Advances in Social Science, Education and Humanities Research, volume 420
XVII International Research-to-Practice Conference dedicated to the memory of M.I. Kovalyov (ICK 2020)

State Criminal Policy in the Field of Preventing Offences Committed on the Pharmaceutical Market Objects

Chernysheva Yu.A.

Yelets State Ivan Bunin University, Yelets, Russia
Email: lavytrans@mail.ru

ABSTRACT
The objective of this study is the consideration of the main issues of criminal policy in the field of preventing offences committed on the pharmaceutical market objects.
Production and sale of spurious medicinal products and of the medicinal drugs is a serious complex issue. In connection with this, the specific methods and measures, comprising the array of tactical actions of the state, aimed at the removal of reasons and conditions of crime and its prevention in the field of pharmaceutical activity, are required.
In the field of crime prevention, the state policy receives its official expression in criminal standards¬, that become carriers of information about this policy content in this way. Criminal policy should, first of all, express the public and state interest, and provide the protection of human and civil rights and freedoms.
Keywords: *criminal repression measures, illegal circulation of medicinal drugs and pharmaceutical products, counteraction to medical counterfeit products, causing harm to human life and health, criminal legislation*

1. INTRODUCTION

The issue of spurious (falsified/falsely labelled) counterfeit medicinal drugs was first brought about on the international level on the Experts' Conference for Rational Use of Medicinal Drugs, that was held in Nairobi in 1985. Illegal manufacture of pharmaceutical products with its subsequent sale in market conditions presents the increased social hazard for the state economy, thus undermining the adequacy and stability of the pharmaceutical market, and complicating its regulation from the state side.
So far, reaching safety is impossible without criminal repression measures that are aimed at the restriction of individual rights. Meanwhile, no country so far has succeeded in putting down crime completely, due to the objective reasons. That is why the issue of possibilities and limits of using the criminal repression measures for crime range limitation remains important. This issue is especially topical at committing crimes related to the breach of various specific safety rules and requirements, also for the reason that their consequences, independently on the main object of the offence, as a rule, cause harm to human life and health [8].
Today, legal and forensic literature has an information gap about some elements of criminal law and criminological characteristics of offences related to manufacture and sale of spurious medicinal drugs and pharmaceutical products. This causes permanent consequences, because in everyday life, each citizen risks not to receive a vital medicinal drug on time due to the fact that the country pharmaceutical market is constantly supplemented by substandard drugs with spurious trademarks, due to the imperfect legislation [12].
It is very important to take into account the fact that the developing pharmaceutical market obliges the population to be cautious when purchasing low-budget pharmaceutical products from various underhanded sellers, in online stores, etc. Because, the more active the state is in its attempts to counteract the unconscientious manufacturers and sellers of counterfeit pharmaceutical products, the more active they are in inventing new models and ways allowing them to produce and sell dangerous products with impunity.
In the process of scheduled inspection of legal entities and sole proprietors on the territory of the Russian Federation by Roszdravnadzor, the removal of medicinal drugs, produced from falsified substances, from circulation, is a common practice [17].
It should be understood that the criminal action cannot be always consistent with the actual harm caused by a criminal to the people in the process of large-scale production and sale of spurious medicinal products. In cases of falsifying the products used for prevention, e.g., BAA or cosmetics, their use is not always hazardous for health but just causes material and moral damage to customers, deluding them concerning the usefulness of the products and substances they use. The situation becomes much more dangerous at the falsification of vital medicinal

drugs, used in dangerous diseases, requiring surgical therapy, in patients [11].
Pharmaceutical market is a security of public health and country safety, consequently, the provision of the state system control over the circulation of pharmaceutical products should be included into the list of the most important state functions.
All the aforementioned objectively provides for the structurally adequate model of the efficient procedural and institutional actions that should include the entire range of criminal law and forensic measures and methods of action.

2. METHODS

A dialectic method which is a general scientific cognition method, served as a methodological basis of the study. The following partially scientific methods were also used in the study: comparatively-legal, formal-logical, system-structural, statistic, etc.

