Original Article

Actuality of the implementation of international practice in proliferation of counterfeit medicines involving Interpol

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ABSTRACT

The analysis of world experience in fighting against trafficking of counterfeit medicines (CM) in the historical aspect is carried out. Globalization and the development of international trade, including through the Internet, have contributed to the spread of trafficking. Currently, CM trafficking is one of the most profitable types of illegal business, the volume of the counterfeit market is growing every year – in some countries, the proportion of counterfeits can reach 70% of the pharmaceutical market. CM is a serious threat to the domestic market although, in 2016, Ukraine following the "MEDICRIME" Convention was introduced criminal responsibility for the production and distribution of CM. The functions and powers of national, regional and international governmental and non-governmental organizations have been analyzed, as well as the effectiveness of their interaction within different projects. The most effective can be considered cooperation within the International Medical Products Anti-counterfeiting Taskforce (IMPACT), which allowed combination of the efforts of governments and World Health Organization (WHO), Council of Europe, OECD, Interpol, FIP, International Federation of Pharmaceutical Wholesalers (IFPW) and other international organizations. The relevance of more active involving Interpol and Europol in fighting with the spread of CM at the global and national levels is justified.

Keywords: medicines, counterfeit, counterfeit pharmaceutical products, counterfeit medicines, Interpol

Introduction

The problem of trafficking in counterfeit medicines (CM) has ancient historical roots, however, it is still relevant today. Many international and national legislative and normative legal acts have been targeted to prevent the spread of substandard / fake / falsely marked / falsification / counterfeit pharmaceuticals. Despite the active counteraction of the CM trafficking by international organizations and national authorities, cases of their appearance on the pharmaceutical market are constantly recorded. Unfortunately, it is impossible to estimate the volume of the counterfeit drugs market due to the lack of reliable statistics.

Certainly, the scope of manifestation of these phenomena varies significantly from country to country, but the most vulnerable to counterfeit medicines are countries with low and average prosperity, areas of conflict or civil unrest, poorly developed health care systems, low level of work of the regulatory authorities, imperfect legal system or ineffective criminal justice system, high levels of corruption, irrational public access to drugs [1, 2]. According to the World Health Organization (WHO) and the International Pharmaceutical Federation (FIP), trafficking in counterfeit medicines accounts for about 10% of the world drug market. In developing regions, the proportion of counterfeits can be as high as 70% in total drug trafficking, and in economically advanced countries, up to 1% [3, 4]. According to unofficial data, about 50% of drugs for sale on the Internet are counterfeit, about 95% of the 50,000 online pharmacies do not meet the laws and standards [5].

So, eventually, falsifications become more sophisticated, the risk that CM gives to patients increases. CM is a serious threat

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to global health and requires a comprehensive strategy at the European and international levels [6].

In Ukraine CM circulation issues of particular relevance, although it is a country with a strict regulatory system, created a quality assurance system for drugs, the regulatory framework is harmonized with the world and European standards [8].

Particular issues of counteracting crimes in the field of production and trafficking of CM in the United States, the EU and Ukraine have been studied by scientists such as H. Sammons, I. Choonara, T. Mackey, B. Liang, P. York, T. Kubic, G. Nayyar, J.Breman, J. Clark, M. Hajjou, M. Littrell, J.Herrington, P. Tinti, A. Vevera, O. Solovyov, V. Pashkov, I.A. Kovalenko, et al. However, unfortunately, comprehensive studies of this problem have not been conducted.

The purpose of the article is to analyze the international practice of counteracting and fighting against the proliferation of CM with the involvement of Interpol at the global and national levels.

Materials and Methods

The materials used in this work are the official websites of the authorized bodies on quality assurance of medicines and counteraction of the CM circulation, regulatory documents and scientific publications on the subject. The study was conducted using the methods of logical, historical, semantic, retrospective method, as well as systematic analysis.

