

On The Current Needs of Changing the Content of the Criminal Law Provision under Article 235.1 of the Criminal Code of the Russian Federation

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Abstract

The article analyzes the discrepancies between the terms used in the norm provided for by the article 235.1 of the Criminal Code of Russia and the notions introduced by special normative legal acts in the sphere of medicine production. The proposal on expediency of changing the existing norm is formed.

Keywords: Illegal Production of Medicines, Compulsory Licensing, Technical Maintenance, Manufacturing of Medicines, Criminal Law.

The volume of shadow economy sectors in the European Union alone currently amounts to over €2.1 trillion [1]. It should be borne in mind that a huge role in the prosperity of the shadow economy is played by the illegal circulation of substances and objects dangerous to life and health. This statement is true not only for narcotic or psychotropic drugs and their analogues, but also for falsified medical products and medicines intended for use by an undefined circle of people.

The problem of combating the illegal circulation of drugs and other medical products is also relevant for the Russian Federation. The issue of the elements of the crime under Article 235.1 of the Criminal Code of the Russian Federation appears to be one of the essential ones, since the disposition of this article is extremely lapidary, which generates legal uncertainty in qualification of the criminal acts. The question about the type of object of this crime is still considered to be debatable. In particular, a number of scientists believe it is fair to place this norm in the chapter on crimes in the sphere of economic activity. They ground their position by the fact that if the legislator did not emphasize the possible harm to the health of citizens from such crimes and the disposition of the norm emphasizes the falsified nature of production of medicines and medical devices, it is reasonable to qualify this provision as an economic crime [2].

In addition, if the production of drugs without a mandatory license (or other special permit) does not in itself endanger the health of an undefined circle of people, because such drugs may well be benign. Accordingly, in this case the rules regulating social relations in the sphere of economic activity are also violated [3].

These statements are supported by the position of the Supreme Court of Russia (hereinafter - the Supreme Court). On the basis of paragraph 5 of the decision of the Plenum of the Supreme Court of the Russian Federation of 18 November 2004 on judicial practice in cases of illegal entrepreneurship, if the performance of pharmaceutical activity without a license did not cause harm to human health or death, but was detrimental to the interests of citizens or an organization or generated a large amount of income, such an act should be qualified as illegal entrepreneurship (article 171 of the Criminal Code) [4].

Judicial practice shows that it is difficult to qualify an act described in article 235.1 of the Criminal Code as illegal business. This is due to the fact that a mandatory feature of article 171 of the Criminal Code is the receipt of large amounts of income or damage to the interests of citizens or organizations. In cases involving the illegal manufacture of medicines, it is extremely difficult to establish the exact amount of such manufacture, since most often the documentation containing information on the number

of medicines created, the quantity of the product sold and other information important for establishing the amount of income from criminal activity is not maintained or is not available for other reasons [5].

An example of this is the criminal case initiated in St. Petersburg against the director of a private company that produced medicines and medical devices without special permission, mandatory for this type of activity. The company was engaged in wholesale trade in these medicines. The case against the director was initiated under article 171 of the Criminal Code, as there were no consequences provided for in article 235 of the Code. The criminal case was later dismissed due to lack of evidence - the documentation required to establish the company's income was missing [6].

Another controversial issue is the concept of "income" from criminal activities. In particular, some courts incorrectly define the amount of income received, based on the economic theory that income is the difference between revenue and expenses. For example, the Savelovsky Inter-Municipal Court of the Moscow City Administrative District relieved the head of a pharmaceutical company operating without a license of criminal liability. The court deducted his expenses from the profit of the legal entity and found that the income from criminal activity was less than 1.5 million rubles and concluded that there was no illegal business [7].

The resulting uncertainty in the determination of income was resolved by a decision of the Supreme Court of the Russian Federation. Ruling of the Plenum of the Supreme Court of the Russian Federation of November 18, 2004 № 23 "On judicial practice in cases of illegal entrepreneurship" recognizes as income all the revenue of the enterprise, received as a result of criminal activity, without deduction of expenses [8].

