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LEGAL FRAMEWORK TO REGULATE ONLINE PHARMACEUTICAL MARKET: COMPARATIVE ASPECTS

Leonid Prokhorov (a), Marina Prokhorov (b), Valentina Kufleva (c), Anastasiya Knyazkina (d), Evgeniya Ilikbaeva (e)*
*Corresponding author

(a) Kuban State University, 149, Stavropolskaya str., Krasnodar, Russia
hooligang@mail.ru, 8 (928) 210-04-87
(b) Kuban State University, 149, Stavropolskaya str., Krasnodar, Russia
hooligang@mail.ru, 8 (928) 239-81-35
(c) Kuban State University, 149, Stavropolskaya str., Krasnodar, Russia
val_swatch@mail.ru, 8 (918) 433-33-95
(d) Kuban State University, 149, Stavropolskaya str., Krasnodar, Russia
knyazkina_a@mail.ru, 8 (900) 246-85-39
(e) Kuban State University, 149, Stavropolskaya str., Krasnodar, Russia
dilaila-77@yandex.ru, 8 (918) 627-05-86

Abstract

The use of poor quality and counterfeit medicines can lead to a worldwide catastrophe. According to the expert estimates, the world market of counterfeit medicines stands at nearly 200 billion US dollars. The use of counterfeit medicines can entail adverse effects on human health and the subsequent loss of life, jeopardizing the efficient treatment of chronic, infectious and life-threatening diseases such as malaria, cancer, pneumonia, tuberculosis and diabetes. Besides, economic and social damage should be mentioned. Despite the fact that the technology to detect such drugs has come a long way about one million people die each year from counterfeit medicines. However, it is necessary to take into account the high latency of the problem. A particular threat can be seen in the sale of counterfeit medical products at a distance. They are used by counterfeiters to make a large-scale sale of fake medicines, bypassing quality reviews of the drugs sold. A significant circumstance to facilitate the spread of this criminal business is the imperfection of legal control over online drug market. Effective legislation should be based on international expertise in the field. The paper analyzes the medical legislation of Russia, Albania, the Council of Europe, the United States, identifies its most positive provisions that are useful in terms of preventing the circulation of counterfeit medical products. Given that the aforementioned concern is global, it seems useful to conduct interstate operations aimed at the identification of the criminal cases committed through online pharmacies.

Keywords: Falsified medical products, counterfeit medicines, legal framework, online pharmacy, comparative aspect.

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1. Introduction

Falsification of drugs and medical products is a growing global concern that has long received an international status. Almost all medicines are falsified: from expensive drugs, whose purpose is to cure dangerous diseases, to relatively cheap generics. Therefore, regulating various aspects to counteract this phenomenon calls for both national and international legislation.

Attempted measures to control the circulation of counterfeit drugs requires not only strengthening the legislative framework and regulatory systems, but also collecting data, utilizing effective technologies, and raising public awareness.

All parties concerned should be engaged in tackling this global challenge. They involve patients, medical staff, public and private organizations, pharmaceutical manufacturers, distributors, wholesalers, retail chains and national law enforcement bodies.

Albanian experience is of great interest. A strong policy emphasis in Albania is placed upon the rational use of drugs. In 1999, the Albanian Pharmaceutical Association published Therapeutic Formulary that contains complete information spanning all medicines registered in the country. It should be noted that in the Russian Federation there is State Register of Medicines. However, information available there can hardly be considered exhaustive, since the document lacks detailed descriptions of drugs, data on pharmacokinetics, side effects, interactions with other drugs, etc. An alternative to this reference, not only in the Russian Federation, is the Vidal drug information system. Throughout the world, the compilation of such reference books is one of the major ways for manufacturers to promote their products. Vidal is published at the expense of manufacturing companies that are charged for the placement of full detailed descriptions of their products as well as photos of packages. It should also be noted that since 2002, Albania has introduced the GPP, Good Pharmacy Practice, guidelines and a number of projects developed by the European Pharmaceutical Forum.

By the way, in Russia the similar order of the Ministry of Health of the Russian Federation No. 647n of 08/31/2016 “On Approval of the Rules of Good Pharmacy Practice of Medicinal Products for Medical Use” came into force on March 1, 2017.

Much attention is paid to the pharmaceutical industry in the European Union. According to the Directive of the European Parliament and the Council of the EU 2001/83 / EU dated November 6, 2011, the mainspring of the pharmaceutical market is its social orientation, i.e. the protection of public health. On February 9, 2019, the European Counterfeit Medicines Directive entered into force. Since then, most prescription drugs on the market must have had safety features that consist in a two-dimensional barcode and an anti-tampering device.

As a result of quality reviews conducted by Roszdravnadzor in 2018, 453 batches of drugs were seized. This is 23% more than in the same period of 2017. Of these, 132 batches were considered substandard according to the results of the conducted quality control, including 73 batches (46 trademarks) were of domestic production and 59 batches (38 trademarks) – foreign.