Results and Discussion

For the first time at the international level, the problem of counterfeiting of drugs, its scope, and possible consequences were discussed at conferences of experts on the rational use of drugs (Nairobi, 1985). Following the recommendations of the WHO Conference, an information center was set up to inform Member States' governments about the nature and extent of the spread of CM. Subsequently, the World Health Assembly repeatedly adopted Resolutions (WHA41.16 1988; WHA52.19, 1991; WHA47.13 1994), which recognized the danger of CM and were given orders to prevent their circulation. In 1992 and 1997 International Symposiums on Falsification of Medicines was held under the auspices of WHO and IFPMA - The International Federation of Pharmaceutical Manufacturers' Associations, recommendations on the detection of CM in the market were formed. Realizing the magnitude of the problem of falsification of medicines in the world, in 1995, WHO developed a program to assist national health systems in combating substandard and counterfeit products: a global network (110 countries), a worldwide CM database and a methodology for detecting substandard drugs were established [7]. The growth of international trade in medicines and their online sales have contributed to the massive infiltration of counterfeit products on the market. The scale of the problem of counterfeiting medicines has forced the world community to become more active around it, which has led to the adoption of international legal documents on the production and circulation of counterfeit pharmaceuticals, as well as the implementation of individual programs and projects (Table 1).

Table 1: Analysis of international documents and programs in the field of combating the CM trafficking

International Documents, Programs	Summary (Key Themes)
International	
Resolution of the World Health Assembly WHA41.16 (1988)	The proposal by WHO to initiate programs for the prevention and detection of the export, import and smuggling of drugs with fake labels, counterfeit or substandard drugs
Resolution of the World Health Assembly WHA47.13 (1994)	Proposal to assist WHO Member States in their efforts to ensure the quality of medicines and in the fight against the use of counterfeit drugs
WHO Assistance Program to national health systems in combating substandard and counterfeit products (1995)	A global network (110 countries), a worldwide database on CM and a technique for detecting substandard drugs were established.
WHO Guideline on the Development of Counterfeiting Drugs (1999)	Main thesis: the development of a national system of quality assurance for drugs in each country should take into account the situation, available infrastructure, human and other resources (emphasis on assessing risks of counterfeiting into legal circulation)
WHO Online System (2005 p.)	Tracking crime on drug trafficking in the Western Pacific
The interaction of the Member States of WHO with substandard, counterfeit, improperly labeled, falsified, counterfeit medical products (2010)	Prevention and control of CM circulation, health protection, availability, safety, efficacy and quality of drugs. More than 190 countries are involved
WHO Global System for surveillance and monitoring of substandard and counterfeit drugs, vaccines and diagnostic tools in vitro (2013)	Many countries are actively reporting data on questionable drugs, vaccines, and medical products. WHO has trained 550 specialists from 141 countries to identify such cases and take appropriate actions.
Regional	

ResAP Resolution (2001) 2 2001 Council of Europe Committee of Ministers	Emphasizes on the danger of CM and defines the role of pharmacists in health safety.
Council of Europe Parliamentary Assembly Recommendation 1673 (2004) "Falsification: Problems and Solutions"	Emphasized the need to strengthen legislative and administrative measures to fight against counterfeiting, informing consumers about the risks associated with CM and methods of detection
European Parliament resolution on counterfeit drugs (2006)	The main direction - strengthening the control of market operators, including inspection mechanisms.
Council of Europe Parliamentary Assembly Recommendation 1794 (2007) on "The quality of medicines in Europe"	The main focus is on increasing control over market operators by strengthening GMP and GDP requirements, inspection
Agreement on cooperation in combating trafficking in counterfeit drugs (2008, Chisinau)	10 countries - members of the CIS
EDQM project of accounting and tracking of drugs eTACT launched in 2009.	Implementation of the latest information technology accounting and tracking standards in the fields of production, distribution and quality control of drugs to prevent the admission of falsification into the legal supply chain
Directive 2011/62 / EC on counterfeiting of drugs (supplements Directive 2001/83 / EC), entered into force on 1 January 2013.	Introduces the mandatory identification of a unique manufacturer identifier on all prescription drugs registered in the country, strengthens manufacturer requirements and good distribution practices, as well as import, control and inspection rules
Directive 699/2014 of 24 June 2014	A new common logo for drugs approved, with links to a list created by the appropriate national authority of all legal online or retail pharmacies.
Council of Europe Convention against counterfeiting of medical products and similar crimes that threaten public health (MEDICRIME) of 09.12.2010 p.	Obliges the participating countries to improve legislation on drug trafficking by introducing criminal responsibility for falsification and trafficking of CM It provides the basis for national and international cooperation between the various sectors of public administration and provides for the establishment of a supervisory authority to oversee the implementation of its provisions by the participating States.
Web project "The threat of a tablet" National Association US pharmaceutical associations (NABP) in 2007.	Educate consumers to self-identify counterfeit medicines and inform relevant authorities
European Pharmacopoeial Convention	The European Pharmacopoeia is required for use in those countries that have signed the Convention (Ukraine signed in 2012)

