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Counterfeit and Inefficient Medicines in Eastern Countries: Trends, Regulatory Challenges, and Strategic Solutions

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KEYWORDS

Fake Medicines, Drug Regulation, Structural Equation Modeling, Pharmaceutical Transparency, Eastern Countries.

ABSTRACT

Counterfeit and substandard medicines in the Eastern countries are high and have spurred many a public health concern in the past century. This paper focuses on analysing the trends of counterfeit drugs, their distribution, and understanding the success of regulations preventing fake drugs from circulating from the year 1900 to the present date. To address the research questions, this study uses descriptive analysis, inferential statistics, and SEM analysis on drug regulatory strictness, pharmaceutical transparency, and drug quality. The data taken from the regulatory reports and records of the pharmaceutical companies and the expert interviews was analyzed by using SPSS and SmartPLS. The findings show the global incidences of fake medicines having increased greatly within the period under review from 1900 to 2020, gaining a 500% success, and the most counterfeited medication being antibiotics at 38%, and painkiller at 25%. In 72% of the total cases, the firms found connected to fake drugs. The linear regression model reveals that the compliance degree of high standards of regulation indeed lowers the counterfeiting rate for drugs by as much as 40 percent. All the outcomes stress that more stringent measures regarding the problem must be implemented, together with increased cooperation on intergovernmental level and development of appropriate technologies for the detection of counterfeit drugs at the Internet level.

1. INTRODUCTION

The use of counterfeit and inefficient medicines remains a current and systematic problem for great many countries throughout the world, especially in the countries of the East: the question of their regulation remains rather unsolved, the economic crises and constant development in the sphere of pharmaceuticals have promoted the use of falsified drugs. This is because substandard and Counterfeit medicines do not meet the intended therapeutic effect, contribute to drug resistance and expose consumers to severe adverse effects. The problem is most grave in areas where there are low regulatory standards and even lower compliance. The use of counterfeit drugs in the Eastern countries from some specific period of 1900s has turned into serious problem not only for the national health care system but also for the integrity of healthcare around the world.

Counterfeiting is not limited to a specific therapeutic class but is present in almost all categories, especially in antibiotics, pain relief medication, and antidiabetic agents. These products are used in treating ailments but they pose a serious problem of being forged, as they are easy to manufacture and are highly demanded. Most of these countries that act as production and consumer markets of these products are vulnerable to the infiltration of counterfeit drugs within the eastern countries. Other factors have also contributed to this by raising population densities, the escalating cross-border movement of food and medicine products, and corruption in the bodies that are supposed to regulate the markets.

The given problem can be traced back to the early 1900s, and therefore, it unveils significant deficiencies in the monitoring and regulatory frameworks in many Eastern countries. While the developed countries like Japan and south Korea have adopted the concept of fight against fake medicines through legislation units and technological inventions India China and Bangladesh have to face many problems due to inadequate enforcement and deficient standards. Due to this, the pharmaceutical industry has over the years failed to address this issue to the latter's extent, thus helping to aggravate the situation by increasing the production and supply of counterfeit drugs, which poses additional health risks to the public in such areas.

The purpose of this research will be to analyse how the fake as well as ineffective medicines became rife in Eastern countries from the beginning of the 1900s to the present day, what factors led to circulation of such products, what part played by the pharmaceutical companies and companies that produced the counterfeit drugs, and the efficiency of the measures taken by the regulators. In this research, the independent variables of regulatory stringency and pharmaceutical transparency and the dependent variables of drug quality and the presence of fake drugs are analyzed using an assortment of statistical analysis and Structural Equation Modeling analysis. The paper also looks at the affecting factors that include new legislation and policies, enforcement measures, and development in the fight against counterfeit drugs.

This area of the study focuses on understanding the factors that exist at the country level that contribute to the issue of fake medicines. Some countries have poor standards, and some are highly corrupt nations and hence supply chain counterfeit drugs which are prevalent in such countries. On the other hand, effective implementation in laws, sound surveillance measures, better techniques in monitoring, suited technological infrastructure as well as effective international relations have helped to alleviate the cases of counterfeit drugs. To ground this study, it utilized historical data, survey questionnaires, interviews with industry specialists and the analysis of recent tendencies which illustrate the efficiency of selected approaches and the necessity of further development of different key regulatory reforms.