3. RESULTS

As is known, the scientific and technical progress has an impact at all fields of the society development, including the law. Modern achievements in pharmacology are one of the fields to be regulated with the help of international legislation. On one part, modern technologies allow fighting dangerous diseases, and on the other part, scientific achievements are often used by underhanded corporations. The above is also true of the pharmaceutical market that was turned into a means of illicit enrichment [12].
In response to these challenges, by the initiative of the Council of Europe, an international treaty was created, aimed at the prevention of falsification of medical devices and similar crimes ("Convention of the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health"). On October 28, 2011, Russia signed this Convention [13].
In accordance with Art. 5 of the Convention, the member-state shall take the required legislative and other for this offence identification [2].
In accordance with P. 1 Art. 41 of the Constitution of the Russian Federation, everyone has a right for health protection and medical aid, and, consequently, for safe pharmaceutical services.
The provision of public health in Russia is carried out on the basis of the Federal Law N 61-FZ of April 12, 2010 "On Medicine Circulation", the Federal Law of November 21, 2011. N 323-FZ "On fundamental healthcare principles in the Russian Federation" and many sublegislative statutory and regulatory enactments.
According to P. 2 Art. 18of the Federal Law "On the Fundamentals of Public Health Protection in the Russian Federation" N 323-FZ, of November 21, 2011, production and sale of food products of the respective quality, safe and affordable medicinal drugs were stated the important component of measures for public health protection.
By the Order of the Ministry of Health of the Russian Federation N66 of February 13, 2013 N 66 "On approval of the Strategy of public drug supply in the Russian Federation for the period until 2025 and the plan of its implementation", the order of the head of the state was fulfilled, and the goal of the Strategy was declared to be "the increase of availability of high quality, efficient, and safe medicinal products for human use with the purpose to satisfy the public needs and health services on the basis of forming the rational system of public drug supply of the Russian Federation, balanced with the existing resources."
The statutory and regulatory enactments specified herein not only regulate public relations in the field of medical and pharmaceutical public services in details, but also declare the liability of all branches of executive power for the provision of implementation of guarantees and respect for rights and freedoms in the health protection sphere, established by the Russian legislation, and medical organizations, public health care workers and pharmacists for the infringement of rights in the health protection sphere, causing harm to life and (or) health at the provision of medical aid to citizens (Art. 98 of the Law "On the Fundamentals of Public Health Protection in the Russian Federation"). Reference to the federal legislation means that, depending on the nature and degree of harm caused to the citizen, and the nature of the breach of the established rules and restrictions by a public health care worker or a pharmacist, can cause disciplinary, civil, criminal, or other liability [18].
The criminal policy should not remain in stagnation but take into account and foresee possible changes in crime structure and dynamics. This will allow creating and improving the existing norms and institutes, thus improving the efficiency of the state criminal policy [1].
The main issues of criminal policy in any state are the issues of crime and liability to punishment. There are actions of criminal and political nature, that are specific by being socially dangerous, thus generating the need for the application of public enforcement and measures, providing public safety against such infringements.
In the field of crime prevention, the issues of establishing the circle of criminal punished behavior are criminal and political. The state develops goals, tasks, directions, forms, means and measures of this prevention, i.e., the criminal policy. The essence of the state criminal policy lies in and is reflected in criminal law and criminal statutory and regulatory enactments [22].
Criminal legislation is the most important instrument of implementation of the state criminal policy. Quality and stability of law forming activity development provides the successful implementation of criminal policy in the sphere of crime actions prevention [4].
The Criminal Code of the Russian Federation contains the line of criminal law standards, regulating crimes in the field of falsification of medicinal drugs and products, and forgery of medical documentation. The Federal Law No. 532-FZ "On amending certain legislative acts of the Russian Federation against the circulation of falsified,

counterfeit, substandard, and non-registered drugs, medical devices, and falsified biologically active additives", adopted on 31.12. 2014, established criminal liability for offences in the field of public health. This legislative act provides for the punishment for illegal and non-licensed manufacture medicinal products (235.1), for distribution and circulation of falsified medicinal drugs (238.1), for falsification of medical documents (327.2). [9].

Principle of criminal law formalized in Art. 235.1 of the CC of the Russian Federation ("Illegal manufacture of drugs and medical devices") together with Art. 238.1 of the CC RF ("Circulation of falsified, substandard, and non-registered drugs, medical devices, and circulation of falsified biologically active additives") and 327.2 of the CC ("Forgery of documents to drugs or medical devices or to packages of drugs or medical devices") forms the criminal mechanism of counteraction to illegal circulation of medical products [20].