A study conducted by Bernard Naughton and Dr David Brindley from Oxford University’s Business School Saïd Business School found that counterfeit medicines constitute a growing global concern, and tend to appear through legitimate pharmaceutical supply chains, including the Internet. Pharmacies. This

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threatens not only public health, but legitimate pharmaceutical companies, as well (Naughton & Brindley, 2017).

Thus, quite often counterfeit drugs are illegally sold through the Internet, and every year the sales increase at an exponential rate (Degardin, Roggo, & Margot, 2014; Pociask & Fuhr, 2013). The data is supported by WHO studies, in particular, on the issue of improving the regulation and detection of counterfeit drugs through the WHO global monitoring system Rapid Alert. Increased control over online pharmacies has forced criminals to shift their activities to a free share of online market. About half of the drugs sold online are counterfeit or falsified (Simms, 2016). In addition, the Internet is an attractive 'market' for the sale of medicines that have not undergone confirmatory analysis in any country across the world.

It is worth noting that those countries participating in the MEDICRIME convention in their criminal legislation provided for the crimes related to the circulation of falsified medical products via the Internet (Albania, Turkey, Switzerland). As for the Russian Federation, on January 10, 2019, the State Duma gave its first-reading approval to the law on toughening criminal liability for selling unregistered and counterfeit medicines online.

Recently, in disrespect for the law more and more Russians and Europeans have been purchasing online counterfeit drugs, largely because online pharmacies offer better pricing than offline stores. Rectal dysfunction, obesity and hair loss drugs are greatly demanded by online buyers (Bartholin, 2012).

The authors believe that, along with legal measures, including criminal laws, raising public awareness about possible health risks plays an important role in preventing the spread of counterfeit medical products. Average online visitors cannot distinguish an actual licensed pharmacy website from a spoof one. Unfortunately, in the Russian Federation, there are still no measures to regulate distance medical marketing (including via the Internet). Since 2017, the State Duma of the Russian Federation has been considering the Federal Law "On Amendments to Certain Legislative Acts of the Russian Federation in the Distance Retail Trade of Medicinal Preparations". Despite the fact that in the Russian Federation it is prohibited to sell medicines other than at a licensed pharmacy, there is an abundance of websites selling drugs on the Internet.

In 2000, the European Commission established a working group to deal with information, advertising and e-commerce in the field of pharmaceutical and medical products, as well as the development of uniform requirements for online pharmacies throughout the EU (Crawford, 2003). In 2007, the Committee of Ministers of the Council of Europe adopted a resolution on the "Good Practice of Postal Distribution of Medicines", including those acquired through the Internet.

This approach is relevant for Russia. It is necessary to adopt the best practices of other countries in developing uniform criteria for online pharmacies, to come up with the standards for the safety sale of medical and pharmacological products at a distance, which undoubtedly will contribute not only to strengthening the economy, but will also guarantee the safety of purchased medical products and the health of Russian citizens.

To crack down on fake medicines, the European Commission proposed to the European Parliament and the Council of Europe to amend Directive 2001/83/EC on the prevention of the entry into the pharmaceutical market of falsified medicinal products. The EU Parliament adopted these amendments on February 16, 2011 in the form of Directive 2011/62/EC.

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As a matter of fact, the operation of online pharmacies in the EU countries is not prohibited (LaínAbril, Holt, & Wilson, 2016) and they make up legitimate organizations. However, their activities are under special control and the Directive contains additional provisions regulating the operation and registration of an online pharmacy, which are as follows:

– it is obligatory to notify the authorities of the launch of its activities and obtain permission;

– it shall be registered at a permanent address;

– the common logo approved by the European Commission shall be clearly displayed on the website;

– the website shall comply with the common European requirements and be connected to the central site of the authority;

– prescription drugs shall be dispensed on prescription only (unless distance dispensing of prescription drugs is prohibited by national law) (Clark, 2015).

In the United States of America, the federal agency, the Food and Drug Administration (FDA), is central to overseeing compliance with pharmaceutical law. Along with it, each state has its own supervisory body.

FDA activities are conducted at the level of cooperation with each state (Imber, 2013). Much attention is paid to the issues of public awareness of possible dangers induced by counterfeit medical products, including those sold through the Internet.

An effective FDA tool in raising public awareness is the MedWatch system that is a database used for reporting adverse events in healthcare by healthcare professionals and patients. This system works as follows: any patient in the event of adverse drug reactions can ask his/her doctor for a special reporting form, fill it in and send it to FDA. Adverse event reports are analyzed and compared with adverse drug reaction reports from manufacturers, with confirmatory analysis, and in case of side effects that are not listed in the annotation, the FDA can issue medical product safety alerts, withdrawals or labeling changes.

A special focus is the Office of Criminal Investigations (OCI), a specific FDA unit established to conduct and coordinate the investigation of suspected criminal violations of US healthcare statutes. OCI is responsible for investigating crimes and offenses in compliance with the pharmaceutical legislation of the country. Relevant drug regulations are contained in Title 21 of the United States Code, which replicates the terms of the Federal Food, Drug, and Cosmetic Act.