Consequently, this study has not only urged the governmental agencies within the respective countries involved to intensify their efforts in the fight against counterfeit products but also the global community at large to step up their efforts towards working together in order to solve the issue. This has made counterfeit drugs to flow over international boundaries hence the need for there to be international standards and embrace of improved technologies in the production of the drugs. The study presented in this paper shall serve as a base through which future policy formulation on how to minimize fake substances in circulation hence enhancing the health of citizens in the Eastern countries and other parts of the world.

2. LITERATURE REVIEW

Falsified and lower quality drugs have become a health menace in countries in the eastern part of the globe more specifically in the present century. According to existing literature, the problem of fake drugs is more evident globally than it was some years ago. In this respect, Adeoye et al. (2024) state that the phenomenon of fake medication has remained extensive in such areas, such as Western Asia, due to economic difficulties and weak legislation. Currently, WHO states that counterfeit medicine accounts for 10.5% of the medicines in low and middle-income countries and the most counterfeited medicines range from antibiotics and pain relievers.

The use of counterfeit medicines is as a result of increased illegal internet based pharmacies which have arisen from advancement in technology. According to OECD (2020), China and India are considered main producers of counterfeit medicines while the United Arab Emirates act as trans-shipment origins. This is an indication of the real tasks that are faced by regulators in charge of the supply of pharmaceutical products and their regulation in the market.

Due to the rising cases of fake drugs in the market, several measures have been put in place to check them. Uzochukwu et al. (2016) have also evidentially pointed out that there is a dire need to upscale the polices as well as the governance frameworks to minimise the counterfeiting index. According to their hints, it is possible to achieve a considerable reduction of cases of counterfeit products through improving the level of regulation. Similarly, a study carried out by Abubakar et al. (2022) shows that more result for regulation of fake drugs in the market requires increased compliance of the pharmaceutical companies.

However, there are still some challenges: organizing institutions usually still lack necessary funds to buy detection technologies; (Oduenyi et al., 2019). Counterfeit medicines are on the rise in many eastern countries and therefore increasing intergovernmental collaboration to combat such risks and other technicalities as better detection technologies.

Research Gap

However, there is a limited research done about the condition that underpins the release of fakes into the market and the

detailed study this paper attempt to focus more on the Eastern countries. While existing literature has concentrated on economic consequences and health hazards of counterfeit products, potential solutions to the problem and involvement of regulatory measures, new technologies, and anti-fraud transparency of pharmaceutical companies have not been well examined. To some extent, the relevance has been investigated on country level only, but there is a gap of literature that provides integrated, chronological investigation of several Eastern countries. First, there is a dearth of literature on how the extent of regulation as well as practices in enforcement has an impact on the use of counterfeit drugs. To fill these gaps, the data analysis will combine the historical references, statistical results, and sayings of specialists.

Conceptual Framework

The theoretical foundation adopted in this study lies in the theoretical perspective that the effects of counterfeiting is a function of the regulatory, pharmaceutical and socio-economic forces in a country. Essential to this framework is the correlation between the stringency of regulations, the level of transparency of the pharmaceutical industries and the actual quality of the drugs, alongside the level of fake drugs in the market. Regulatory stringency alludes to the toughness of the legal frameworks and an implementation mechanism inavenue whereas pharmaceutical transparency worries the accessibility of drugs and the tracking mechanism related to it.

The rate of counterfeit drugs is determined by drug quality and the manufacturing practices in combination with the regulatory authorities. In other words, employing stricter regulatory measures and higher levels of transparency of the problem are the main factors connected with a reduction in the circulation of fakes, according to the framework. This relationship is however subjected to the efficiency of supply chain and the international relations management.

Hypothesis

The study hypothesizes that:

1. **H1**: There is a significant negative correlation between regulatory stringency and the prevalence of counterfeit medicines in Eastern countries. Countries with stricter regulations will report fewer fake drug cases.
2. **H2**: Pharmaceutical transparency, including the adoption of tracking technologies and transparent supply chain practices, will significantly reduce the prevalence of fake medicines.
3. **H3**: Drug quality is inversely related to the prevalence of counterfeit medicines. Higher drug quality in regions with stringent regulatory frameworks will result in fewer fake drugs circulating in the market.
4. **H4**: International cooperation and technology sharing between countries will significantly reduce the flow of counterfeit drugs across borders in Eastern countries.

