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HOW DOES THE STATE COMBAT FALSE AND COUNTERFEIT MEDICINES

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Abstract:

The purpose of the study is to analyze and evaluate the effectiveness of measures taken by the state to combat false and counterfeit medicines. The study aims to identify key strategies and tools used to prevent the production and distribution of counterfeit medicines, and to assess their impact on the quality and safety of medicines available to the public.

Keywords: Falsification, counterfeit, medicines, quality control, liability, fine, imprisonment

Falsified and counterfeit medicines pose a serious danger to the health of the people and require due attention from the state. No state has comprehensive protection of its citizens and pharmaceutical business from invasion of the market of falsified and counterfeit medicines.

According to the definition of the World Health Organization (WHO), "**a falsified medicine** (hereinafter referred to as a drug) is a product that is intentionally and illegally provided with a label that incorrectly indicates the authenticity of the drug and (or) the manufacturer".[1] **Counterfeit medicines** are medicines whose real name or origin is intentionally hidden[2].

In the Republic of Uzbekistan, according to Article 3 of the Law of the Republic of Uzbekistan **"On Medicines and Pharmaceutical Activities",** counterfeit medicines are medicines accompanied by false information about the composition or characteristics or about the manufacturer. They may contain incorrect ingredients, incorrect dosages or even be completely fake[3].

Usually, counterfeit medicines look like real ones, this can lead to ignorance not only for the patient, but also for the doctor. The patient thinks that he is taking a genuine medicine, but in fact he is in danger. A fake may contain an excessive or insufficient amount of the active substance or not at all, as a result, the patient does not receive the appropriate treatment. Falsification of medicines is an illegal activity that has serious consequences for public health and patient safety.

Illegal copies of medicines registered in the Republic of Uzbekistan, in other words, **counterfeit medicines** , are medicines that infringe intellectual property rights, such as patents or trademarks. They can be produced without the permission of the copyright holder and are often sold under the guise of original medicines[4].

Counterfeit drugs also pose a likely threat to patients. For such drugs, it is difficult to prove the legality of the supply chain, and therefore compliance with the necessary storage or transportation conditions, which is a prerequisite for ensuring the proper quality of medicines.

In the Republic of Uzbekistan, the legal regulation of falsified and counterfeit medicines is carried out on the basis of the Law **"On Medicines and Pharmaceutical Activities".**

It is also worth noting that Uzbekistan has strict control over the fight against falsified and counterfeit medicines. According to the data provided by the Center for the Safety of Pharmaceutical Products, information on identified falsified and low-quality medicines has been published annually since 2015[5].

[1] https://www.who.int/ru
[2] https://www.who.int/ru
[3] Law of the Republic of Uzbekistan No ZRU-399 "On Medicines and Pharmaceutical Activities"
[4] Law of the Republic of Uzbekistan No ZRU-399 "On Medicines and Pharmaceutical Activities"
[5] https://uzpharm-control.uz/pages/information-on-identified-falsified-and-substandard-unsuitable-drugs-and-medical-products

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For example, in 2021, a significant number of substandard drugs were identified (110 cases), which led to increased control and inspections. In 2022 and 2023, the trend continued, and the number of detected cases remained high. These data show that the problem of substandard medicines remains relevant, and control over them continues to be strengthened.

To combat falsified and counterfeit medicines, Uzbekistan has developed a comprehensive approach, which includes legal, organizational and technological measures:

1. Tightening of legislation. In recent years, Uzbekistan has significantly strengthened the legislative framework regulating the pharmaceutical market. Thus, in 2018, the President of the Republic of Uzbekistan adopted a resolution on measures to improve quality control over medicines and medical devices.

2. Seizure and destruction. According to Article 23 of the Law of the Republic of Uzbekistan **"On Medicines and Pharmaceutical Activities",** falsified and counterfeit drugs, in cases of detection of facts confirming their harmful effect on human health, are subject to withdrawal from circulation and destruction in the manner determined by the Cabinet of Ministers of the Republic of Uzbekistan[6].

3. Control and supervision. In Uzbekistan, quality control of medicines is carried out by several key bodies, such as:

- ✓ **Ministry of Health of the Republic of Uzbekistan**
  - ➢ Forms the state order and ensures control over the availability of the main types of medicines and medical products in state medical institutions.
  - ➢ Carries out state registration of medicines, medical devices and medical equipment.
  - ➢ Controls the quality of medicines at all stages of their circulation.
- ✓ **State Institution Center for Safety of Pharmaceutical Products under the Ministry of Health of the Republic of Uzbekistan**

This center is responsible for state registration, quality control, standardization and certification of medicines, medical devices and medical equipment.

- ✓ **Laboratory of Quality Control and Standardization of Medicinal Products**

It conducts certification tests, chemical analysis and quality control of medicines sent as part of humanitarian assistance.

