur J Hosp Pharm Sci Pract., 23(3):183-186.
45. Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products. [Accessed on 23 August 2017]; Official Journal of the European Union. Available at: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf
46. Qadri S (2014) the current status and implementation of the Falsified Medicines Directive in the EU. Regulatory Rapporteur. 11(5):11-15.
47. Sinclair-Jenkins B, Andrews R, Rees I (2014) the falsified medicines directive: A regulatory perspective. Regulatory Rapporteur. 11(5):5-7.
48. Price R (2016) Falsified Medicines Directive news: EDQM announce collaboration with the European Medicines Verification Organisation. Eur J Hosp Pharm Sci Pract., 23(1): 61.
49. Smith G, Smith JA, Brindley DA (2014) The Falsified Medicines Directive: How to secure your supply chain. J Generic Med.11 (3-4):169–172.

