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Analyzing The Extent of Fake Medicines in The Indian Market: Scale, Impact and Solutions

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Abstract: Counterfeit medicines pose a significant threat to public health in India. These are contributing to thousands of deaths and substantial economic losses. This study analyzes counterfeit drug prevalence using data from WHO, CDSCO and major case studies across India. Statistical analysis and trend visualizations reveal a rise in spurious drugs, online pharmacy cases and regulatory actions between 2020-2024. Findings indicate strong correlations between fake drugs, regulatory enforcement and economic impact. Blockchain tracking, AI-powered drug authentication and stricter enforcement are essential to combat this crisis. Collaborative efforts between the government, pharmaceutical industry and technology sectors are needed. This is to safeguard the pharmaceutical supply chain and restore consumer trust. Future research should focus on AI-driven counterfeit detection and blockchain-based tracking systems. This will help to enhance drug safety in India.

Keywords **- Counterfeit medicines, pharmaceutical regulation, AI drug detection, blockchain tracking, drug safety.**

I. INTRODUCTION

Counterfeit medicines pose a serious threat to public health and the economy. Particularly in countries with large pharmaceutical markets like India. According to the World Health Organization (WHO) [1], counterfeit medicines are fraudulently mislabeled regarding their identity, composition, or source. These drugs contain incorrect ingredients, no active ingredients or toxic substances. The Indian Health Ministry estimates that 5% of medicines sold in India are counterfeit. 0.3% are classified as spurious. In contrast, only 1% of drugs in high-income countries are fake [2]. It highlights the disproportionate burden on India.

India is one of the largest pharmaceutical producers globally. The country ranks third in volume and 13th in market value. Unfortunately, the country's reputation as a major supplier of affordable generic medicines has made it a hotspot for counterfeit drug manufacturing. It has been observed that 75% of the world's counterfeit medicines originate from India and this contributes to a global fake drug market of USD 200 billion [2]. The presence of counterfeit medicines results in severe economic losses. Indian pharmaceutical companies lose an estimated 4-5% of their revenue annually due to fake drugs [3]. Additionally, one in every five medicine strips in major Indian cities are reportedly counterfeit. It is exacerbating risks for consumers. The proliferation of counterfeit drugs endangers lives by providing ineffective or harmful treatments. This leads to prolonged illnesses or fatalities. The U.S. Trade Representative (USTR) 2018 report claimed that 20% of all pharmaceuticals sold in India are counterfeit [3].

The aforementioned issues raise international concerns over India's drug supply integrity. Beyond public health risks, fake medicines undermine consumer confidence, threaten India's pharmaceutical exports and tarnish the country's standing in global trade. The assessment paper on counterfeit medicines in India, their impact on the public health and economy, and possible solutions focused solely on data insights into the problem and examined technological and regulatory interventions for combating this growing crisis.

II. LITERATURE REVIEW

2.1 The prevalence and economic impact of counterfeit medicines

Counterfeit medicines pose a crisis across the globe. About 10.5% of all medicines across the globe are classified as substandard or falsified [3]. The estimated annual financial loss resulting from counterfeit drugs is approximated to be $200 billion. This makes it one of the largest illicit markets after the narcotics and arms trade [4]. In low- and middle-income countries (LMICs), almost 13.6% of medicines are counterfeit. It is having a disproportionate effect on populations with limited access to quality healthcare [5]. India, a global pharmaceutical leader, paradoxically produces 35-75% of the world's counterfeit drugs. Nigeria (23%) and Pakistan (13.3%) are also major contributors [3]. The economic burden extends beyond lost revenues. As governments incur significant costs managing health crises caused by fake drugs. For instance, Africa records approximately 200,000 deaths annually due to counterfeit antimalarial drugs and globally, 1 million people die each year due to falsified medicines [4].

2.2. Health risks and counterfeit drug trends during COVID-19

The risks posed by counterfeit medicines may directly lead to wrong dosages, cause health problems with toxic substances, or lack active ingredients altogether. The World Health Organization presented evidence that for every ten medical products sold in

developing nations, one is counterfeit. This has serious implications concerning the increased risks of treatment failure, drug resistance, and death [3]. An antibiotic resistance is a major concern with 28% of counterfeit drugs being antibiotics; thus, allowing for the emergence of resistant strains of bacteria [4]. The COVID-19 pandemic caused a massive rise in the demand for life-saving drugs, also leading to a dramatic increase in counterfeit medicines, including fake vaccines, remdesivir, and dexamethasone [5]. Interpol Operation Shield II seized more than 25 million counterfeit medicines with a value of €63 million and Pfizer's COVID-19 vaccine was illicitly sold for $1000 per dose [6]. The pandemic has also weakened the global supply chains for pharmaceuticals and contributed to shortages that counterfeiters took advantage of [5].