- ✓ **Department of Licensing of Pharmaceutical Activities**

This department is engaged in the organization of pharmaceutical activities and control over compliance with licensing requirements and conditions.

- ✓ **Pharmacopoeia Board**

The official expert body of the Ministry of Health, which is also involved in the quality control of medicines.

4. Educational work. One of the key tasks in the fight against counterfeit medicines is to inform the population. The Ministry of Health is actively conducting campaigns aimed at raising awareness of the risks of purchasing medicines outside pharmacies, on the "black market" or on the Internet.

5. Establishment of the State Agency for Quality Control of Medicines. In 2017, the State Center for Expertise and Standardization of Medicines, Medical Devices and Medical Equipment was established under the Ministry of Health of Uzbekistan. The center's activities are aimed at ensuring strict control over the quality of manufactured and imported medicines, as well as preventing counterfeit products from entering the market.

6. Digitalization and labeling of medicines. In order to strengthen control over the circulation of medicines, the pilot phase of the Asl belgisi monitoring program was launched in June 2021**[7].** This program is aimed at improving the transparency and quality control of medicines by introducing mandatory labeling. Data **Matrix** labeling has become mandatory for medicines since September 1, 2022[8]. This system allows not only to track the movement of drugs, but also provides patients with the opportunity to verify the authenticity of drugs through a special mobile application.

Customers can scan the code on the package with a smartphone and get all the necessary information about the drug, including the manufacturer and expiration date. This increases the credibility of pharmaceutical products and reduces the risk of using counterfeit medicines.

[6] https://www.lex.uz/acts/2856466

[7] https://crpt-turon.uz

[8] Resolution of the Cabinet of Ministers of the Republic of Uzbekistan No322 "On measures for the implementation of pilot projects to expand the list of goods subject to mandatory digital labeling"

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7. Improvement of customs control. As part of the fight against counterfeiting, border control measures have been strengthened. Customs authorities of Uzbekistan actively use modern technologies to identify illegal supplies of medicines.

8. Sanctions: For the circulation of falsified and counterfeit

Administrative and criminal sanctions are provided.

Administrative liability: This is the most common type of liability for such offenses. It is provided for **by the Code of the Republic of Uzbekistan on Administrative Responsibility** and is applied to individuals and legal entities guilty of the production, storage or sale of counterfeit medicines.

The most common sanctions are:

Fines: The amount of the fine may vary depending on the severity of the offense and can be imposed on both individuals and legal entities.

Confiscation: Seizure and destruction of counterfeit medicines (confiscation of instruments and objects of offenses).

Suspension of activities: For legal entities, an administrative suspension of activities may be applied for a certain period.

Criminal liability: In the event that the production or sale of counterfeit medicines has entailed serious consequences for human health or life, the guilty persons may be held criminally liable. **The Criminal Code of the Republic of Uzbekistan** provides for various types of penalties that may be applied in such cases, depending on the specific circumstances of the case. For example, punishment in the form of a fine in the amount of one hundred to three hundred basic calculation values or correctional labor up to three years, or restriction of liberty from two to five years, or imprisonment up to five years (Article 186).[9]

Civil liability: In addition to administrative and criminal liability, the guilty persons may be held civilly liable. Victims have the right to claim compensation for damage caused to health or property as a result of the use of counterfeit medicine.

9. Cooperation with international organizations. Uzbekistan actively cooperates with international organizations such as the World Health Organization (WHO) and Interpol, which help in the fight against counterfeit medicines at the global level. This includes information exchange, joint operations and training of specialists.

The problem of falsification of medicines remains one of the most acute in modern pharmaceuticals. The state is taking comprehensive measures to solve it, including improving the legislative framework, strengthening control at all stages of the circulation of medicines, developing a traceability system, raising public awareness and strengthening international cooperation. However, despite the results achieved, the problem has not been completely resolved. Further research is needed to identify counterfeits, develop new methods of quality control and improve state regulation mechanisms.

REFERENCES

1. Normative legal acts

1.1 Law of the Republic of Uzbekistan No ZRU-399 "On Medicines and Pharmaceutical Activities" dated 05.01.2016;

1.2 Code of Administrative Responsibility of the Republic of Uzbekistan;

1.3 Criminal Code of the Republic of Uzbekistan;

1.4 Resolution of the Cabinet of Ministers of the Republic of Uzbekistan No322 "On measures for the implementation of pilot projects to expand the list of goods subject to mandatory digital labeling" dated 20.05.2021.

2. Internet resource

2.1 https://www.lex.uz/ru;

2.3 https://www.who.int/ru;

2.3 https://crpt-turon.uz;

2.4 https://uzpharm-control.uz/;

[9] Criminal Code of the Republic of Uzbekistan