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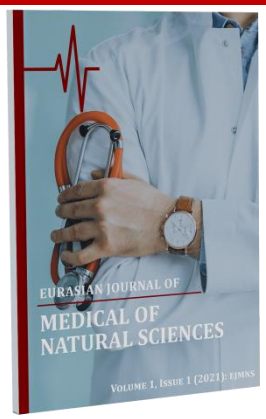

COUNTERFEITING OF MEDICINAL PRODUCTS IS A GLOBAL PROBLEM

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ABSTRACT

The following text provides an overview of the problem of falsification of medicinal products and the scale of this issue worldwide. Kazakhstan is part of the global community and has not escaped this problem. According to official data, in Kazakhstan, more than 1% of medicinal products are falsified, and in reality, this figure is undoubtedly higher. In recent years, the state has devoted a lot of attention to this issue and has taken a series of effective measures to enhance national security in providing the population with medicines.

Falsified medicinal products (FMPs) exist in every country, regardless of whether official statistics acknowledge the presence of counterfeit drugs in the pharmaceutical market. For example, in Belarus, they deny even the possibility of their appearance, citing a rigorous control system. In some African countries, on the other hand, it is openly stated that 50% of the total market volume consists of counterfeit drugs. In the USA, according to research by consulting companies, despite the latest protection systems and strict control, FMPs account for 10%. In the EU, where increased attention is also given to this issue, the average presence of counterfeit drugs is 2-5%. The profit from the sale of FMPs (World Congress of Pharmacy and Pharmaceutical Sciences, 2006) is approximately $50 billion USD, exceeding even the profits from drug sales, and in 2010 it reached $75 billion USD. For comparison, the global turnover of medicinal products today is approximately $980 billion USD 1,2.

Medicines have always been counterfeited everywhere. However, the events of recent years lead to the conclusion that medicine counterfeiting has turned into a major international underground business, comparable in scale to the turnover of drugs, with the significant difference that no one is immune from the threat of being harmed by counterfeit drugs, regardless of social status and income level 2. According to the WHO, from 1982 to 1997, drug counterfeiting was identified in 28 countries, and in 1997 alone - in 41 countries 3. At present, it is unlikely that there is a country completely free from counterfeit drugs, because the quality of counterfeits has increased to the point where they are sometimes indistinguishable from genuine drugs. Uzbekistan is no exception in this regard.

Every year, dozens of names of medicinal drugs are counterfeited, including well-known brands like Cavinton, No-shpa, Trental, Sumamed, Valocordin, Claphorane, Festal, Viagra. This not only harms the manufacturers and the country's budget but also poses a direct or potential threat to the health of anyone who takes counterfeits.

So, what exactly is a counterfeit drug? The definition of a "counterfeit medicine" was first formulated in 1992 in a joint document by the World Health Organization (WHO) and the International Federation of Pharmaceutical Manufacturers (IFPMA) 4. In 1999, this definition was included in the WHO's Guidance on Combatting Counterfeit Medical Products 5: "A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to its identity and/or source. Counterfeiting can apply to both branded and generic medicines. Counterfeit products may include those with the correct ingredients or the wrong ingredients, with no active ingredients, insufficient active ingredients, or counterfeit packaging." Specialists identify four main types of counterfeit drugs.

The first type is "dummy drugs." These "medicines" usually lack essential therapeutic components. Those taking them often do not feel the difference, and in some cases, the placebo effect of taking "dummy drugs" can have a positive impact.

The second type is "imitation medicines." These "medicines" use cheaper and less effective active components compared to the genuine medicinal product. The danger lies in the insufficient concentration of active substances needed by the patients.

The third type is "altered medicines." These "medicines" contain the same active ingredient as the original product but in larger or smaller quantities. It is natural that the use of such products is unsafe because it may lead to intensified side effects (especially in cases of overdose).

The fourth type is "copy medicines." These are the most common types of counterfeit drugs in the CIS countries (accounting for up to 90% of all counterfeits), typically produced by underground facilities and finding their way into batches of legal drugs through various channels. These drugs contain the same active components as legal drugs, but there is no guarantee of the quality of the underlying substances, adherence to production technological processes, etc. Therefore, there is an increased risk of consequences from taking such drugs.