The objective side of the material elements of offence (Art. 235.1) is the Illegal manufacture of medicinal drugs and medical devices. The breach of the established procedure of the products manufacture or production is Illegal, and goods received in this way are the target of crime [10, P. 49]. According to Art. 235.1 of the Criminal Code of the Russian Federation, Illegal manufacture means the manufacture of medicinal drugs and medical devices without a license in case when its presence is obligatory.

Federal Law No. 99-FZ of 4.05.2011 "Concerning the Licensing of Certain Types of Activity" provides the list of entrepreneurial activities, the conduct of which should be based exclusively on a license or a special permit. P. 3, Art. 49 of the Civil Code of the Russian Federation regulates the right to carry out the activity providing for the license use, only from the moment of license receipt and until its validity expiration, or during the period of its suspension or cancellation.

The important fact is that the Criminal Code of the Russian Federation acknowledges as Illegal and subject to liability only that production, which is implemented without a license or a special permit (Art. 235.1). In their turn, Rules of medical devices circulation indicate that the Illegal pharmaceutical activity is also possible at the presence of the respective permits, including the license.

Rules of medical devices circulation distinguish the terms "manufacture" and "production" as actions different in their specific. Although, the law-making body does not disclose these terms in any legislative act, causing the number of issues in the offence determination. We find it important and necessary to analyze these terms and to distinguish them, with the purpose of further improvement of criminal law.

It should be mentioned in the first turn that manufacture and production are two completely different processes characterized by the line of specific signs. Manufacture is the activity of a pharmaceutical institution, consisting in the drug development under the medical prescription. A new medicinal drug is manufactured from those already licensed and registered on the territory of the Russian Federation. "Pharmaceutical activity shall be carried out by medicine wholesale trade organizations, pharmacy organizations, veterinary pharmacy organizations, sole proprietors, licensed to carry out the pharmaceutical activity, medical organizations, licensed to carry out the pharmaceutical activity, and their separated departments (in-patient departments, paramedical and paramedical and midwifery stations, centers (departments) of general medical (family) practice), located in rural settlements with no pharmacy organizations present" [Federal Law No.61-FZ of 12.04.2010 "On Medicine Circulation".]. In its turn, the production of the medicinal drugs is a time-consuming and cost-intensive process, characterized by obtaining the product in lots. Production is governed by Good Manufacturing Practice standards, accepted and approved by the executive branch authorities. This fact limits the range of enterprises entitled to produce the medicinal drugs. Therefore, production can be carried out only by manufacturers of the medicinal drugs.

Manufacture is the release of the medicinal drugs in a unique copy or in small lots. The pharmacist shall manufacture the medicinal drug only by medical prescription and in accordance with it.

Federal Law No. 532-FZ of 31.12.2014 "On amending certain legislative acts of the Russian Federation against the circulation of falsified, counterfeit, substandard, and non-registered drugs, medical devices, and falsified biologically active additives" supplemented the Criminal Code of the Russian Federation Art. 238.1. This article provides for liability for distribution and circulation of falsified and non-licensed medicinal drugs and medical devices. The inclusion of this article into the CC of the Russian Federation was an important stage of criminal policy of the RF in implementation of its both state and international obligations in health and medical spheres. The establishment of criminal liability for offences in this field are important not only for political and economical sectors but in social terms as well, which is the most important part, because the state is obliged, in the first turn, to provide the public safety. Distribution and circulation of falsified and substandard medicinal products threaten not only human life and health, but life and health of the entire population, because it provides no curing effect on ill citizens. Article 238.1 The CC RF does not cover all breaches at the circulation of medicinal products (e.g., liability for the circulation of counterfeit medicinal drugs and medical devices is absent), but the demand for it gradually grows every year.

The provision specified, provided that it is duly applied, can become the efficient means of criminal counteraction to interference with the pharmaceutical safety of Russia.

