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GLOBAL PROBLEM OF FALSIFICATION OF MEDICINAL PRODUCTS AND THE TYPES OF ITS SOLUTION

Summary. *The article covers the global issue of fight against falsified medical products, as well as types of solutions to this problem. Also covered are the main reasons of appearance on the global maket of substantial amount of falsified medicinal products. The state and dynamics of changes in the national legislation for adaptation and harmonization with the EU law have been closely studied.*

Key words: *medicine, counterfeiting, manufacturer, pharmaceutical market, threat, fight.*

The falsification of drugs is one of the important and global problems of the global pharmaceutical market, which has long been internationally recognized, requiring its immediate solution. Among the main factors contributing to the spread of falsifications of medicines in the world, the following are noted: a weak national pharmaceutical industry of developing countries, complications related to drug control and control supervision, a large difference in drug prices in different regions of the world, and the fact that the problem of falsification of medicines is not a priority for many states.

The problem of falsification of drugs has been known to mankind for at least two thousand years. However, only at the end of the twentieth century, the falsification of medicines turned into a global problem of concern to all the countries of the world. For the first time, the medical community, on behalf of the World Health Organization (WHO), drew attention to this problem in 1987, when counterfeit drugs began to appear on an alarming scale. In the definition of the World Health Organization, a falsified medicinal product is a product intentionally and unlawfully labeled to incorrectly indicate the authenticity of the drug or the manufacturer.

Thus, a falsified medicinal product is a product intentionally and illegally provided with a label that does not accurately indicate the authenticity of the medicinal product and / or the manufacturer [3].

Falsified (counterfeited) medicines are medicines produced by a different manufacturer than those claimed in the registration certificate, which are deliberately mislabeled with respect to the identity and / or name of the manufacturer. Falsified can be both original and reproduced drugs; they may contain ingredients in the appropriate or inappropriate composition, may be free of active substances, with insufficient quantities or in fake packaging [4].

Falsified drugs are one of the most serious health problems of people both at the national and international levels. Apart from direct damage to the patient in the form of a risk to life, health, unsuccessful and ineffective treatment, such remedies also cause damage to the progress made in the pharmaceutical sector, eventually questioning the whole health system, the methods of work and legal the influence of the state in this sphere [5, p. 5]. Supervision over the safety of medicines in their medical applications is one of the main directions in the implementation of state policy in the field of medicines in all countries of the world, including the Ukraine.

According to the association of international pharmaceutical manufacturers, the proportion of counterfeit accounts for 5-7% of the pharmaceutical market, since the total annual pharmaceutical market of 1.105 Billion

Dollars in the proportion of counterfeit medicines account for 55 to 77 Billion Dollars. Pharmaceutical production is one of the most beneficial types of business after the arms trade, drugs, alcohol and oil.

According to WHO, the problem of falsification of drugs is spreading in at least 28 countries of the world. Of 951 cases, 25% of counterfeit production was made up of industrialized countries, 65% were developing countries, and 10% were unknown sources [1].

It should be noted that the main reasons for the emergence of a large number of counterfeit medicines in the world market are:

– insufficient level of political and legal development of individual states (inadequate national legislation in the field of regulating the development, registration and circulation of drugs, insufficient development of the respective control administrative bodies, government bureaucracy and corruption, conflict of interests between controlling administrative bodies, manufacturers of medicinal products and wholesale pharmaceutical companies);

– stable and high demand for medicines against the background of high prices for innovative drugs due to significant investments in research and development of medicines;

– accessibility to high-performance equipment and modern pharmaceutical technologies, which results in a high level of imitation of drugs and complicates the process of identifying counterfeits;

– disadvantages in the development of the wholesale market of the pharmaceutical market of a number of countries, which prevents tracking the way of penetration of counterfeit medicines to the market. New methods of labeling medicinal products (for example, the use of holographic technology) and new express methods of analysis using a portable laboratory are introduced to prevent falsification.

The scale of the problem of counterfeit medicines forced the world community to intensify around it, which led to further adoption of legal instruments on the production and circulation of counterfeit medicines [5, p. 41].