The problem of FLS in the CIS countries is very relevant. For example, in the pharmaceutical market of Russia, 12% of medicines are counterfeit (according to a study conducted by the Association of Pharmaceutical Manufacturers and the Coalition for the Protection of Intellectual Property), causing damage to pharmaceutical producers of $250 million annually. Although if we accept the estimate of the Center for Marketing Research "FarmExpert" of the volumes of the Russian pharmaceutical market, the share of "pure" counterfeit medicines in this case is slightly over 1% of the total volume of the Russian pharmaceutical market. The rest is potentially substandard drugs and counterfeit products.

The distribution of counterfeit medicines by the countries they come from into the Russian market is also assessed very ambiguously today. Some experts claim that approximately two-thirds of counterfeit medicines are produced in Russia itself, and one-third comes primarily from Southeast Asian countries and a few percent from CIS countries. Others believe that no less than half of the counterfeit medicines entering Russia come from the CIS countries, India, Bulgaria, China, Poland, and even the USA.

National, including pharmaceutical, security depends not only on the state of the economy, the quality of its legal framework, but also on the correct assessment of threats to this security.

In terms of profitability, the global shadow pharmaceutical market ranks third after the weapons and drug markets. Currently, according to some experts, its volume exceeds $400 billion.

The main task of the legal pharmaceutical market is to provide the end consumer with effective and affordable medicines. It is this market that serves as the most accurate criterion for the quality of the state's social policy in ensuring the rights of citizens to life and health. In turn, the health of the nation, being the main social value and the most important economic resource of society, today serves as an indicator of progress in social and economic development, synthesizing the achieved level of quality of life of people and the economic well-being of the country. The safety of the nation's health largely determines the level of national security as a whole. Counterfeiting of medicinal products represents a real threat to the economic and social security of the country, to the health of every person taking medication.

According to a study conducted in 2002 by the Association of International Pharmaceutical Manufacturers (AIPM) and the Coalition for Intellectual Property Rights (CIPR), among the leading international and Russian pharmaceutical companies operating in the Russian market, every fifth respondent estimated annual losses from counterfeiting their products at more than 1 million dollars.

The responsibility for providing the population and medical institutions with medicinal products is entrusted to the state. The quality control system of medicinal products, aimed at preventing the entry of counterfeit and substandard drugs into the market, is of particular importance in the implementation of pharmaceutical policy. The Universal Declaration of Human Rights, adopted by the UN General Assembly in 1948, is the primary international document defining human rights. Article 25 of this document states that everyone has the right to a standard of living adequate for the health and well-being of himself and his family.

The strategic tasks facing our country in the 21st century require the maintenance and strengthening of people's health in all its manifestations (physical, spiritual, and social).

The health of the population of Uzbekistan is considered the foundation of the nation's well-being and a crucial factor in the country's national security. Recognizing this, the state takes on responsibilities to maintain a certain level of public health, providing citizens with corresponding benefits (rights) and guarantees in the field of health protection.

The Constitution of the Republic of Uzbekistan enshrines the right of citizens to healthcare and medical assistance. To implement these constitutional guarantees, the Government of the Republic of Uzbekistan has developed a number of state programs ensuring the quality of medical care for the population. However, an analysis of the organizational and legal foundations of state regulation in the field of pharmaceuticals circulation and quality control of pharmaceuticals shows that a comprehensive management system in the field of pharmaceuticals circulation, with the crucial element being the fight against the falsification of pharmaceuticals, is currently insufficiently implemented. The main obstacles to creating such a system in the Republic of Uzbekistan are:

- The absence of a legal framework that comprehensively regulates the behavior of subjects in the field of pharmaceuticals circulation.
- Weak interaction and interdependence of individual elements of the pharmaceuticals circulation management system.
- The absence of a priority on economic methods for combating pharmaceutical falsification, which is a characteristic of methods to combat the shadow economy in general in the Republic of Uzbekistan.
- The absence of monitoring of factors that contribute to the circulation of counterfeit pharmaceuticals in the Republic of Uzbekistan.

Drug counterfeiting was first recognized as a global problem in 1951 in a well-known resolution by the WHO Executive Board EB7.R79, which instructed to consider possibilities for unifying methods of control over the circulation and quality of pharmaceuticals on a national level 10. However, it took about half a century to develop balanced approaches to the implementation of international programs to prevent and detect the export, import, and smuggling of falsely labeled, counterfeit or substandard pharmaceuticals 11.