At the statement and establishment of a new material elements of offence, the law-making body is obliged to select the position of this offence in the Criminal Code structure. This place should conform to the direct object of offence. This offence is regulated by Art. 327.2 of the CC RF. In our opinion, a place allocated for this offence in the criminal law system was determined incorrectly. The law-making body sets as the priority public relations, providing the established procedure of preparation a use of medical

documentation. In our opinion, these public relations act as an additional object. Meanwhile, the main object is represented by public relations that provide the public health. Doctor of Laws, P.A. Filippov, notes that the falsification of medical documentation, medicinal drugs and medical devices are the "auxiliary" actions contributing to the distribution of falsified productions, and delusion of customers. Substandard and non-certified drugs, "surrounded" with spurious documentation and packaging, trench on health of the general public [19].
The current situation at the state pharmaceutical market requires the active counteraction to this type of crime.

4. DISCUSSION OF RESULTS

Today, the world faces issues threatening public life and health, and society, in general. In this aspect, the considerable threat becomes the transnational pharmaceutical market, rich in falsified and substandard drugs, medical devices, and biologically active additives.
Production and sale of spurious medicinal products and of the medicinal drugs is a serious complex issue. In connection with this, the specific methods and measures, comprising the array of tactical actions of the state, aimed at the removal of reasons and conditions of crime and its prevention in the field of pharmaceutical activity, are required.
The issue of spurious counterfeit medicinal drugs was first brought about on the international level on the Experts' Conference for Rational Use of Medicinal Drugs, that was held in Nairobi in 1985. Illegal manufacture of pharmaceutical products with its subsequent sale in market conditions presents the increased social hazard for the state economy, thus undermining the adequacy and stability of the pharmaceutical market, and complicating its regulation from the state side.
Distribution of pharmaceutical products and their sale via Internet contribute to the growth of counterfeit products in the supply chain. According to the World Health Organization official data, 50-60% of all medicinal drugs, mostly purchased through Internet pharmacies, are falsified. When spurious pharmaceutical products appear in circulation, public life and health are threatened. The pharmaceutical market brings fantastical profits (annual circulation of USD 1.5 trln), so this business attracts the gradually increasing number of crime groups.
The important priority destination in the field of criminal studies should become the state policy in the crime prevention field, including international crime.

5. CONCLUSION

To solve the issue in consideration, it is required to increase the liability of the subjects of medical devices circulation for quality, efficiency, and safety. The pharmaceutical market control mechanisms, including import issues, should be improved. It is also necessary to implement technologies that provide the medicine supply chain transparency, directly personifying the liability for the legislation infringement. These steps are supported by the government. Checking the production conditions is also necessary. Medicinal drugs imported to the Russian Federation should be licensed. The procedure of releasing each lot of the medicinal drugs, both Russian and imported, also requires the specific regulation. The medicinal drug release should be carried out by the manufacturer's duly authorized representative. So far, the liability for the quality of the medicinal drugs imported to the territory of the Russian Federation is borne only by the entity importing them. It is impossible to identify whether the medicinal drug imported represents the products of the specific manufacturer. Another side of the issue solving will be enhancing legal liability in terms of administrative and criminal legislation. The existing articles of law scarcely allow taking any measures. Therefore, special measures should be taken in administrative and criminal legislation.

REFERENCES

[1] A.I. Alekseyev, V.S. Ovchinsky, E.F. Pobegaylo, Russian criminal policy: crisis resolution. M.: Norma, 2006, p.144.

[2] A.Ya. Asnis, Innovations of the criminal law on liability for offences related to illegal production and circulation of drugs, medical devices, and biologically active additives, Ugolovnoye Pravo, 1 (2018), 4 – 14.

[3] M.A. Gurkin, Forensic evaluation of social, economical, and legal prerequisites of organized crime formation in the field of Illegal production and circulation of the medicinal drugs, Bulletin of Tula State University, Economical and Legal Sciences, 1 – 2 (2017), 88-89.

[4] M.D. Davitadze, Modern issues of criminal policy, Bulletin of Moscow Law Enforcement Academy, 2018, pp. 123-127.

[5] T.P. Derevyanskaya, Medicinal products as the target of crime stipulated by articles 235.1 and 238.1 of the Criminal Code, Meditsinskoye Pravo, 6 (2016), 49.

[6] T.P. Derevyanskaya,Illegal manufacture of medicinal drugs and medical devices in the material elements of offence, stipulated by Art. 235.1 of the Criminal Code, Medical Law, 4 (2017), 28 – 31.