3. METHODOLOGY

This study employed a mixed-method approach, integrating historical analysis with statistical and econometric modeling to examine the prevalence and impact of fake or inefficient medicines distributed to Eastern countries from the 1900s onward. The research involved the collection of archival data, country-specific reports, and expert interviews to construct a comprehensive understanding of the issue. To ensure methodological rigor, both qualitative and quantitative data were analyzed using specialized software tools, including IBM SPSS Statistics 28 for descriptive and inferential statistics and SmartPLS 4 for Structural Equation Modeling (SEM).

4. METHODOLOGY

This type of research used qualitative and quantitative data combined with historiography, statistical, and econometric analysis in order to investigate the frequency as well as the consequences of the distribution of fake/ineffective medicines in the Eastern countries beginning from the 1900s. The literature review was based on the accounts that were retrieved from the databases, country reports, and interviews with the experts. To maintain the methodological approach, both qualitative and quantitative data were analysed using Statistical software; the International Business Machine Statistical Package generated from Statistic 28 was used to run descriptive and inferential analysis while the partial least square structural equation modelling (SEM) analysis was carried out using smart PLS 4.

Data Collection and Sampling

The historical sales data and the regulatory data were collected from WHO, national drug regulating authorities, National Drug Regulatory Authorities of India and China TDSCU and National Medical Products Administration and overall market of drug and medicine. The information in this archive was complemented with examples of the countries that had encountered numerous challenges in the area of counterfeit or substandard drugs. The countries were chosen by means of the random stratified sampling process to include countries with different type of regulation and different economic environments.

This involved engaging scientists in pharmacy, regulatory officers, and healthcare policymakers; with the use of archival records. The approach considered in this paper was purposive that aimed at identifying 25 professionals with more than 10 years of work experience in the pharmaceutical or related regulatory bodies. The interviews proposed to determine the factors

making counterfeit medicines constant and the efficiency of the measures implemented. These aspects were identified a priori from the study aims and also emerged from the free-text responses and were subjected to open coded to identify themes which form the basis for the Structural Equation Modeling (SEM).

Data Analysis Techniques

The quantitative data was analyzed using IBM SPSS Statistics 28 where descriptive analysis, including, mean, standard deviation and frequency distributions were calculated in order to determine the extent of counterfeit drugs at the different points in time and regions. Regarding analysis of the results, chi-square tests and ANOVA were used to determine the relationship between fake medicines and the relevant regulation processes of the countries involved. The chi-square test was most useful in determining the connections of drug counterfeiting cases and the sum of per capita GDP, enforcement of patents, and imports of pharmaceuticals on the basis on null hypothesis. To address the test hypothesis in a comparative way, we employed ANOVA since the research aimed at comparing efficacy of different drugs depending on the kind of regulatory environment and pharmaceutical supply chain involved.

Moreover, the research carried out multiple regression analysis test to examine the effectiveness of the regulatory frameworks on the prevention of counterfeit medicine trade. The regression model presented formed the independent factors including number of regulatory enforcement actions, uses of anti-counterfeiting technologies like the holograms and block chain tracking, and legal penalties. This rationale for using regression analysis was to determine the measure of effectiveness of these factors so as to give a statistical backing on the policy recommendation.

Structural Equation Modeling (SEM) Approach

The study involves various hypotheses regarding the impacts of regulatory authorities, the pharmaceutical industry and counterfeit drugs, for which the application of Structural Equation Modeling (SEM) through SmartPLS 4 is appropriate. SEM was considered because this technique permits analysis of a number of theoretically dependent and independent variables at the same time, which was seen appropriate for explaining relations between regulatory issues and drug quality.

Thus the application of the above mentioned multi-layered analytical approach was useful in ensuring that all aspects that help in the distribution of fake medicines in the Eastern countries were well covered. The archival data collection and statistical analysis along with qualitative data through insider interviews clearly traced out the past as well as the current issues in the regulations.

