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Counterfeit and illicit drugs trade: A quantitative data on how counterfeit drugs impact globally

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Abstract: The purpose of this paper is to focus on the challenges of counterfeit drugs facing the pharmaceutical industry globally. Counterfeit drugs create a serious threat to public health and patient safety. Increasing Internet accessibility and uncontrolled social media platforms for unethical trade, illicit drug supply through dark web and COVID-19 created opportunity for criminals and counterfeit drug traders to reach wider public. Hence, there is an intense need to secure and authenticate pharmaceutical products in the emerging counterfeit product market.

Objective: This study intends to empirically examine the social and financial impact of Counterfeit/falsified drugs in the global supply chain.

Keywords: Counterfeit drugs, falsified, pharmaceutical industry, Online trade, patient safety, Food and Drug Administration, World Health Organization.

I. INTRODUCTION

Falsified or counterfeit drug have been a serious threat to public health for a long time. Several international forums debated the definition of falsified or counterfeit pharmaceutical drugs multiple times. In several instances issues related to the definition of "counterfeit medicines" were addressed at both the World Trade Organization (WTO) and the World Health Organization. It has been primary discussion points for WTO to assess the negative economic impacts of illicit and counterfeit drugs, which seem identical to real drugs as per packaging and drug forms, often fail to properly treat the disease or patient condition and can lead to serious health consequences, including severe injury and death.

Counterfeit medicines hugely impact on health and the global economy, and it must distinguish from generic medicines, (a legal medicine which is replication of Branded medicine with same pharmaceutical ingredients) were also discussed in the context of the detention of in transit generic medicines by European Union Customs. In 2017, citing the confusion surrounding substandard and falsified products and the protection of intellectual property rights, the WHO adopted new definitions. The new definitions refer to products which are either:

- ❖ **Substandard:** Also called "out of specification", these are authorized medical products that fail to meet either their quality standards or specifications, or both.
- ❖ **Unregistered/unlicensed:** Medical products that have not undergone evaluation and/or approval by the national or regional regulatory authority for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.
- ❖ **Falsified:** Medical products that deliberately/fraudulently misrepresent their identity, composition, or source.

In the majority of research, quantitative analysis also includes profit driven unauthorized manufacturing, stolen and diverted pharmaceuticals products. This is because, as for any quantitative analysis on illicit markets, drug sourcing, research on trade in counterfeit medicines is largely data driven. Unfortunately, the existing datasets rely on largely incomplete, incompatible, and different methodologies and taxonomies that in some cases also include stolen and diverted goods because of their unproven authenticity and unknown source of origin. Importantly, stolen, and diverted goods enter the market without the consent of the right owners, and in many instances, they also deceive final consumers. Diverted drugs which are not manufactured and authorized to supply specific markets, cause serious threat to patients as it does not create any financial or social liabilities.

II. GLOBAL ECONOMIC IMPACT CAUSED BY COUNTERFEIT DRUGS

Following table summarized the negative economic impacts faced by the healthcare sector due counterfeit and illicit drugs. It reduces the health sector's revenue and capacity to expend on pharmaceutical research and innovation and economic growth. It also forces pharmaceutical manufacturers to reduce their human capital which causes loss of high paying jobs. To assess the precise size of the counterfeit drug market, four potential scenarios are evaluated that are associated with an estimated global counterfeit drug market of \$100 billion, \$200 billion, \$300 billion, and \$431 billion, respectively. (Henry I. Miller & Wayne Winegarden, 2020) [1]

Summary of Annual Economic Costs Due to Counterfeit Drugs

	ESTIMATED SIZE OF GLOBAL COUNTERFEIT DRUG SALES			
	\$100 BILLION	\$200 BILLION	\$300 BILLION	\$431 BILLION
Lost R&D Revenue (billions)	\$17.00	\$34.00	\$51.00	\$73.30
Lost Number of New Drugs	6	13	19	28
Lost Revenue to U.S. Industry (billions)	\$37.60	\$75.20	\$112.80	\$162.10
Lost U.S. Output (billions)	\$82.00	\$163.90	\$245.90	\$353.30
Lost Federal and State Tax Revenue (billions)	\$4.50	\$9.00	\$13.60	\$19.50
Lost U.S. Jobs	57,495	114,990	172,485	247,803