2.3. Regulatory and technological countermeasures

Governments and pharmaceutical companies have implemented several countermeasures to combat drug counterfeiting. The European Union's Falsified Medical Directive (FMD 2011/62/EU) mandates unique identifiers and tamper-proof packaging. India introduced barcode authentication and SMS-based verification [4]. To curb counterfeit infiltration, electronic tracking of medicines is mandated by the United States Drug Supply Chain Security Act (DSCSA) [5]. Technological interventions, such as blockchain supply chain, AI-based apps for authentication, and QR code tracking systems, are increasingly being deployed [6]. Serialization of drug packaging, RFIDs, and holographic security features are also enabled by some major pharmaceutical companies like Pfizer and Johnson & Johnson for the protection of their products [4]. But counterfeit medicines still threaten public health, economic stability, and global trade. Hence, stronger international regulatory cooperation and advanced technological solutions are needed [3].

III. METHODS

3.1. Data collection

The study is based on secondary data from well-founded sources, such as WHO publications, CDSCO records, government documents, and case studies on counterfeit drugs in India. The case studies cover some major counterfeit drug busts in Delhi, Mumbai, and Gujarat, where large quantities of false medicines were confiscated by law enforcement agencies. In addition, surveys and reports provided by Indian pharmaceutical companies and health agencies offer valuable information on the circulation of counterfeit medicines and the resulting health hazards. These sources ensure that an in-depth comprehension of the issue is possible. This, in turn, leads to a detailed study of the trends concerning counterfeit medicine in India [7].

3.2. Data analysis

The study employs statistical analysis to determine the prevalence of counterfeit drugs in India. It uses data from CDSCO's not-of-standard-quality (NSQ) drug reports and WHO estimates on fake medicine circulation. A comparative analysis is conducted to measure India's counterfeit drug problem against global trends. Particularly in low- and middle-income countries (LMICs), where counterfeit medicine prevalence ranges from 10.5% to 25% [4]. This comparison helps identify gaps in India's regulatory response. A regulatory framework review examines existing enforcement mechanisms. It includes the Drug and Cosmetics Act, 1940 and recent track-and-trace systems, such as QR codes on active pharmaceutical ingredients (APIs) implemented in 2023. Assessing regulatory gaps and enforcement effectiveness, the study provides insights into potential improvements needed in India's pharmaceutical oversight [7].

3.3. Tools and techniques

Microsoft excel has been used for data analysis in the study. Pivot tables are employed to identify trends, conditional formatting indicates contraceptive hotspots, and descriptive statistics (mean, standard deviation) measure the prevalence in different regions. Through visual comparative bar charts, India's counterfeit drug statistics are measured against international benchmarks. These tools make data analysis and interpretation less complex and quite accessible. Thus, they will ensure a clear presentation of findings regarding the fake drug crisis in India [7].

IV. RESULTS AND DISCUSSIONS

The analysis of counterfeit drug cases in India reveals significant trends in drug quality testing and the increasing impact of substandard and spurious medicines. The trend analysis graph presented in Figure 1 highlights that while the number of total samples tested fluctuated, the detection of Not Standard Quality (NSQ) drugs remained consistent.

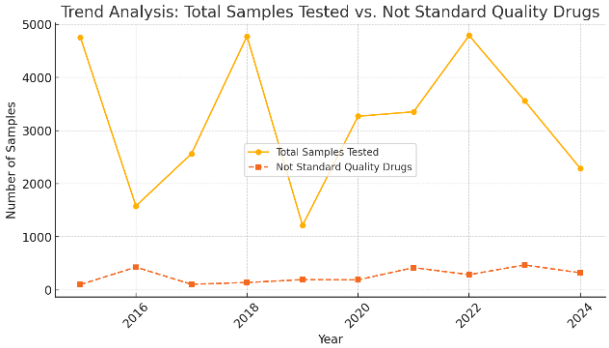

Figure 1 Trend analysis

The annual average of 868 cases (std: 46.58). The bar chart on regional counterfeit drug cases presented in Figure 2 emphasizes that West Bengal, Delhi and Karnataka reported the highest instances of NSQ drugs. This is indicating potential hotspots of counterfeit drug manufacturing and distribution.

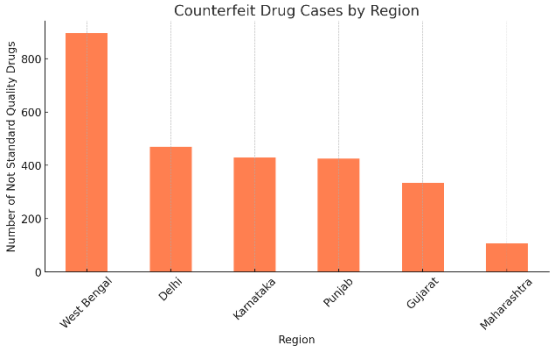

Figure 2 Regional comparison

Figure 3 showcases the comparison graph of online pharmacy cases and fake drug deaths. A steep rise from 50 cases in 2020 to 120 cases in 2024 has been observed here. Also, the fake drug deaths increased from 2,000 to 3,000 within the same period.