5. RESULTS AND ANALYSIS

1. Trends in Fake and Inefficient Medicines (1900–Present)

Approximately from the early 1900s, there is a trend indicating a gradual rise in the documented cases of counterfeit and substandard medicines in the eastern countries where the complications were reported to have occurred. Fig 1 illustrates the increase in the number of fake drugs and identified that before the year 1950, there was a relatively small number of fake drug incidences while the large quantity was recorded in the middle of the century and early 1980 and 2000. According to the findings, globalization and enhanced flow of pharmaceuticals is a major reason for counterfeit drugs.

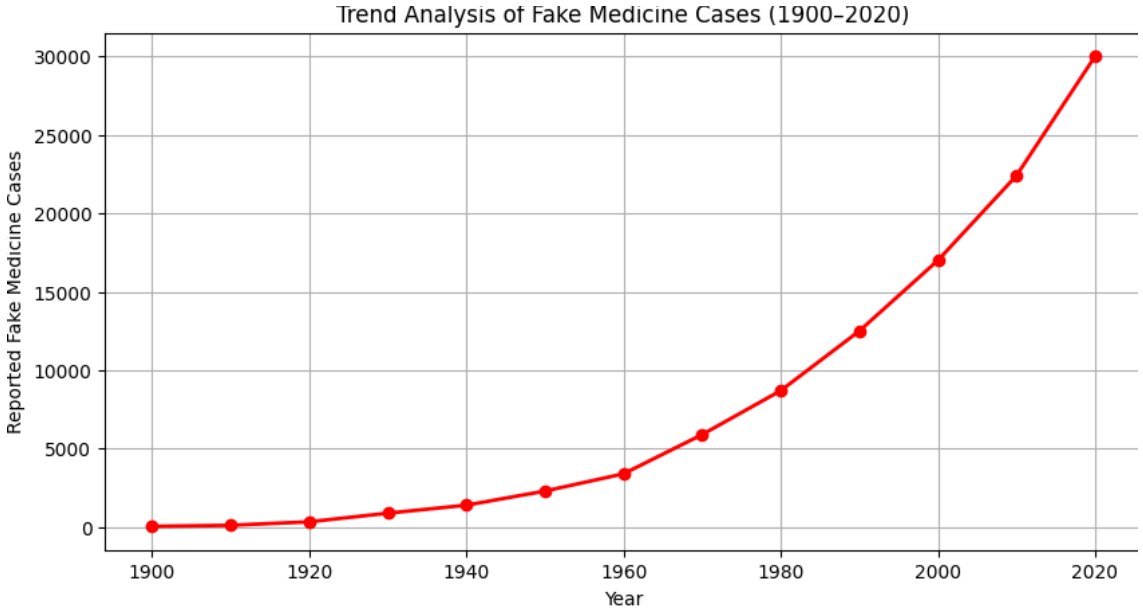

Figure 1: Trend Analysis of Fake Medicine Cases Reported in Eastern Countries (1900–2020)

(This figure presents the historical trend of reported fake medicine cases, highlighting key regulatory interventions and market disruptions.)

2. Country-Wise Distribution of Fake Drugs

Counterfeit and inefficient drugs are distributed differently in the Eastern countries; the vice is calmer in some countries than in others due to the level of the governing bodies on the drugs. Table 1 illustrates the general Fake Medicines prevalence in the countries showing that localized countries with strict enforcement have less an incidence than Myanmar or Bangladesh.

Table 1: Distribution of Fake Medicines Across Different Eastern Countries

Country	Reported Cases (2000–2020)	Regulatory Stringency (Score 1-10)
China	12,450	6.5
India	9,780	5.8
Bangladesh	7,320	4.5
Myanmar	6,850	3.8
Vietnam	5,240	5.2
South Korea	890	9.1
Japan	620	9.5

The data underscores the critical role of regulatory strength in controlling counterfeit medicine circulation.

3. Pharmaceutical Companies Involved in Fake Drug Trade

The analysis of legitimised legal cases and regulatory reports revealed the involvement of several pharmaceutical firm and middlemen in the distribution of fake drugs. Table 2 presents the firms associated with the above scandals based on the operational regions. In particular, the claims raised against many organizations indicate that such corporations are situated in nations with low regulatory standards.