For example, the first case of drug counterfeiting in the CIS countries (a blood substitute - reopolyglukin) was officially registered in the Republic of Uzbekistan in 1997. Three years after the first case of pharmaceutical falsification was identified, the number of counterfeit pharmaceuticals detected in Russia increased by more than ten times. Objective reasons for this included the almost zero statistical level of registration of such counterfeits before 1996, the final degradation of the former post-Soviet model of pharmaceutical circulation, significant growth in the activity of major foreign pharmaceutical suppliers in the Russian market to protect their interests, and increased attention to the problem from Russian law enforcement and regulatory bodies.

The following text translates to English: In just one year (2001), over 1.5 thousand cases of counterfeit medicines being sold in Russian pharmacies were recorded. Among them, 62% were counterfeit drugs manufactured in Russia, 15% were from Baltic and CIS countries, and 23% were from distant foreign countries. Typically, the most popular medications were targeted for counterfeiting [12].

According to the Ministry of Health of Russia, only in the first quarter of 2002, the operation of 31 pharmaceutical production licenses was temporarily suspended, and three licenses were revoked. In 2004, a total of 249 counterfeit medicine series of 57 names were identified in Russia. Among them, St. Petersburg alone had 76 series of medicines of 30 names. However, some experts note that only 5-6% of counterfeit medicines have differences that can be detected through technological methods. Another problem is the public perception of the scale of counterfeit drugs in the pharmaceutical market. For instance, according to nationwide surveys conducted by VCIOM, 10% of citizens constantly encounter counterfeit drugs and misleading advertisements for medications, while an additional 44% of citizens have been victims of counterfeit medicines once or twice [13]. However, these sources of information do not explain what the surveyed citizens understood as counterfeit drugs and how they identified if a medication was counterfeit (considering that the majority of them do not seek assistance from specialists).

The distribution of counterfeit medicines from countries entering the pharmaceutical market is also estimated ambiguously. For example, regarding Russia, some authors claim that approximately 67% of counterfeit drugs are produced within Russia, 2% come from CIS countries, and 31% primarily originate from Southeast Asian countries [7]. Others (citing official data) suggest that around 60% of counterfeit medications are produced domestically, while the remaining 40% are imported [14]. Some opinions state that approximately 50% of counterfeit medicines are of Russian origin, while the other half comes to Russia from CIS countries, India, Bulgaria, China, Poland, and even the USA [14].

In reality, according to Russian experts, the situation is not as straightforward. Firstly, since only detected counterfeits are considered, it cannot be confidently stated that the actual geography of counterfeits corresponds to the studied part. Secondly, the fact that the packaging of counterfeit medicines indicates their production in Russia or the USA, for example, does not necessarily mean it is true. It is naive to assume that those who counterfeit drugs would disclose authentic production locations and countries of origin on the packaging or accompanying documents. Medicine counterfeiters always strive to "blend in" with reputable manufacturers and distributors of medications, exploiting the trust of the population [2].

According to various sources, medications with the highest demand among the population are most susceptible to counterfeiting. Among counterfeit drugs, 35-47% are antibiotics, 18-20% are hormonal preparations, 7% are antifungal agents, and a significant portion consists of therapeutic cosmetics and dietary supplements. Up to 80% of counterfeits are attributed to mid-priced imported drugs. It is believed that counterfeiting expensive medications is not profitable since they have slow turnover.

Analysis of the latest quality control practices for pharmaceuticals shows that high-tech packaging execution, including the use of special protective measures such as holographic stickers, is not sufficient to prevent counterfeiting of medicines.

Counterfeit products are produced in many countries. The original is presented for inspection, while the copy is put up for sale. Hospital and pharmacy staff generally cannot distinguish between the original and the counterfeit. The Western experience of withdrawing counterfeit products looks as follows: inspectors constantly make test purchases. Upon finding counterfeit products, pharmacies return the medicine to the distributor at the direction of the supervisory authorities, the distributor returns it to the wholesaler, and the wholesaler returns it to the manufacturer. As a result, the falsified batch is destroyed. In the markets of the CIS countries, including Uzbekistan, all measures to recall medicines are forced to be carried out by the manufacturing companies, which ask the supervisory authorities to inform all institutions about the presence of counterfeit products. Based on the above, the following preliminary conclusions can be drawn:

1. As a comprehensive social system, the circulation of medicines represents the unity of two opposite elements: on the one hand, it is the consumer market sector, the functioning and development of which are determined by objective market laws and mechanisms; on the other hand, one of the spheres of the social sector - healthcare, which has a special status among other sectors of the economy, as it determines the relationship between a "healthy economy" and people's health in the system of socio-economic security of the country.