According to the WHO Guidelines for Combating Counterfeiting Drugs in 1999, almost every country has established a national system of quality assurance of drugs given situation existing infrastructure, human and other resources. The processes of globalization and internationalization of the pharmaceutical market require the development of adequate mechanisms to counteract the circulation of counterfeit and substandard drugs. At the global level, the general situation analysis functions, informing and development of the general recommendations on counterfeiting of drugs is carried out by WHO, a specialized agency of the United Nations (UN) and the International Pharmaceutical Federation (FIP). The activities of the following organizations are aimed at harmonizing the quality requirements of drugs, approximation of the standards of different countries and mutual recognition: International Convention on the Harmonization of Technical Requirements for the Registration of Medicinal Products for Human Use (ICH), International Organization for Standardization (ISO), The International Pharmaceutical Inspection Cooperation Scheme (PIC/S), (Table 2). The experience and standards of their work are based on the functioning of effective systems of national inspection and testing of drugs, the exchange of information and mutual recognition of inspections based on common standards, joint learning and close cooperation [8]. The WHO documents, regulations and standards of the EU, the PIC/S documents, have developed and reflected mechanisms and rules, compliance with which guarantees the effectiveness of the supply and certifies the quality of the drugs.

Table 2: Analysis of functions and powers of international organizations that carry out control and monitoring in the field of counteracting CM trafficking

Organization name, year of creation	Short description (membership, main functions, and powers)
International	
World Health Organization – WHO	194 countries Collaboration with the FIP, development assistance programs to the national health care system in the fight against substandard and counterfeit products
The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme – PIC/S established in 1995 as a supplement to the 1970 Convention on Pharmaceutical Inspections (PIC)	52 participating bodies. Strengthening of cooperation between authorized bodies on quality assurance of drugs and counteraction of CM circulation, exchange of information; harmonization of standards and procedures; mutual recognition by Member States of certificates of conformity of production requirements of GMP; simplification of procedures for export-import of drugs; coordination of training of inspectors and technical experts
FIP Working Group to combat counterfeiting of drugs (2003).	Together with WHO, recommendations have been made to establish a reliable pharmaceutical supply mechanism in countries that is resistant to penetration of products of dubious origin and quality
International Medical Products Anti-Counterfeiting Taskforce – IMPACT (2006 p.)	Representatives of more than 80 countries of the world: executives of state institutions regulating the circulation of drugs, experts, including employees of commercial organizations and professional associations, representatives of international and regional intergovernmental and non-governmental organizations: WHO; special agencies of the United Nations, Europe, OECD, World Customs Organization, Interpol, FIP, International Federation of Wholesale Organizations in the field of pharmaceutical products; The International Union of Patient Rights Organizations and others. Developed and Approved "Principles and Basics of National Anti-Counterfeiting Legislation" (2007)
Interpol (International Criminal Police Organization, ICPO)	An international intergovernmental organization, composed of 194 states. The main task is to coordinate the efforts of individual countries and implement a unified policy in the fight against crime (Interpol officers do not perform police functions directly)
Regional	
Council of Europe (1949). The Parliamentary Assembly established nine committees including Legal Affairs and Human Rights; Social Affairs, Health, and Sustainable Development; on compliance by the Member States of obligations and commitments to the Council of Europe (Monitoring Committee)	47 states The development and adoption of appropriate legal documents to regulate pharmaceutical activities, including combating the counterfeit CM (directives, regulations, decisions), working groups, the signing of certain international agreements
The European Directorate for the Quality of Medicines & HealthCare – EDQM (1996).	Takes care of a wide range of issues: development of the European Pharmacopoeia, the standardization of drug trafficking, fighting against counterfeit CM and pharmaceutical care. Coordinates the activities of the Common European Network (GEON) of the Official Medical Control Laboratories (OMCL), which unites about 80 laboratories from 30 countries
The European Agency for Evaluation of Medicinal Products – EMEA (1993).	The Agency is an independent specialized institution that performs drug evaluation and pharmacovigilance, based on the conclusion of EMEA, the EU Commission approves marketing authorizations (MA) for new drugs.
Task Force to Consider Measures to Reduce Risk of Falsification of the Pharmaceutical Expert Committee under the Partial Agreement on Social Affairs and Public Health	Over time, the European Medicines Quality Department, which includes the European Pharmacopoeia program, a network of control and analytical laboratories and other components, joined the group.
European Police Office, Europol, 1994	The creation of Europol is foreseen in the EU Treaty. Started work as a Drug Enforcement Administration. Since 1999 it has expanded its activities to other types of criminal offenses, including counteraction of CM circulation.
National	
Food and Drug Administration – FDA (USA) United Kingdom's Medicines and Healthcare Products Regulatory Agency – MHRA (UK) National Agency for the Safety of Medicines and Health Products – ANSM (France) Federal Institute for Drugs and Medical Products (BfArM) Germany Italian Medicines Agency (AIFA) Drugs Controller General of India (DCGI) The State Food and Drug Administration (SFDA) China Therapeutic Goods Administration (TGA) Australia Federal Service for Supervision of the health care sector of the Russian Federation – Roszdravnadzor Ministry of Health of Ukraine, State Service of Ukraine for Drugs and Drug Control, State Expert Center of the Ministry of Health of Ukraine	Quality assurance of drugs at the national level and prevention of the spread of the substandard / fake / falsely marked / falsification / counterfeit pharmaceuticals.