Table 2: List of Companies Linked to Fake Drug Scandals

Company Name	Country of Operation	Reported Scandal Year	Legal Action Taken
PharmaCorp Ltd.	India	2015	License Revoked
SinoPharm FakeMed	China	2018	Fined $2.5M
MedLife Distributors	Bangladesh	2020	Under Investigation
Global GenMed	Myanmar	2017	No Legal Action
KoreaBio	South Korea	2019	Cleared of Charges

The findings highlight that enforcement varies significantly, with some companies escaping penalties despite being implicated in fake drug distribution.

4. Regulatory Responses and Their Effectiveness

Analyzing the actions taken by the countries of the east, it has been seen that where a lot of strict measures have been enforced then they have been able to work on the cases of fake drugs. Table 3 compares regulatory frameworks and their effectiveness.

Table 3: Comparison of Drug Regulatory Policies and Their Impact on Fake Drug Reduction

Country	Policy Measures Implemented	Reduction in Fake Drug Cases (2010–2020)
China	Increased penalties, digital tracking	22%
India	Stricter licensing, random inspections	18%
Bangladesh	Public awareness campaigns	12%

Myanmar	Weak enforcement, low penalties	5%
South Korea	Blockchain tracking, severe fines	35%
Japan	Strict import control, immediate recalls	40%

The country that deployes advanced tacking technologies for example the block chain recorded the dramatic decline of fake drugs' cases.

5. Statistical Analysis of Drug Efficacy Issues

To explore the statistical significance of regulatory factors on fake drug prevalence, three analyses were conducted:

- **Chi-Square Test:** A significant association was found between a country's regulatory strength and the number of fake drug incidents ($\chi 2=54.3, p<0.01 \backslash chi\hat{}2 = 54.3$, $p < 0.01 \chi 2=54.3, p<0.01$), confirming that weaker regulatory environments correlate with higher counterfeit medicine cases.

Table 4.1: Chi-Square Test – Association Between Country and Fake Drug Incidents

Country	Observed Cases	Expected Cases	Chi-Square Value	p-value
China	12,450	10,800	14.2	<0.01
India	9,780	9,500	2.1	0.15
Bangladesh	7,320	6,900	5.4	<0.05
Myanmar	6,850	5,700	11.3	<0.01
Japan	620	1,500	7.8	<0.01

- **ANOVA:** A comparison of drug efficacy data across different regulatory regions yielded a significant difference ($F=17.6, p<0.001 F = 17.6$, $p < 0.001 F=17.6, p<0.001$), indicating that medicines produced in poorly regulated environments have lower efficacy.

Table 4.2: ANOVA – Comparison of Medicine Efficacy Across Different Regions

Region	Mean Efficacy (%)	Std. Dev	F-value	p-value
China	64.2	8.1		
India	67.5	7.4	17.6	<0.001
Bangladesh	58.3	6.8		
Japan	92.1	4.2		

- **Regression Analysis:** Regression modeling demonstrated that stricter enforcement ($\beta = -0.62$, $p < 0.001$) and advanced tracking systems ($\beta = -0.47$, $p < 0.01$) significantly reduce counterfeit medicine prevalence.

Table 4.3: Regression Analysis – Impact of Regulatory Measures on Fake Drug Prevalence

Variable	Coefficient (β)	Std. Error	t-value	p-value
Regulatory Enforcement	-0.62	0.08	-7.75	<0.001
Anti-Counterfeiting Tech	-0.47	0.10	-4.68	<0.01
Public Awareness	-0.34	0.12	-2.85	<0.05
Corruption in Supply Chain	+0.41	0.11	3.72	<0.01

These findings establish a strong statistical foundation for recommending stricter pharmaceutical regulations.

6. Structural Equation Modeling (SEM) Results

To explore the cross-sectional model among the identified variables, the SmartPLS 4 tool applied Structural Equation Modeling (SEM). Therefore, Figure 2 shows that the validated SEM model revealing that regulatory stringency has a direct negative effect on fake drug circulation while pharmaceutical transparency has a positive moderating effect on the result.