2. The specific features of the circulation of medicines as a socially significant sphere objectively limit the operation of market laws.
3. Since the late 90s, a stable and growing trend in the development of the pharmaceutical market in the CIS countries has been the intensification of shadow manufacturing and sales of counterfeit medicines, which poses a real threat to the socio-economic security of the countries.
4. The development of the pharmaceutical market should be based on the principles of the priority of state management of the production and circulation of medicines as a sphere that significantly affects the socio-economic security of various entities.

Shadow economic activity exists in all countries, and since the mid-80s of the 20th century, there has been a clear trend towards its growth both in individual countries and on a global scale. According to the European Commission, the share of the shadow economy in the European Union currently ranges from 7 to 16% (in the 1970s, this figure was 5%). In Russia, according to some expert estimates, the share of the shadow economy is 30 - 40%. The structure of the shadow economy consists of both criminal and non-criminal elements. The criminal economy includes economic activities prohibited by law and systematically violating it. This includes "black markets". There is no doubt that the counterfeiting of medicines is a criminal sector of the shadow economy. The situation is further complicated by the fact that doctors and representatives of retail drug trade are faced with the problem of duplicating brands of medicinal products, which confuses them. The lack of information about the comparative advantages and disadvantages of new drugs further reduces their ability to provide professional help to patients. As a result, consumers increasingly become victims of manufacturers of counterfeit medicines.

In Uzbekistan, there are not many large domestic leading companies, as is the case in Russia. Our pharmaceutical manufacturers compete not with domestic but with foreign (generic) companies. Only companies from the CIS countries, India, China, and some former socialist countries that produce generics and sell them at roughly the same price as Kazakhstani manufacturers pose a competition to the domestic manufacturer. Therefore, we expect the inflow of counterfeit products not from the domestic market (although this is not excluded), but more from the outside.

The abundance of resellers contributes to the sale of counterfeit products because at every stage, there is a possibility of substitution or completion of drugs with counterfeits. For comparison: in Germany, there are ten distributors in the pharmaceutical market, while in France, there are four. In Uzbekistan, the introduction of a single republican distributor, TOO "SK-Farmatsiya," significantly organized this process. One of the major problems in the pharmaceutical market, including Kazakhstan's, is electronic pharmbusiness. In the Republic of Uzbekistan, the number of Internet users increases every year, and according to statistics, one in six users visits an online pharmacy. In the absence of legislation regulating this type of commercial activity, electronic pharmbusiness potentially leads to an increase in the circulation of counterfeit drugs.

One of the main issues in the pharmaceutical industry is the production of substances. Currently, only 2% of medicinal products are produced based on domestic substances. The remaining substances are of foreign production. Consumers (both intermediaries - doctors

and end-users - patients) are poorly informed about the problem of drug counterfeiting. Many of them point out episodes of insufficient therapeutic effect when using well-known medications, manifestations of atypical action, and increased frequency of allergic reactions. Usually, these are attributed to incorrect selection of the drug, dosage, or individual body characteristics. At the same time, authenticity of the medication is rarely questioned, assuming that purchasing it from a pharmacy guarantees its quality. The level of health culture is a crucial factor influencing the development of relationships in the pharmaceutical market. A low level of health culture becomes a criminogenic factor, leading to the presence and growth of the shadow sector of the pharmaceutical market. Facts confirming that health culture is not the most important value for the population of the Republic of Kazakhstan have been identified during sociological studies: lack of knowledge in the field of valeology; consumers of drugs trust advertising and the opinions of acquaintances more than doctors; they believe that the problem of counterfeit drugs is not a priority for the healthcare system; often purchase medicines at pharmacy points; prefer cheaper medications; and are confident that the fight against counterfeit drugs is the responsibility of government agencies, while not attaching much importance to their own prudence when buying medications. However, it is these factors that allow supply entities to artificially create a demand for drugs that turn out to be counterfeit.