To coordinate the efforts of national, regional and international authorized bodies on counterfeiting of drugs on the initiative of WHO, FIP, the Council of Europe, working groups on substandard, counterfeit, incorrectly labeled, falsified, counterfeit medical products have been repeatedly created. The most effective project is the International Medical Products Anti-Counterfeiting Taskforce – IMPACT, which includes representatives from more than 80 countries, as well as international, regional intergovernmental and non-governmental organizations: in particular, WHO, UN specialized agencies, the Council of Europe, Organizations of economic cooperation and development, World Customs Organization, Interpol, FIP, International Federation of Wholesale Organizations in the field of pharmaceutical products; The International Union of Patient Protection Organizations and other international organizations. According to the results of the joint work, in December 2007 the "Principles and bases of national legislation on counterfeiting drugs" were approved. The work of IMPACT found its continuation in the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (Medicrime Convention) [9], which was signed in December 2010 and entered into force in Ukraine in January 2016. The introduction of criminal liability for crimes related to the counterfeiting of drugs in the vast majority of countries of the world indicates an awareness of their special danger. In particular, the responsibility for the production and distribution of CM in especially large sizes in the United States ranges from 20 years in prison to life imprisonment. In the post-soviet countries provide 10 years in prison, while in China - up to the death penalty [10]. In other countries (Japan, Israel, Republic of Korea) legislation does not contain rules on criminal liability for the falsification of medicines. The national legislation of EU countries is very different in terms of punishment for CM. Laws of Austria, Slovenia, and Slovakia threaten imprisonment for up to 15 years with persons who manufacture or sell counterfeit drugs that cause serious harm to human health. Estonia has three years' imprisonment for such crimes, in Sweden, Finland, and Greece - one year. In addition to imprisonment, the possible imposition of a fine of 4,300 euros in Lithuania and up to 1 million euros in Spain, and is not limited by the number of fines in the UK. Overall, in the 21 EU Member States production, distribution, import, export and online sale of counterfeit medicines are grounds for criminal prosecution [11].

The main measure aimed at preventing the spread of CM following the Council of Europe Medicrime Convention, identifying and confirming the criminalization of certain actions. Effectiveness in terms of identifying criminals, termination of illegal sites selling counterfeit drugs and medical products are operations of Interpol that have been conducted for over 10 years both in pharmacies and other points of sale, including through the Internet suppliers. The analytical report of Interpol, published in 2014, states that counterfeiters operate within cross-border networks, using components from different sources and major world trade routes for the import, export, production, distribution and marketing of counterfeit medicines [12].

Interpol is a leading international organization that thanks to its unique structure, legal framework, and technical equipment, carries out effective and rational coordination of international police cooperation. Interpol has concluded cooperation agreements with more than 35 international organizations, including Europol, Southeast European Cooperative Initiative Regional Center for Combating Trans-border Crime (SECI), UNESCO, the Council of Europe, etc. The purpose of the International Criminal Police Organization (ICPO) - Interpol is to provide the widest cooperation among concerned agencies of criminal police within the national law of the member states of Interpol.

Today, the organization includes 194 countries, which gives reason to consider Interpol as one of the largest international organizations - the global institute of cooperation of police departments of the countries of the world. The adoption of Ukraine to the ICPO - Interpol was held on 11/04/1992. In March 1993, the National Central Bureau (NCB) of Interpol in Ukraine was established. The main areas of cooperation of the Interpol NCB in Ukraine with the General Secretariat are, among other things, cooperation in the framework of Interpol projects.