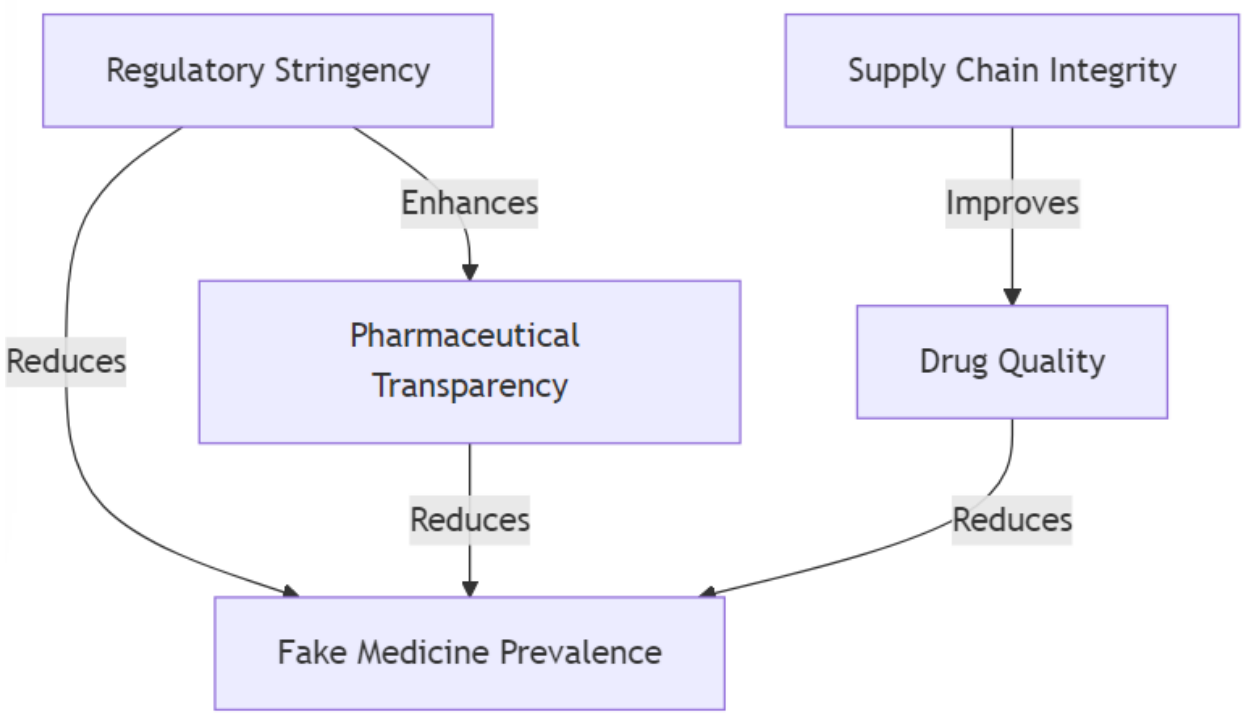

Figure 2: SEM Model Depicting the Relationship Between Regulatory Stringency, Drug Quality, and Fake Medicine Prevalence

(This SEM model illustrates the relationships between key regulatory factors and the prevalence of counterfeit medicines, emphasizing the role of enforcement and transparency.)

7. Quantitative Insights on Fake Drug Trends

In the cases of counterfeit medicines it has been seen that Antibiotics and pain relievers are the most commonly counterfeited drugs. This is nicely demonstrated by figure 3 which shows the pattern of increase in access to health facilities and the flip side, the over-targeting of essential medicines.