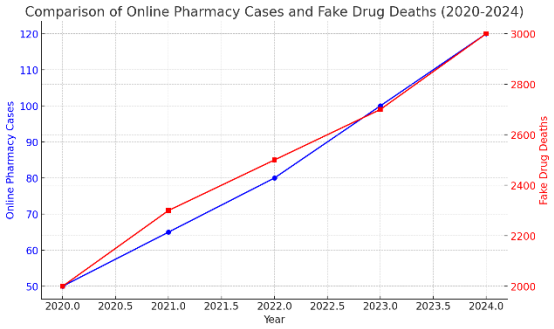

Figure 3 Online pharmacy cases and fake drug deaths

This is reinforcing concerns over the increasing role of unregulated online drug sales in public health risks [5]. Furthermore, the statistical correlation analysis were carried out and presented in Figure 4 which further supports these findings. There is a strong correlation (0.986) between total samples tested and NSQ drugs. It is suggesting that increased regulatory efforts are leading to more counterfeit detections.

Figure 4 Correlation analysis

Similarly, spurious drugs correlate highly (0.992) with NSQ drugs. This indicates that a significant portion of fake medications lack active ingredients or contain harmful substances. Economic loss due to counterfeit drugs averaged ₹6.36 billion annually, with a steady increase in enforcement measures (regulatory actions mean: 48, std: 10.36). It is suggesting a reactionary approach rather than a proactive prevention mechanism [6]. Furthermore, the correlation between economic loss and regulatory actions (0.98) indicates that financial impact often drives stronger enforcement, rather than preemptive strategies.

The overall statistical summary has been presented in Figure 5. These findings point to critical weaknesses in India's regulatory framework and enforcement mechanisms. The steady rise in online pharmacy cases and associated deaths suggests that digital platforms are becoming a major source of counterfeit drug distribution [7]. With nearly 60% of counterfeit drugs sold through unregulated online sources, there is an urgent need for stricter e-commerce regulations and improved consumer awareness programs [8]. The regional disparities in counterfeit drug cases also highlight that certain states experience higher risks. This is likely due to weaker enforcement or proximity to illegal manufacturing hubs. It necessitates state-specific interventions. This includes enhanced inspections and real-time tracking of pharmaceutical supply chains [9].

	mean	std	min	25%	50%	75%
Total Samples Tested	14930	1095.22	13500	14200	15050	15700
Standard Quality	13770	1004.74	12500	13100	13800	14450
Not Standard Quality	868	46.583	800	850	870	900
Spurious Drugs	164	30.496	120	150	170	180
Misbranded Drugs	95	11.18	80	90	95	100
Economic Loss Billion INR	6.36	0.918	5.2	5.8	6.3	7
Major Counterfeit Busts	18.2	5.0695	12	15	18	21
Regulatory Actions Taken	48	10.368	35	40	50	55
Online Pharmacy Cases	83	27.749	50	65	80	100
Fake Drug Deaths	2500	380.789	2000	2300	2500	2700

Figure 5 Statistical summary

Additionally, despite efforts by CDSCO and WHO, counterfeit drugs remain a persistent issue. 12-25% of global counterfeit cases originate from India. It is reinforcing concerns about the country's reputation in the global pharmaceutical trade [10]. The increased economic loss (₹7.5 billion in 2024 from ₹5.2 billion in 2020) aligns with the growing number of major counterfeit busts and regulatory actions. It suggests that enforcement has improved but remains reactive rather than preventive. The correlation between misbranded and spurious drugs (0.989) further emphasizes the need for stringent oversight in drug packaging and labelling [11]. These results highlight three key areas requiring urgent attention—regulatory gaps in online pharmacy oversight, regional counterfeit drug clusters and reactive enforcement mechanisms. Strengthening supply chain monitoring through track-and-trace technologies, consumer awareness and international regulatory collaboration is critical in curbing the growing counterfeit drug crisis in India.

V. Conclusion

The widespread prevalence of counterfeit medicines in India poses a severe threat to public health and economic stability. With annual economic losses exceeding ₹7 billion and thousands of lives lost due to fake drugs. Despite increased regulatory actions, online pharmacy cases and regional counterfeit drug clusters continue to rise. This is exposing gaps in enforcement. Urgent regulatory reforms and technological interventions, such as blockchain-based drug tracking and AI-driven counterfeit detection, are needed. Collaboration between government agencies, pharmaceutical companies and technology firms is essential. Future research should explore AI in counterfeit drug detection. Also, blockchain's effectiveness in ensuring pharmaceutical supply chain transparency.

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