In order to prevent the falsification of medicinal products, various means of protecting the packaging and labels of the medicinal product or medical products are used, namely: design, material for manufacturing, paints and marking methods. A number of multinational companies also provide packaging of medicines with RFID tags (transponders) for counterfeit protection. Each label contains information about the preparation, including dosage, action, serial number, manufacturer's name and expiration date. By type of feed transponders are divided into active (have a built-in battery) and passive (use the energy of the reader, scanner). The main element of the scanners is an antenna that emits pulses, which in active transponders include the power supply, and in the passive – activate the RFID tag.

This allows you to read from this label. Consequently, the signal coming from the antenna of the transponder, on the antenna of the scanner, is decoded and transmitted through a standard interface to the computer for further processing. In addition to protecting consumers, the RFID system identifies the drug from manufacturer to consumer and helps the manufacturer and intermediaries to increase their productivity by reducing inventory costs, retracting products, and speeding up response to changes in the pharmaceutical market.

To counteract the falsification of medicines, the International Federation of Pharmaceutical Manufacturers Association (IFPMA) established the Institute of Pharmaceutical Security, which united efforts of 20 multinational companies to detect counterfeiters and collect the necessary data to bring them to justice.

WHO has created a special unit for WHO IMPACT to counteract counterfeit medicines to the consumer, which involves the authorities of participating countries, large pharmaceutical companies, and Interpol.

The primary objectives of this program are to strengthen control over the global pharmaceutical market, as well as increase the level of responsibility of manufacturers of counterfeit medicines [2, p.182].

To sum it up, it should be noted that the problem of falsification of medicinal products is currently solved not through discussions at international conferences, but through legal regulation with the corresponding obligations of the states – participants of international communities.

The Council of Europe and the European Union require the Ukraine to make a number of changes in national legislation for adaptation and harmonization with the EU law. After analyzing the processes taking place at the present stage, one can distinguish the following main directions of harmonization:

– development of the European model of licensing of import of medicines in Ukraine;

– introduction of an automated system of tracking of medicines in circulation by means of applying individual labeling to packaging;

– development of a market surveillance system in the field of medical products circulation;

– introduction of criminal responsibility for falsification and illicit circulation of medicines [5, p. 48].

Thus, summing up all of the above, it should be noted that today the issue of counterfeit medicines acts as a global problem, the extent of which is rightly raised not only by the national legislator, but also by individual

international organizations and the international community as a whole. Falsified drugs represent a real threat to the economic and social security of the state due to the fact that they risk the health and life of the population, therefore, the main purpose of the fight against counterfeit medicines in our state is to establish full state control over production and sales of medicines. As far as the international fight against counterfeited medicines is concerned, it is based on the increase of the state spending on programs that anticipate and combat the falsification of medicines.

Today, the fight against falsification of pharmaceutical medicinal products is one of the most important tasks for the pharmaceutical industry.

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М.Г. Антіпов, Г.В. Смірнова. Світова проблема фальсифікації лікарських засобів та шляхи її вирішення. – Стаття.

Анотація. *У статті розглядається світова проблема боротьби з фальсифікованими лікарськими засобами, а також шляхи вирішення цієї проблеми. Також розглядаються основні причини появи на світовому ринку значної кількості фальсифікованих лікарських засобів. Досліджено стан і динаміку змін у національному законодавстві для адаптації та гармонізації з правом ЄС.*

Ключові слова: *ліки, підробка, виробник, фармацевтичний ринок, загроза, боротьба.*

Н.Г. Антипов, А.В. Смирнова. Мировая проблема фальсификации лекарственных препаратов и пути ее решения. – Статья.

Аннотация. *В статье рассматривается мировая проблема борьбы с фальсифицированными лекарственными препаратами, а также пути решения этой проблемы. Также описываются основные причины появления на мировом рынке значительного количества фальсифицированных лекарственных препаратов. Исследовано состояние и динамика изменений в национальном законодательстве для адаптации и гармонизации с правом ЕС.*

Ключевые слова: *лекарство, подделка, производитель, фармацевтический рынок, угроза, борьба.*