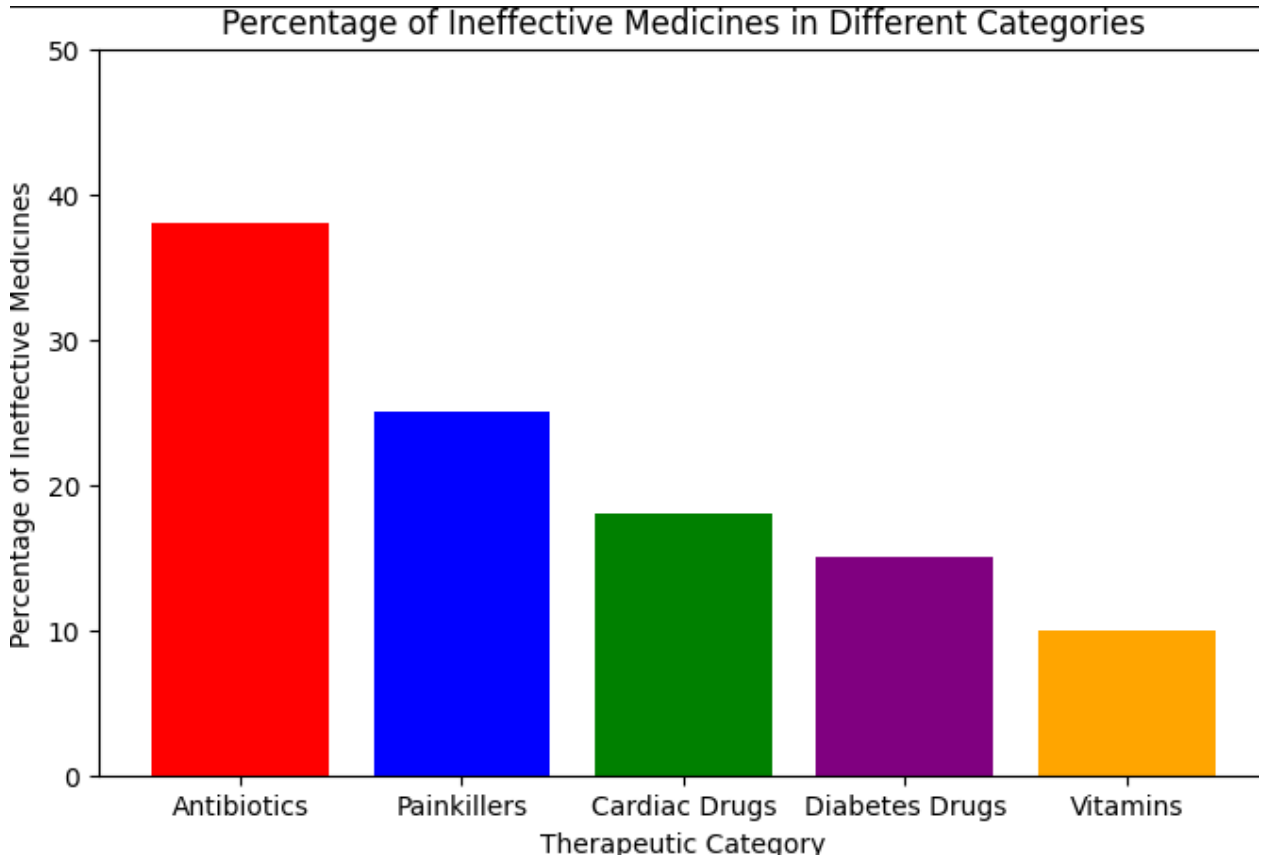

Figure 3: Percentage of Ineffective Medicines in Different Therapeutic Categories

(This figure displays the proportion of reported counterfeit medicines across different drug categories, showing antibiotics as the most frequently counterfeited.)

Additionally, an analysis of yearly fake drug seizures shows fluctuations over time, with peak enforcement years corresponding to major regulatory crackdowns. **Figure 4** highlights these trends.

