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«СОЦІАЛЬНА ФАРМАЦІЯ: СТАН, ПРОБЛЕМИ ТА ПЕРСПЕКТИВИ»

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загалом характеризують рівень поширення фальсифікації як середній та вказують на недостатню ефективність державного контролю.

Серед ключових причин поширення фальсифікації визначено слабкість регуляторного нагляду, недостатній рівень обізнаності населення та розвиток нелегального онлайн-ринку. Найбільш ефективними заходами протидії, на думку респондентів, є впровадження цифрових систем контролю, посилення відповідальності учасників фармацевтичного ринку та підвищення рівня професійної підготовки фармацевтів.

Висновки. Фальсифікація лікарських засобів і медичних виробів є складною багатофакторною проблемою з вираженими медичними, соціальними та економічними наслідками. Її ефективне подолання можливе лише за умови системного, ризик-орієнтованого підходу, що поєднує вдосконалення державного регулювання, цифровізацію систем контролю (серіалізація, верифікація), гармонізацію нормативно-правової бази з міжнародними стандартами, а також підвищення відповідальності всіх учасників фармацевтичного ринку.

ANALYSIS OF THE MAIN CAUSES OF DRUG SHORTAGES IN THE COUNTRIES OF THE EUROPEAN UNION

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The availability of medicines is the basis of the safety of the healthcare system, and any failure creates a chain reaction of negative consequences. When a patient cannot receive the necessary medications in a timely manner, the problem quickly goes beyond medicine, turning into a social and economic crisis. Shortages of medicines in the European Union (EU) are a chronic and systemic problem that has worsened significantly in recent years. In 2023–2024, the EU saw a record level of shortage reports (over 130 critical drugs).

The purpose of the study is to analyze the causes of drug shortages and ways to solve the problem. To systematize the data, an analysis of the report of the Pharmaceutical Group of the European Union and the European Medicines Agency (EMA) was carried out. The study used general theoretical methods of analysis.

The causes of drug shortages are complex, and problems can arise at every link in the pharmaceutical chain, from production disruptions to vulnerabilities in the supply of key ingredients.

More than 50% of reported deficits are caused by production problems. Global competition for resources and the concentration of production in several countries exacerbate the problem, especially when there is dependence on one or a limited number of countries. The unexpected increase in demand for medicines (16.7%), in particular for antibiotics and antiviral drugs, exceeded the projected production figures. Supply chain disruptions make the delivery of finished products unstable and account for 10.6% of the total causes of drug shortages.

Drug quality problems directly account for 2.6% and affect shortages in EU countries, as any non-compliance with standards leads to the immediate withdrawal of batches from the market and the shutdown of production lines for inspections. One of the key factors causing chronic shortages of medicines (1.3% of the total) is regulatory issues, and the EU's outdated and fragmented regulatory framework exacerbates these risks. Policies of strict price regulation aimed at ensuring the availability of medicines for patients often have the opposite effect, making the production of certain drugs economically unprofitable. Impact of national pricing and procurement strategies, regulatory changes: too low prices make the production of medicines uneconomical, too high prices limit availability.

The EU is currently working on strategic directions to address these challenges, in particular by strengthening the resilience of supply chains and shaping a common regulatory policy. The Critical Medicines Act is one of the tools to counter this, as part of the broader EU legal framework that ensures the availability of medicines to all patients. A new law that should strengthen security of supply and reduce dependence on imports of raw materials.

Pharmacists play an important role in addressing drug shortages, and their efforts are aimed at minimizing the negative impact on patients' health. The solutions they can offer for this purpose vary depending on the national legislation of the countries. Since the beginning of 2024, some EU countries have been working on legislative initiatives to give pharmacists expanded powers to manage drug shortages.

According to the results of the study, it was found that the availability of drugs is crucial for an effective health care system, and the shortage of certain goods in the absence of alternatives has an obvious negative impact on the health of patients, as well as economic losses. An analysis of the situation with shortages of medicines in the countries of the European Union shows that the problem has become systemic and chronic. The main causes of shortages are multifactorial and cover the entire supply chain. EU actions to address the shortage of medicines are aimed at increasing production in Europe, stimulating local production of generic medicines and improving the security of supply of critical medicines.