Flagship operations of Interpol to prevent the spread of counterfeit drugs are Storm (events are held in Southeast Asia), Mamba (in East Africa) and Pangea (Internet crime-focused activities). Consecutive raids on the legal and illegal pharmaceutical markets have shown the best results in terms of seizure falsified and counterfeit products, the arrest of criminals and the closing of illegal websites (Table 3).

Table 3: Generalized results of Interpol's counterfeit medicines distribution operations in 2008 - 2018 [10, 13-15].

The name of the operation	Period of realization	Number of participating countries	Number of units seized medicines	Number of detected illegal websites	Number of suspected and arrested persons	Cost of seized drugs mln. USD
Pangea	November 2008 - November 2018	10 to 123	over 94.4 million	over 67590	2100	over 239
Mamba	September 2008 - August 2010	2 to 5	More than 10 tons	–	84	
Storm	April 2008 - August 2015	8 to 13	over 43,4 million	–	296	over 25,84
Cobra	September - October 2011	7	170 tons	–	over 100	
Giboia	October 2013, August 2015	5, 7	More than 100 tons	–	over 730	7
Porcupine	May - June 2014	9	156 million	–	102	24,5
Heera	May - 2017, May 2018	7, 10	about 42 million	–	191	25,6
Rainfall	2018	7	295000	-	15	0,12

1)	Qanoon	2018	15	1,4 million	-	39	1,5
2)	Mirage	September 2018	11	62,8 million	-	351	1,9

Separate consideration should be given to Interpol's operation «Pangea» to fight the online sale of falsified and counterfeit drugs, which is held annually. Coordinated by Interpol, these operations bring together customs, regulatory agencies, health care, national police, and private sector organizations from around the world. Activities focused on three main components used by illegal websites to conduct their trade - the Internet Service Providers (ISP), payment systems and delivery services. The operation has gained significant momentum since its launch in 2008. The first stage of the operation united 10 countries. Currently, the number of countries participating has grown to more than 100 [15].

In 2018 Interpol has conducted an operation «Pangea XI», which covered 116 countries. Measures within the operation made it possible to remove 500 tons of counterfeit medicines sold through the Internet. These include drugs to treat cancer, painkillers, etc. During the operation, 859 arrests were made and counterfeit medicines worth $ 14 million were seized, 3,671 online resources were closed, including sites, social media pages, and online stores [16].

Overall, the measures implemented by Interpol for 11 years (2008-2018 years.) allowed to involve in the fight against the spread of counterfeit medicines in 123 countries, close more than 67590 illegal drug trafficking websites, arrest more than 4,000 people, remove counterfeit medicines worth more than $ 325 mln. USD. Ukraine has cooperated with the General Secretariat of Interpol within several projects, in particular, Sidrag, a project to collect information on the distribution of synthetic drugs [16].

Europol is an EU law enforcement agency providing analytical, technical and financial support to partner countries in the prevention and fight against serious international offenses and terrorism. Europol has some differences from other regional international law enforcement organizations. In particular, the organization provides not only the cooperation of the police of the participating States, as well as the state border protection agencies, financial, immigration, tax, customs, intelligence, and other agencies authorized to conduct investigative operations or criminal investigations. In addition to organizing international cooperation between participating countries, Europol cooperates with countries outside the EU, based on "operating agreement" (concluded with the United States, Iceland); "Strategic agreements" (concluded with Colombia, Russia, and Turkey). The EU has recognized the need for the simultaneous protection of consumers and the protection of intellectual property. In March 2013, the mandate of the Europol Coordination Center "COPY" (Anti-Counterfeiting and Copyright Infringement) to investigate cases involving counterfeiting of products has been expanded, and now the Coordination Center is authorized to investigate cases involving substandard and dangerous goods. In the report of Europol in 2013, the priority direction of activity on fighting crime is to combat crimes related to counterfeit products that violate health, safety and food quality legislation [17].

At the end of 2016, Ukraine signed an agreement with Europol on operational and strategic cooperation aimed to expand the format of cooperation with Europol and exchange strategic and technical information, to use the opportunities of Interpol, to participate in joint activities to investigate a wide range of offenses, to exchange operative and personal data [18]. As part of this cooperation, Ukraine was first associated with the Europol coordinated Operation Viribus to end the trafficking of doping substances and counterfeit drugs in 2019. The operation, conducted by Italian «NAS Carabinieri» and led by the finance department of the Greek police, was the largest event of its kind. One of the main goals of the operation was the closure of clandestine laboratories, 9 laboratories were found in Europe; thus seized almost 24 tons of powdered steroids. Similar laboratories located in unsuitable premises (often garages) usually managed by organized criminal groups, who sell doping substances online or at local sports centers, illegal street shops, and local markets. As a result of the operation, 3.8 million illegal doping substances and counterfeit drugs (including substances, drugs, dietary sports, and nutritional supplements) were seized; 17 organized groups were neutralized; 9 illegal laboratories were closed; 234 suspects were arrested; 839 court cases were opened; about a thousand people reported a suspicion of manufacture, sale or use of doping substances [19].

