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FAKE AND COUNTERFEIT DRUGS: A BIG PROBLEM IN INDIAN HEALTHCARE SYSTEM

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ABSTRACT

In India, the phrase "counterfeit drug" refers to pharmaceuticals that have exceeded their expiration date, drugs that have been mislabeled, drugs that have been stored at unsuitable temperatures and drugs that have been created under adverse conditions. The supply of counterfeit medications is a major worry for the Indian government, regulatory authorities, and industry experts. Despite the existence of rules and guidelines to manage supply, a considerable proportion of operational outcomes have yet to be accomplished. To ensure the flow of legitimate medications across the supply chain in India, the health-care system must be properly monitored. To restrict the operations of counterfeit drug peddlers as much as possible, a high degree of monitoring and assessment must be implemented at all stages of the health care supply chain. The goal of this study is to identify and assess the present difficulties that permit gaps in the healthcare supply chain in India, as well as to offer solutions for reducing how counterfeit medications enter the supply chain.

Keywords: Counterfeit Drug, Fake Drugs, Spurious Drugs, Indian Pharmaceutical Supply Chain.

I. INTRODUCTION

Supply chain management, according to the Council of Supply Chain Administration Professionals, entails the planning and administration of all supply operations, including sourcing, procurement, conversion, and other logistical activities. The manufacturer, distributor, retailer, and eventually the customer are all part of the distribution channel. The pharmaceutical supply chain covers all organizational, operational, and value-added processes that help in the safe transportation of drugs from the producer to the client (Olson, 2020). The most challenging challenge in every industry is effective supply chain management.

Managing the supply chain especially in healthcare may be a highly difficult and fragmented operation. Healthcare supply chain management is a multi-faceted process that includes everything from acquiring resources and managing supplies to delivering products and services to clinicians and patients. Physical commodities and information regarding medical products and services must pass through a number of independent stakeholders, including manufacturers, insurance companies, hospitals, providers, bulk purchasing groups, and many regulatory authorities, for the process to be effective. However, there is an added danger and complexity in healthcare since a faulty supply chain might jeopardize the patient's safety. Increased technological use and globalization in an industry with various stakeholders have resulted in a convoluted health supply chain.

The Indian healthcare system has a complicated and distinct structure owing to a number of elements such as the size of the population served, the existence of both organized and unorganized healthcare services, economic disparities, and government structure, among others.

II. OVERVIEW OF COUNTERFEIT DRUGS

Counterfeiting is defined as imitating anything original in order to tear it down, rob it, or modify it in order to use it in illicit transactions or to fool others into believing that the fake goods are the same as or better than the original. Counterfeit products are imitations or unlicensed copies of the original product. Counterfeit items are frequently made in order to profit from the phony product's high value. The quality of counterfeit goods is frequently poor and hazardous, and one of the primary consequences is a significant number of deaths, particularly in the pharmaceutical business.

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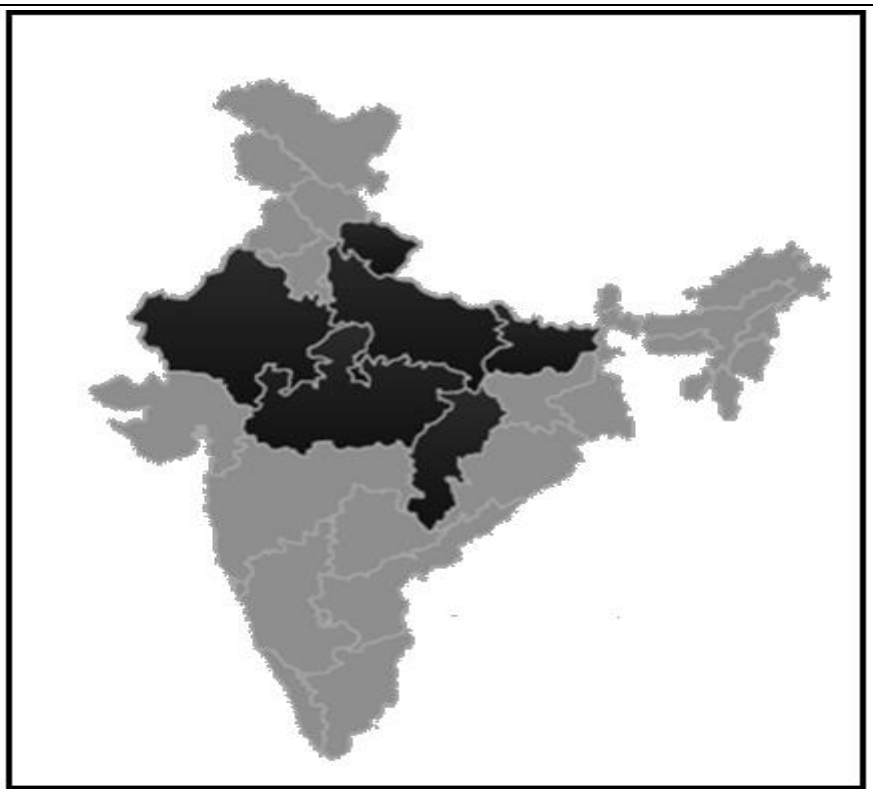

Fig 1: States Position with highest number of counterfeit inidents (Pharmaceuticals) reported (ASPA 2020)

The phrases substandard and falsified medical products (SF) are increasingly being used to describe counterfeit, inferior, and degraded pharmaceuticals, despite the fact that there is no universally agreed definition for these items. Substandard medications are genuine items that do not fulfill their quality requirements or specifications, whereas faked medicines are inauthentic products that intentionally falsify their identity, composition, or source (WHO 2017). Substandard pharmaceuticals are frequently the result of manufacturing flaws, insufficient storage, or poor distribution techniques whereas falsified drugs are typically created with the intent of profiting from them. A set of activities that include commerce such as claiming to be a licensed product of another company using another company's mark drug, manufacturing and marketing of medical drugs that do not contain the correct ingredients and appropriate quantities, concealing important information about the drug, its symptoms, and harmful effects on people, particularly those with certain diseases is called as pharma fraud. As a result, legal medicine manufacturers lose money and people's health is harmed by these counterfeit drugs. Furthermore, due to the problem of tax evasion, it may cause significant losses to governments. Counterfeit medications can be easily found on unregulated websites as well as in illicit street markets, pharmacies, clinics, and hospitals.