The analysis of the main components of the market allows us to conclude that the Kazakhstani pharmaceutical market (which is essentially the case for all CIS countries) is a producer's (seller's) market. As known, such a market serves the interests of the producer, not the consumer, and the goal of its functioning is to generate profits through price competition. Offering consumers low-quality products at lower prices is one way of engaging in price competition.

The problem of counterfeit medicines is an issue of international scale. Therefore, various international organizations are involved in developing measures to combat it. The World Health Organization (WHO) particularly plays a significant role in this regard and has identified the main causes of counterfeit medicines:

- Inadequacy of legislative regulations
- Ineffective enforcement of existing legislation
- Lack of a national regulatory body or insufficient authority, financial resources, and personnel
- Inadequate penalties for violating pharmaceutical regulations
- Complex distribution schemes, involving numerous intermediaries and high prices
- Ineffective cooperation between the national regulatory body, customs, law enforcement, and judicial authorities
- Opportunities for improving the production of medications, illegal services, and the illegal market

Simultaneously, the WHO emphasizes that with the increasing number of counterfeit medicines, special attention should be given to quality control in their distribution. The responsibility for ensuring the population's access to effective and safe medicines primarily lies with the government. This responsibility has three basic dimensions: social, economic, and functional.

The social dimension is manifested in the implementation of responsibilities provided by the Constitution of the Republic of Kazakhstan and relevant legislative acts concerning the government's responsibility for ensuring the nation's health.

The economic dimension is expressed in the objective need for the government to preserve and reproduce the country's labor resources, as well as to ensure labor productivity growth by reducing periods associated with temporary disability of citizens.

The functional dimension of the government's responsibility is its duty to monitor the compliance of medication circulation with the requirements of regulatory acts. If a significant share of counterfeit products is present in the domestic market, it should be considered as a criterion of the insufficient effectiveness of the existing quality control and safety system for medicines.

Any government aiming to establish highly effective control over the circulation of medicines is "doomed" to find a comprehensive solution to the problem. The tool for such a comprehensive solution is a program-targeted approach. The proposed measures can only be effective if certain conditions are met:

1. Society must realize the particular danger and the destructive socio-economic consequences associated with the circulation of counterfeit medicines. Mass media and relevant public organizations play a leading role in raising awareness about this issue.
2. The executive authorities should not only pay attention to the problem of neutralizing counterfeit drugs but also take an active and initiating role in it. Law enforcement agencies should play a leading role here.
3. Doctors and pharmacists should have incentives to ensure cost-effective treatment, with a key criterion being the availability of comprehensive information for the patient about the therapeutic effect, the price of a specific type of medication in the regional pharmacy network, the cost of home delivery of the medication, etc.
4. Significant improvement in the quality of life and increased purchasing power.
5. Increasing the level of consumer culture in the population regarding the consumption of drugs.
6. High-level impartiality and effectiveness of state control over the circulation of pharmaceuticals.

In Uzbekistan, in recent years, the priority of combating counterfeit drugs has been increasing. Moreover, Uzbekistan has joined the "MEDICRIME" Convention, the first international legal act obliging the implementation of criminal liability for the counterfeiting of medical products and similar crimes. The document was approved by the Committee of Ministers of the Council of Europe in 2010. Its main goal is to enhance the effectiveness of the fight against counterfeits. The provisions of the Convention cover not only counterfeiting but also the production, distribution, and offering for sale of medical products without the necessary permits or in violation of quality, effectiveness, and safety requirements. The Convention's provisions on the prevention of offenses, particularly through the implementation of quality and safety requirements for medical products at the national level, ensuring the safety of supplies including through adequate source tracking systems, and prevention of risks through interdisciplinary training courses, information campaigns, distribution chain control, agreements with internet providers, and domain name registrars,

are of particular value. The Convention also proposes measures to protect the rights of victims, including providing compensation at the expense of those who committed the offenses. At the seminar on the problem of counterfeit drugs in Kazakhstan, an officer of Interpol, A. Andreu, presented the results of Interpol's unit's work in combating counterfeit drugs and pharmaceutical crimes. To this end, the International Medical Products Anti-Counterfeiting Taskforce (IMPACT), involving representatives from over 80 countries, was formed in partnership with the WHO. IMPACT conducts three operational activities annually: "Storm" involving 8 Southeast Asian countries (20 million counterfeit FL drugs confiscated from July 2009 to January 2010); "Mamba" is a joint action involving 5 Eastern African countries and Zanzibar (16 tons of counterfeit drugs were seized during August 2010); "Pangea," an international internet action week conducted in 44 countries (297 sites were closed, 278,524 packages inspected from October 5 to October 12, 2010, of which 11,783 were counterfeit).

