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Criminal and Regulatory Laws on the Exchange of Authentic Medicines Between Pharmacies Across Continents

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ABSTRACT

The exchange of authentic medicines between pharmacies across continents is a critical process governed by stringent criminal and regulatory laws to ensure public health and prevent issues such as smuggling and counterfeiting. This study examines the legal frameworks regulating medicine exchange in Asia, Europe, North America, Africa, and Oceania, drawing on credible sources from international health organizations, including the World Health Organization, the U.S. Food and Drug Administration, and the European Medicines Agency, among others, published between 2015 and 2025. The analysis highlights regional variations, such as Iran's TTAC system, the EU's Falsified Medicines Directive, and the U.S.'s Drug Supply Chain Security Act, while identifying challenges like inconsistent standards and infrastructure disparities, particularly in Africa. Key findings underscore the need for global cooperation, advanced tracking systems, and staff training to enhance compliance with Good Distribution Practices. This research contributes to global health policy by advocating for harmonized regulations and technological advancements to ensure the safety, quality, and accessibility of medicines worldwide.

Keywords: Criminal Laws, Medicine Exchange, Authentic Medicines, Pharmacies

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Introduction

Medicines, as strategic commodities, play a vital role in ensuring public health. The exchange of authentic and official medicines between pharmacies is a sensitive process that requires adherence to criminal and regulatory laws to prevent smuggling, counterfeiting, and illegal distribution. This article examines the criminal and regulatory laws related to the exchange of authentic medicines between pharmacies across different continents and analyzes the legal frameworks and existing challenges.

Methods

This study was conducted using credible sources and legal documents from international databases and websites of health organizations, such as the World Health Organization (WHO), the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and Iran's Food and Drug Organization. The collected information is organized using the Vancouver referencing style. It included resources published from 2015 to 2025 related to drug exchange laws and its legal aspects.

Laws Across Continents

Asia

In Iran, the guideline for the exchange of medicines between pharmacies was issued by the Food and Drug Organization in 2024. This guideline aims to facilitate the supply of medicines needed by patients, prevent resource wastage, and ensure public health. According to Article 2 of the guideline, the originating pharmacy must register precise details of the medicines, including the Unique Identifier (UID), in the Tracking, Tracing, and Authenticity Control System for Health Products (TTAC). The receiving pharmacy is also required to verify and confirm this information. Violations of these regulations can lead to legal action under the Penal Law of 1988. However, due to numerous problems, this directive has not been implemented. (1). In other Asian countries, such as India, similar regulations are enforced under the supervision of the Central Drugs Standard Control Organization (CDSCO), which regulates medicine exchange under Good Distribution Practice (GDP) standards (2).

Europe

In the European Union, the European Medicines Agency (EMA) and Directive 2011/62/EU provide a comprehensive framework for medicine exchange. This directive emphasizes the use of tracking and serialization systems to prevent counterfeit medicines from entering the supply chain. Pharmacies are required to use verification systems such as the EU Falsified Medicines Directive. Violations can result in hefty fines and criminal penalties, including up to 7 years of imprisonment (3). In the United Kingdom, the Medicines and Healthcare products Regulatory Agency (MHRA) oversees medicine exchange, and non-compliance with GDP standards may lead to the revocation of a pharmacy's license (4).

North America

In the United States, the Drug Supply Chain Security Act (DSCSA) of 2013 regulates the exchange of medicines. This law mandates that all pharmacies use electronic tracking systems to record and verify the authenticity of medicines. Violations can lead to financial penalties and suspension of business activities (5). In Canada, Health Canada oversees medicine exchange and mandates compliance with GDP standards to ensure quality and safety. Violations may result in criminal penalties or license suspension (6).

Africa

In Africa, regulations for medicine exchange vary due to differences in healthcare systems across countries. In South Africa, the South African Pharmacy Council (SAPC) enforces strict standards for medicine exchange, including GDP requirements and detailed transaction

records. Violations can lead to fines or license suspension (7). In Kenya, the Pharmacy and Poisons Board oversees medicine exchange and emphasizes the importance of maintaining the cold chain for sensitive medicines (8).

Oceania

In Australia, the Therapeutic Goods Administration (TGA) regulates medicine exchange under the Australian Code of Good Wholesaling Practice. Pharmacies are required to use tracking systems, and violations may result in financial penalties or license revocation (9). In New Zealand, the Ministry of Health oversees medicine exchange and enforces similar requirements to ensure the authenticity and quality of medicines (10).

Challenges and Solutions

One of the main challenges in medicine exchange is the variation in laws and standards across continents and countries. For instance, while the European Union employs advanced serialization systems, some African countries lack similar infrastructure. Additionally, medicine smuggling and the entry of counterfeit medicines into the supply chain remain global issues. Proposed solutions include strengthening international cooperation, developing global tracking systems, and training pharmacy staff to adhere to GDP standards.

Conclusion

Criminal and regulatory laws governing the exchange of authentic and official medicines between pharmacies across continents are designed to ensure safety, quality, and timely access to medicines. However, regional differences and implementation challenges necessitate greater coordination among countries and international organizations. Developing technological infrastructure and enhancing oversight can improve this process.

Conflict of interest

None.

Ethical deceleration

None declared.

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