III. GROWTH OF ONLINE ILLICIT AND COUNTERFEIT DRUGS TRADE

According to the 2019 PMMI Business Intelligence White Paper "Senior-Friendly Healthcare Packaging" as many as 19 million Americans purchased medication outside of the secure supply chain, mostly from 50,000 global online pharmacies. A comprehensive study of 11,700 online pharmacies accessible to U.S. customers found that 95% failed to fully comply with laws and industry standards to protect Patients safety and health. PMI also estimated that the counterfeit drug market is growing at an alarming rate of 20% per year which is twice the growth rate of the legitimate pharmaceutical market. (P. 14) (Senior-Friendly Healthcare Packaging) [2]

Most trading activity is believed to take place on the surface web. Some pharmaceutical products are also distributed via dark web platforms. The dark web allows for anonymous transactions between manufacturers, distributors, and consumers. Online pharmacies selling counterfeit medication online typically pose as legitimate vendors. The number of unauthorized and unregulated online pharmacies selling counterfeit pharmaceutical products is continuously growing. (Drug and Darknet, 2017). [10]

FDA issued warning signs that online pharmacies may be unsafe if they posed followings (FDA warning - Risk of online pharmacy) [9].

- Does not require a doctor's prescription.
- Is not licensed in the United States and by your state board of pharmacy.

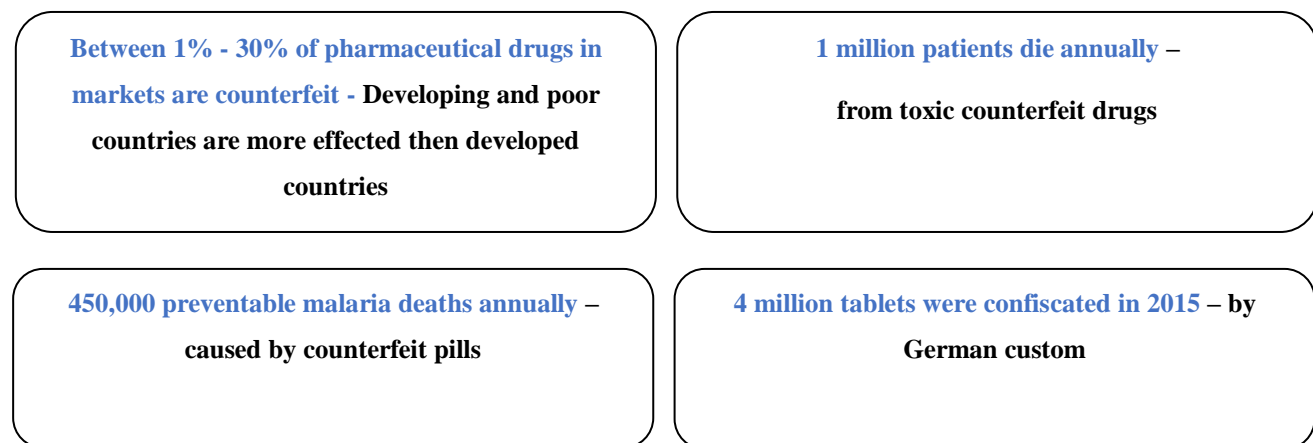
- Does not have a licensed pharmacist on staff to answer your questions.
- Sends medicine that looks different than what you receive at your local pharmacy, or arrives in packaging that is broken, damaged, in a foreign language, has no expiration date, or is expired.
- Offers deep discounts or prices that seem too good to be true.
- Charges you for products you never ordered or received.
- Does not provide clear written protections of your personal and financial information or sells it to other websites.

Counterfeit Pharmaceuticals are widely advertised and offered for sale on social media platforms. These online sales typically involved prepaid credit card or cryptocurrency payments. Online trade offers criminal networks some operational security, including encrypted email traffic and instant messaging applications.

In recent years COVID-19 exposed more opportunities to criminals attempting to circulate counterfeit drugs online. Due to public safety and minimizing the risk of virus spread, Governments and regulatory bodies curb public movement in many instances. The illicit sale of medical and personal protective equipment products has increased significantly in online platforms. In some instances, criminals were able to introduce counterfeit drugs in the legal supply chain. During the pandemic, many false online advertisements have been seen for offering Vaccines and supplementary COVID-19 drugs from unlicensed dealers.

Exhibit -1

Potential health risk by counterfeit drugs. (P.7, Fighting-Counterfeit Pharmaceuticals) [3]



The counterfeit and illegal drug trade is a growing and serious problem for public health. Globalization of drug markets and liberalizing trade policies creates new opportunities for criminals and medicine traffickers to expand their illegal trade and operation to new geographic locations. Illicit trade undermines Government's good policies, national or international laws, public trust deficit in government which ultimately creates political instability. The need of authentic pharmaceutical drugs to save/improve patient lives is utmost important. One side, the Government should make productive procedures and policies to stop counterfeit drugs in high-risk countries. On the other hand, the pharmaceutical industry should adopt sufficient infrastructure to support Government policies and procedures to stop counterfeit drugs from being distributed in the supply chain.