The manager for investigations at Eli Lilly, K. Moore, characterized the market for counterfeit drugs and outlined the main directions of the strategy to counter the spread of falsified medicinal products. These measures are aimed at securing the legitimate supply chain of pharmaceutical products and preventing the infiltration of falsified medicinal products, as well as halting their distribution. This work is carried out by a specialized department in close cooperation with regulatory, customs, and law enforcement agencies. An important part of this effort is the control of the company's own distribution chains, especially the network of distributors. This involves continuous monitoring of internet websites, as the intensified promotion of falsified medicinal products through the internet serves as an early indicator of their presence in the market. Other sources of information, such as the sale of packaging materials, are also tracked. The main direction of the strategy is the development of partnership relations. While one company may be powerless, the effectiveness increases when several companies join forces to combat falsified medicinal products and work closely with regulatory authorities. In addition, active lobbying for the strengthening of government measures against falsified medicinal products is an important part of the work. Training and close cooperation with health authorities, law enforcement agencies, and international organizations are also vital parts of the work. However, despite the efforts of government bodies and private companies, the scale of falsification is growing. This is partly due to the lack of interdisciplinary training, specific documentation, and a global database in this field. To address this problem, the International Institute for Combating Counterfeit Medicines was established with the support of the French government and the European Commission. The Director of Research at this institution, V. Roche, discussed the main directions of its work, including training specialists in identifying counterfeit medicines and conducting investigations, developing documentation, and conducting research and expertise. The factors contributing to the spread of counterfeit medicines on the Kazakh market include a decrease in the purchasing power of the population, leading to an increased demand for inexpensive drugs. To effectively combat the spread of counterfeit and substandard medicinal products, it is necessary to establish barriers at all stages of distribution and introduce the concept of "shared responsibility" for all market participants in the prevention of counterfeit medicines.

Caution should be exercised not only by regulatory authorities, but also by wholesale and retail organizations. According to the Association of International Pharmaceutical Manufacturers of the Republic of Uzbekistan, to effectively combat the spread of counterfeit medicines, it is necessary to introduce criminal liability for the production and distribution of counterfeit medicines, especially in cases of repeated, group, or large-scale violations. Additionally, individuals who report the counterfeiting of medications should be rewarded with monetary compensation. A unified information system of the Ministry of Health and the National Center for Expertise of Medicines and Medical Equipment should be utilized to promptly notify all interested parties (regulatory bodies, wholesale and retail sectors) about counterfeit batches of medications. One of the employees of the Committee on Control of Medical and Pharmaceutical Activities of the Ministry of Health of the Republic of Uzbekistan should be responsible for continuously monitoring the organization's efforts to combat counterfeit medicines. The heads of territorial departments of the Committee should be personally responsible for bringing each case of counterfeit medicines to a logical conclusion (identifying the source, punishing the guilty parties, and destroying the counterfeit items). A permanent interdepartmental commission, consisting of employees of the Pharmaceutical Control Committee and the Ministry of Internal Affairs, Ministry of Justice, and the Prosecutor General's Office, should be established to monitor the situation related to counterfeit medicines. It is necessary to develop a state concept for combating the circulation of counterfeit medicines (in accordance with the recommendations of the WHO), which would be adopted by a resolution of the Government of the Republic of Uzbekistan. To prevent the appearance of counterfeit medicines, pharmaceutical manufacturers often change their packaging, which requires adjustments to the registration dossier, taking up valuable time. This procedure needs to be simplified, as is the practice in the European Union (manufacturers only submit written notification and a sample of the new packaging). Additionally, there is a proposal to provide training in visual recognition methods for detecting counterfeit products. According to market participants, criminal liability for the distribution of counterfeit medicines should be introduced cautiously (since the first-line pharmacist may not be aware that they are dispensing counterfeit medications). In conclusion, it should be noted that only coordinated actions of all structures, including government, non-governmental organizations, and pharmaceutical manufacturers, can reduce the danger of the problem of counterfeit medications and thereby decrease the risks to the health and lives of the population of Uzbekistan.

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