III. PREVALENCE OF COUNTERFEIT DRUGS

Because of the underground nature of the industry, it is impossible to establish a reliable statistic or proportion of the worldwide scope of counterfeit pharmaceuticals trade. Counterfeiting occurs 24x7, and affects all major industries and sectors to some level. It is not a new problem in India. In fact, one out of every three Indian individuals has been a victim of counterfeit items purchased from one or more e-commerce websites, making online counterfeiting the fastest-growing crime in the country. Every year, it costs the Indian economy INR 1 trillion. Counterfeit pharmaceuticals can enter the market for a variety of reasons, including a supply-demand mismatch for the genuine product or its constituents. Due to excessive demand and insufficient supply, unscrupulous individuals may benefit by providing fake or defective goods. Furthermore, SF goods might be caused by poor supply chain procedures or insufficient quality control at production facilities. Due of implications on production capacity, raw material availability, consumers' confusion about treatment

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effectiveness, and their feeling that they need to discover viable alternative remedies promptly during COVID19 pandemics, the incidence of SF products grows even more.

CDSCO (Central Drugs Standards Control Organization), India's National Medicine Regulatory Authority, performs a monthly analysis of samples gathered around the country. From January to December 2020, 39 incidents of methanol-containing hand sanitizers were recorded. In September 2020, remdesivir was pulled from the Indian market due to its poor quality. Multiple cases of substandard dexamethasone were also reported in 2020: Dexamethasone, along with 24 other drugs, was ruled substandard by the Indian national regulator due to the presence of free dexamethasone, a defective API assay, and sterility concerns. Indian intelligence obtained information in July 2020 about a consignment being shipped to Lagos that included a large amount of counterfeit dexamethasone.

IV. TECHNIQUES FOR DETECTING COUNTERFEIT DRUGS

Various techniques are used to detect counterfeit drugs such as

1. Visual inspection

Detection of counterfeit medicines starts with visual inspection of packaging materials. The packaging of counterfeit pharmaceuticals may be missing or misplaced expiration dates, lack instructions or production information, lack a batch number, or differ in a variety of other ways from real packaging. Some inferior medications are clearly of poor quality. Poor manufacturing procedures result in broken or falling apart tablets. Similarly, the medications may have the incorrect color, size, or form, have incorrect markings, have a different coating or texture, or otherwise deviate from what is anticipated. Visual examinations are sometimes inaccurate since counterfeit and inferior pharmaceuticals, as well as their packaging, can seem identical or extremely similar to real items. Criminals have duplicated holograms, barcodes, container designs, even tablet colors and markings with incredible precision.

2. Chemical Testing

There are several analytical methods available for determining the validity of pharmaceutical preparations while taking the content level of the Active Pharmaceutical Ingredient(s) into account (APIs). High-performance liquid chromatography with UV detection, liquid chromatography combined with mass spectrometry, gas-chromatography, and other methods are the most involved. Chromatography is the process of separating mixtures into their constituent elements using a range of chemical and physical characteristics. It may be used to isolate medication components for further testing and gives both qualitative and quantitative information about active substances and contaminants when combined with suitable detectors. Spectroscopy is a type of analytical method that examines the interaction of matter with radiation, providing information about the chemical structure and contents. In most circumstances, spectroscopic procedures are simpler, nondestructive, and less expensive than chromatographic approaches. For a quick investigation of several samples, the spectroscopic approach appears to be the best option. However, these approaches cannot provide complete information on the chemical composition of the material or point to its distinctive chemical markers. They become a more potent analytical tool when combined with chemometric approaches, principal component analysis (PCA), or cluster analysis (CA).

V. CONVOLUTION NEURAL NETWORK (CNN)

Convolution neural network (CNN), a typical deep learning technology, can extract the counterfeit characteristic and determine whether images are false. Using CNN, a set of inexpensive paper cards known as Paper Analytical Devices (PADs) that can efficiently categorize pharmaceuticals based on their chemical makeup has been produced.

VI. BLOCKCHAIN TECHNOLOGY

Blockchain is a peer-to-peer network in which the interconnected systems are completely open and transparent to one another. It is made up of blocks that are connected together to form a Blockchain. Each block is made up of transactions that have been signed by the authenticated users. Because to its decentralized, transparent, and irreversible nature, blockchain can manage inventory as well as eliminate counterfeiting and theft concerns of drug, and it has the ability to improve the security, integrity, data provenance, and

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functionality issues in the pharmaceutical supply chain. The use of blockchain in the pharmaceutical supply chain can allow for the precise placement of pharmaceuticals.

VII. CONCLUSION

The issue of counterfeiting medications is critical for the Indian government and pharmaceutical corporations to address since counterfeiting medicines can result in the loss of human lives. The safety of the pharmaceutical medication supply chain is a key problem for worldwide public health, since the epidemic of drug counterfeiting along the supply chain is a growing hazard to everyone's health. This study demonstrates how several methods may help prevent medicine counterfeiting and enhance monitoring and tracking at all levels of the supply chain.

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