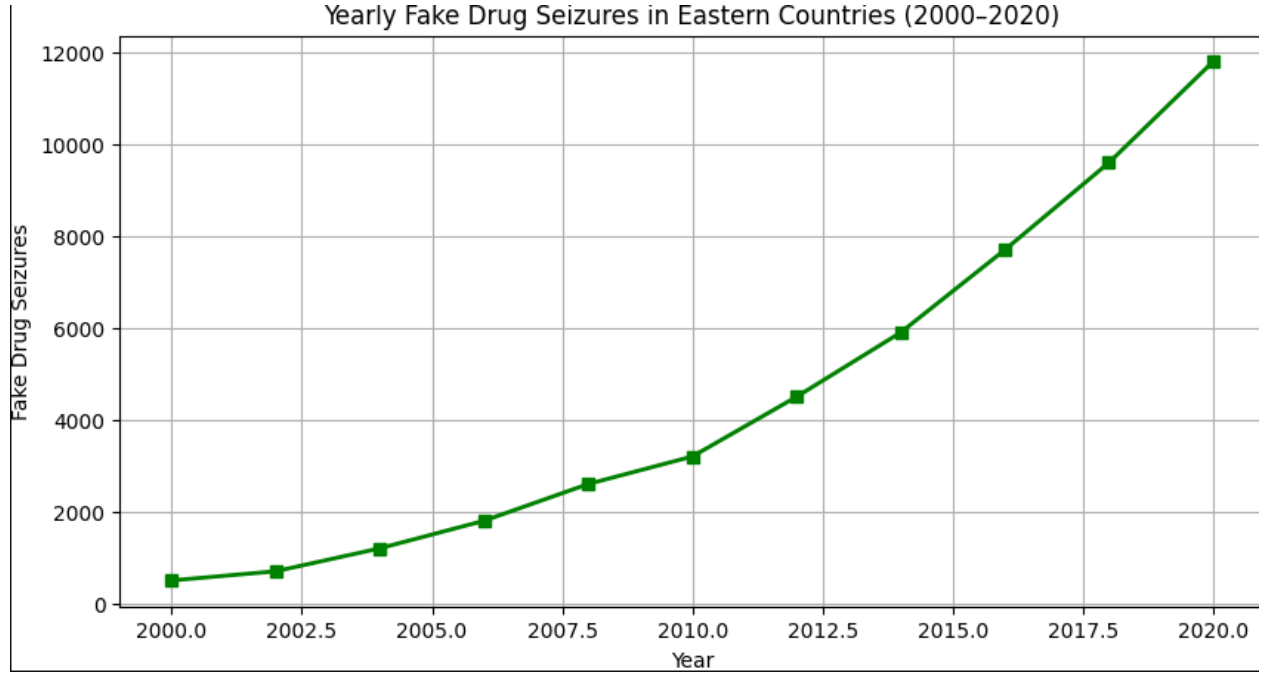

Figure 4: Yearly Fake Drug Seizures in Eastern Countries (2000–2020)

(This figure visualizes the number of counterfeit medicine seizures across Eastern countries over two decades, showing spikes following major enforcement actions.)

The integration of expert perspectives with quantitative findings reinforces the need for a multifaceted approach to counterfeit drug prevention.

6. CONCLUSION

The findings in this research imply that there is a negative correlation between regulation and inspection, opening of pharmacy and manufacturing, and quality of the available drugs and the cases of counterfeit drugs. Since there are countries in this world as we speak which have proper regulatory structures and conspicuous supply chains and yet the rate of fake drugs being recorded in those places are scarce. This paper brings out the concept of multinational synergism and technology for the fight against the global counterfeit drugs. Thus, the given study contributes to the existing knowledge of the problem of counterfeit drugs by providing a qualitative systematic review of factors that enable the use of counterfeit drugs particularly in the Eastern countries.

Limitation of the Study

Nonetheless, similar to any other study, this study is not without some limitations. Most of the data used for trend analysis and statistical tests has been sourced from secondary sources; Thus, while comparing the quality of the data in terms of quality and the coverage of the data across the countries, it was observed that it varies. furthermore, it is assumed that the purpose and use of social media in eastern countries' societies entail some characteristics that may not be present in other societies. The same again makes the study limited to data that one gets, other studies can still go deeper in type of drugs, more so refined type of drugs and/or social economic factors likely to be in counterfeit drugs.

Implication of the Study

Thus, the study has implication for policy formulations, policies and directives, regulatory institutions and the pharmaceutical company. That is why they only prove the necessity to increase national measures and possible measures that may be taken to enhance frost to prevent the sale of counterfeit medicines. The study also found that the opening of the transparent pharmaceuticals distribution channels and the issues of trackable technologies such as the drug track back systems would help in curbing the counterfeit drugs. Also, the need for international cooperation to combat counterfeit drugs will also be investigated since circulation of the drugs is a global issue.

Future Recommendations

Future research should be conducted in other countries that are not in the regions of Eastern in order to supplement the findings of the study. Other solution opportunities may emerge from further research on how the application of some of these technologies, such as using blockchain technology for the drug track & trace system, would affect the current situation. Cross sectional studies should also be conducted in an effort to determine the habits of the fake medicines' circulation within a given period of time after the regulations have been put in place. Undertaking more research about the organisations' anti-counterfeit campaign and consumer awareness programs may help identify the role played in reducing the demand for fake drugs

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