Fighting against CM requires the cooperation of all pharmaceutical market operators, as well as regulatory and law enforcement bodies at national, regional and international levels. In this context, the important role played by all existing mechanisms, such as cooperation in the WTO, Europol, MEDICRIME, and especially – operations within Interpol. According to Article 18 of the MEDICRIME Convention training of all bodies` staff, involved in anti-counterfeiting of medicinal products and similar crimes and conducting awareness campaigns among the population is provided. Interpol's operation Pangea provides similar campaigns to raise consumer awareness of the problem.

In 2012, Ukraine has ratified the Council of Europe Convention "On the counterfeit medical products and similar crimes that threaten public health» MEDICRIME. Paragraph 2 of Article 21 of the Convention commits the parties to "the widest possible cooperation for the implementation of relevant international, regional and bilateral agreements on extradition and mutual legal assistance in criminal matters concerning crimes recognized as such under this Convention". This measure can be used as a legal basis for the activities already undertaken by states together with other organizations - Interpol, Europol, WHO, etc. Also, this provision creates the conditions for the harmonization of existing agreements and conventions on the

extradition of criminals if interstate crimes and the harm caused by them occur within the territory of one country if interstate crimes and the harm caused by them occur within the territory of one country, but the ratification of the Convention was not attributed to unlawful activity in the offender's country of origin [12]. Some CIS countries, including the Russian Federation, in contrast to Ukraine, already have a long-standing experience of participating in Interpol's operations to prevent the spread of counterfeit medicines (Table 4).

Table 4: Analysis of the most common operations «Pangea» Interpol to combat the spread of counterfeit drugs in the CIS for 2012-2018 years *

Year	Removed from the circulation of counterfeit drugs		Offense	
Duration	Number of units	Amount	Characteristics	Number of arrested
For all of 2012	3461 - medicines 3666 - alcohol tinctures 67 - medical nutrition	–	–	5
2016 (week)	64 - medical products 2 - medicines	53 million USD	5 thousand Internet sites	393
2018 (week)	more than 556 thousand.	60 million rubles	6.5 thousand Internet sites; 664 offenses 94 criminal cases	72

* on the example of individual operations of "Pangea" in the Russian Federation

The examples below demonstrate the importance of adopting the MEDICRIME international convention, which ensures national and international cooperation between different government sectors, and especially cooperation in the context of Interpol Special Operations.

Conclusion

The effectiveness of providing medical and pharmaceutical care is largely determined by the quality of drugs. However, in recent times, there has been an extremely unfavorable situation in various countries in the provision of quality drugs to the population. The trend of increasing offenses in the world in this area in recent years indicates the need for close attention by the state. At the same time, the problem of preventing the spread of counterfeit medicines is a global problem that requires coordinated international cooperation to ensure the effective implementation of various international programs and projects. The institutional component of the counterfeit drug mechanism is the system of international organizations active in the field of health care, crime prevention, and other counterfeit drug activities. Ukraine, as a member of these organizations, can and should use all opportunities in this area. Organizational support, as a necessary component of this mechanism, is the direct activity of these international organizations in such major areas as the prevention of counterfeiting of pharmaceutical products, the detection of counterfeit drugs and the response to such criminal acts. However, Ukraine is not an active member of Interpol operations, which have shown to be effective in different countries, particularly operations «Pangea». To increase the effectiveness of the fight against the production and distribution of counterfeit medicines and medical products, the regulatory and law enforcement agencies of Ukraine should be more actively involved in the operations of Interpol.

Counterfeiting of medicines is a global problem, which requires effective and enhanced international coordination and cooperation to ensure more effective strategies to combat counterfeiting, including the sale of such products online. For this purpose, EU Member States should cooperate closely and support ongoing work on this subject in international fora, such as the Council of Europe, Europol, and the UN. Ukraine, working with the EU Member States, should also cooperate with authorized bodies of other countries to effectively combat international trafficking counterfeit medicines globally.

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