The subject matter of the composition in question is also a reason for discussion among lawyers. The article provides for two types of subject matter: a medicinal product and a medical device. It follows from the meaning of Article 45 of the Law "On Circulation of Medicines" that from the point of view of Article 235.1 the production of medicinal products and medical devices is considered illegal, the circulation of which is not prohibited on the territory of Russia, but such production was carried out without mandatory permission or license. In case of production of falsified or inferior quality medicinal products such act shall be qualified under Article 238.1 of the Criminal Code of the Russian Federation.

The question of the objective side of the offence, the nature of which is set out in article 235.1 of the Criminal Code, requires special consideration. It should be noted that it is described in the wording of the article succinctly - the offence is the production of medicines and medical devices without a mandatory permit or license.

In international law, the concept of manufacturing a medicinal product includes any stage of the technological process of manufacturing the product and bringing it into a ready-made form [9].

However, this definition requires bringing it in line with the peculiarities of Russian criminal law. In particular, the domestic legislator distinguishes between the concepts of "production" and "manufacturing". In Russian law, "manufacturing" means a single action aimed at creating at least one instance of an object of crime (regardless of the purpose of such creation). In contrast to manufacturing, production is characterized by serial creation of a product [10].

These distinctions have been reflected in jurisprudence. For example, the Plenum of the Supreme Court has confirmed the argument that it is necessary to have a criterion such as the serial receipt of a product in order to qualify an act as illegal proceeding. The Ordinance further elaborates on the signs of illegal production, including the use of special equipment, the adaptation of premises and others [11].

In the case of medical devices and pharmaceuticals, the definition of production is limited to the actual technological processes of manufacturing an object, including storage and sale of the product. In accordance with special legislation, the concept of "circulation of medical devices" includes production, manufacturing, import into the territory of the State, various tests and studies, and other actions. In general, it may be noted that the production and circulation of medical devices are related as part and whole [12].

In this regard, in our opinion, the reasoned point of view is that the production within the meaning of Article 235.1 of the Criminal Code of the Russian Federation should be considered illegal activity aimed at serial production of medicines and medical devices if at least one crime subject ready for consumption has been created as a result of this activity [13].

Of special scientific and theoretical importance for the analysis of Article 235.1 of the Criminal Code of the Russian Federation is the provision on mandatory permission (license) for the production of medicines and medical devices. Criminal liability under this Article is incurred only in the absence of a permit for this type of activity. The Institute of Licensing regulates social relations in the economic (entrepreneurial) sphere, which demonstrates the expediency of including the norm in the chapter on economic crimes.

The Criminal Code of the Russian Federation provides for criminal liability only for production of medicines and medical devices without a license, which creates uncertainty in connection with other special laws.

While criminal liability is provided only for the production of medicines without a relevant license, under federal law 99 of 4 May 2011, not only production but also maintenance of medical equipment is subject to compulsory licensing. The obligation to obtain a license for the maintenance of medical equipment for entrepreneurs is also stipulated in many other normative acts. These provisions demonstrate the great importance of the process of maintenance of medical equipment, since the consequences of

improper maintenance can lead to the same serious consequences as the production [14].

As for the subject of the crime under Article 235.1 of the Criminal Code of the Russian Federation, it can be any natural person who has not received a special permit (license) to produce medicines. At the same time, the Regulations on licensing the production of medicines provide different requirements for applicants for a license to manufacture medicines and for the maintenance of medical equipment. In particular, the former must have a higher education in the profession corresponding to this type of activity, as well as 5 years of experience in the field of pharmaceutical production. For applicants for a license to provide maintenance of medical equipment requires secondary education and work experience of at least three years, as well as additional professional education [15].

The above analysis provides sufficient grounds to assert that Article 235.1 of the Criminal Code of the Russian Federation must be amended.

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