According to official data, every year OCI investigates approximately 1,200 criminal cases of drug falsification.

Besides criminal investigations, OCI oversees civil cases, where one party is healthcare professionals who are accused of violating the law, and the other is the state. A vivid example is the case in which, in October 2011, a subsidiary of GlaxoSmithKline pharmaceutical giant was found guilty of falsifying drugs – anti-depressant Paxil CR, ointment for the treatment of skin infections Bactroban, antiemetic drug Kytril and anti-diabetic agent Avandamet. A civil claim filed by the OCI in the amount of U.S. $ 600 million was considered in court.

The authors believe that legal framework to ensure drug security is supposed to comprise the following: development of legislation in this area, its harmonization with international standards, government oversight of drug circulation compliance, including the sale via online pharmacies, and legal regulation of preparation and dissemination of drug safety information; improvement of the system for

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rational prescription and use of medicines; legal support to the use of information technology in medical practice. The implementation of these areas will contribute to the advancement of international cooperation, as well as improved public awareness in the field of drug safety.

2. Problem Statement

The WHO estimates that about 1 million of the world's population annually dies from counterfeit medicines. In Africa alone, more than 200,000 people die each year as a result of the consumption of counterfeit antimalarial drugs (Fatokun, 2016). The truth is that a patient who takes counterfeit drugs often does not even realize this, as it is not so easy to imply a direct link between a disease and the use of low-quality or counterfeit drugs. In this regard, it is difficult to determine the real number of victims or dead. Falsified medical products may contain some amount of active substance, but to a much lesser extent than required for the treatment of a particular disease. With the development of information technology, the sale of medical products at a distance, including through the Internet, is prevalent. Real challenges to exercise control over such activities bring about a large-scale spread of online pharmacies selling counterfeit medical products. The problem is compounded by poor public awareness of the threats posed by purchasing medicines through online pharmacies. One of the effective mechanisms to reduce sales of counterfeit drugs through the Internet seems to be the enhanced legal framework to govern the relevant sphere and improved measures to strengthen law enforcement in relation to online pharmacies. What is more, the analysis and synthesis of the experience of various states is viewed as rather useful.

3. Research Questions

The paper examines the issues of legal regulation of on-line pharmaceutical market through the study of relevant international experience.

4. Purpose of the Study

The study aims to come up with the most feasible and comprehensive legal framework to regulate on-line pharmaceutical market through the study of relevant international experience.

5. Research Methods

The author applied in the research a literature analysis method that involves such web search engines as MEDLINE / PubMed, Google Scholar and ProQuest through the keywords including "falsified medical products", "counterfeit medicines", "counterfeit drugs", and "counterfeit medical products". In addition, the author analyzed such online sources as the official websites of: the World Health Organization, U.S. Food and Drug Administration, Inspections, Compliance, Enforcement, and Criminal Investigations, Official Journal of the European Union, etc. The author also used a comparative method to study the legislation of various states in the field under study.

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6. Findings

During the study, the following results were obtained:

– the sale of medical products through the Internet might constitute a potential danger of the spread of counterfeit drugs;

– patients in most countries of the world are poorly aware of the threats related to purchasing counterfeit medicines through online pharmacies;

– the legal framework governing the relevant sphere is not perfect enough.

All this combined contributes to the fact that the purchase of medicines using the Internet is turning into a serious public health problem.

7. Conclusion

To sum up, high-quality medicines are used to treat diseases and facilitate public health promotion. However, this is ignored by counterfeiters who make money off other people's health and lives. They have little incentive to provide patients with medication that is equivalent to the original brand. Even if a counterfeit drug contains some active substance, it is of lower quality than the original. Due to a large number of global intermediaries and suppliers, sales of counterfeit medicines through illegal online pharmacies, regarded in most countries as criminal, are difficult to control for law enforcement bodies (Toscano, 2014). Such crimes are mostly committed using illegal domains, electronic payment systems registered to unauthorized persons and so on. Separate law enforcement efforts within one particular country will not be able to put an end to such sites but will do little more than temporarily suspend their work. Being aware of the need to integrate efforts, Interpol together with representatives of different countries annually conducts a global joint operation Pangea, aimed at identifying the facts of online counterfeit sales. The operation helps to identify manufacturers and distributors of counterfeit medical products. In 2018, during Interpol Pangea XI operation, the coordinated police actions in 116 countries around the world made it possible to exempt 500 tons of counterfeit preparations sold online. Such international cooperation to combat the online sale of counterfeit drugs should continue with more countries to be involved. However, the fight against counterfeit medical products should not be limited to legislative, law enforcement measures and global cooperation of state bodies. Multilateral strategies are needed involving the introduction of new technologies to combat falsification and raising awareness of all stakeholders, mainly the general public, as well as the development of more sophisticated legal frameworks based on international expertise in the related area. Such actions can be pivotal in the fight against this type of illegal business.

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