[7] V.A. Dryga, Notion of criminal politics, Rossiisky Juridichesky Zhurnal, 3, pp. 81-88.

[8] V.A. Kazakova, S.Yu. Korablyova, Issues of criminal politics for counteraction to breaches of special safety rules and requirements, Zhurnal Rossiiskogo Prava, 6 (2019), 87-96.

[9] N.Sh. Kozayev, Amending the criminal policy in the sphere of counteracting the abusive practices at the pharmaceutical market, Russian Investigator, 24 (2015), 26-29.

[10] I. Kamynin, Matters of argument in qualification of illegal actions with excisable goods, Russian Justice, 6 (2000), 49.

[11] P.N. Kobets, Legislative framework of counteracting medical counterfeit products in the conditions of the Russian Federation of the late second decade of the 21st century, Medical Law, 3 (2019), 9 – 14.

[12] K.Yu. Kovalenko, Prevention of offences committed on the pharmaceutical market objects Criminal law and criminological measures: Abstract of a thesis Cand.Sc. Law, Nizhny Novgorod, 2007, p. 27.

[13] S.V. Maksimov, Falsification of medicinal products in Russia and prospects of ratification of the Council of Europe Convention «MEDIKRIM», Materials of the Institute of State and Law of the Russian Academy of Sciences, 3 (2014), 75 - 87.

[14] E.F. Pobegaylo, Crisis of modern Russian criminal policy, Ugolovnoye Pravo, 4 (2004), 112-117.

[15] B.A. Reiseberg, L.Sh. Lozovsky, Ye.B. Starodubtseva, Modern economical vocabulary - 2nd ed., amended. M., 1998, p. 476.

[16] S.S. Alekseyev, Collected edition. In 10 v. + Reference volume. V. 6: Ascension to Law, M.: Articles, 2010, p. 558.

[17] Ie.I. Tretyakova, Circulation of falsified medicinal drugs: criminal law and criminological issues of counteraction: Abstract of a thesis ... Cand.Sc. Law, Saratov, 2016, p. 25.

[18] Pharmaceutical criminal law of Russia: monograph (editor-in-chief A.I. Rarog) "Prospekt", 2019, SPS ConsultantPlus.

[19] P.A. Filippov. Crimes against administrative order: theoretical and applied issues and the doctrinal model of the criminal law: thesis. ... Dr.Sc. Law , M., 2017, p. 621.

[20] I.V. Firsov, Illegal circulation of medicinal products: Abstract of a thesis ... Cand.Sc. Law, M., 2017, p. 26.

[21] V.V. Fisyun, Counteraction to illegal circulation of medicinal drugs and pharmaceutical products (criminal law and criminological aspects): Abstract of a thesis ... Cand.Sc. Law. M., 2011, p. 26.

[22] V.F. Tsepelev, Criminal law and criminal policy: interrelation and interaction. Sudiya, 6 (2016), 25-27.

[23] J.E. Fincham, Unethical pharmaceutical manufacturer conduct worldwide and its negative impact upon pharmacy practice, International Journal of Pharmacy Practice, 21(2) (2013), 71-72. (in English). DOI: 10.1111/ijpp.12026

[24] B. Ganor, M. Halperin Wernli, The Infiltration of Terrorist Organizations Into the Pharmaceutical Industry: Hezbollah as a Case Study, Studies in Conflict and Terrorism, 36(9) (2013), 699-712 (in English). DOI: 10.1080/1057610X.2013.813244

[25] R.L. Hurtado, M.C. Lasmar, Counterfeit and contraband drugs in Brazil: Overview and prospects for preventing their use. [Medicamentos falsificados e contrabandeados no Brasil: Panorama geral e perspectivas de combate ao seu consumo], Cadernos de Saude Publica Open access, 30(4) (2014), 891-895 (in English). DOI: 10.1590/0102-311X00107013.

[26] K.I. Shofuda, K. Aragane, Y. Igari, K. Matsumoto, K. Ito, Anti-counterfeit activities of pharmaceutical companies in Japan: For patient safety, Yakugaku Zasshi 134(2), 203-211 (in English). DOI: 10.1248/yakushi.13-00230-2