United State of America

Fortune Business Insight [4] estimated that the U.S. pharmacy market is projected to grow from \$560 billion in 2021 to \$861.67 billion by 2028 at a CAGR of 6.3% in forecast period, 2021-2028. There are multifactor for the growth of the pharmacy market including increasing prevalence of disease in the U.S, aging population, and increasing healthcare

expenditures are some of the major factors driving the growth of the pharmaceuticals market in the country. For instance, in 2020, physician offices prescribed around 860 million drugs, and hospital emergency departments provided or prescribed around 336 million drugs. In 2019, an estimated 3.79 billion prescription drugs were billed or dispensed in the U.S.

A larger number of populations prefers doorstep delivery of medical products due to the unavailability of certain products in local drug stores or unavailability of products at reasonable or low cost. In addition, increasing accessibility of the internet boosted the online drug market. As per World Bank Data, in the U.S., around 89% of the population is using the internet. Drug traffickers or potential counterfeit drug manufacturers identify their prospective online buyers through their online search history and propose lucrative prices.

European Union

Counterfeit pharmaceuticals continue to pose “a substantial threat to the EU and affect most, if not all, Member States, (Europol, 2022) [8] according to Europol. The trade of counterfeit pharmaceutical products in the EU has been increasing over the recent year. The number of counterfeit medicines and other goods seized by EU customs authorities reached 1,172,076 units in 2019, entering the top 10 list of seized products by number of articles. The trend was confirmed in 2020 with medicines appearing as the seventh most seized at the EU’s external border. In 2019, India and Singapore were the countries of origin most detected but in 2020 both Singapore and India were replaced by Turkey and lesser extent Vietnam. Iran, Switzerland, and the United State were identified as transit points of fake pharmaceutical products shipped to the EU. Criminals rely primarily on post and parcel services to ship counterfeit drugs which are mainly traded online. Criminals take advantage of weak global supply chain procedures and detection technologies. Free trade zone are also misused to supply counterfeit drugs in EU countries due to non-existence of regressive detection and lighter regulations. (Europol, 2022) [8]

Diversion of legal supplies or stolen drugs has also been observed in the European market. Due to globalization and internet accessibility, physical sales have been shifted to online sales. Online pharmacies are a potential threat to public life as most of a drug’s traceability of origin is either very difficult or non-exist.

As per Europol, the online distribution of fake and substandard goods has been a key criminal activity during the pandemic. The crisis caused by covid-19 has highlighted that criminal organizations recognize no borders and take advantage of the slightest weakness or lack of coordination to strengthen their grip. (Europol, 2022) [8]

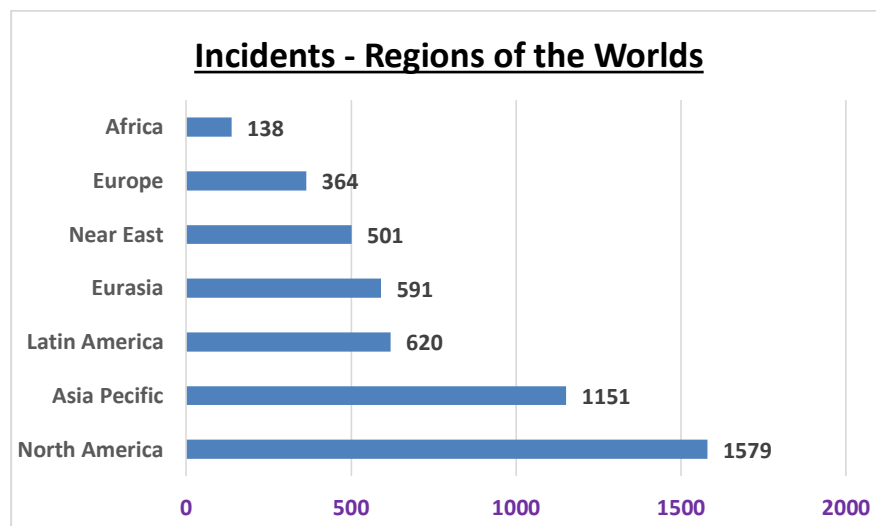
From falsified Lipitor tablets to imitation Viagra and Cialis capsules, counterfeit pharmaceuticals are a €188 billion (US\$200 billion) annual business, making them the largest segment of the €1.6 trillion in fraudulent goods sold worldwide every year. Even in the most developed countries in the world, it’s estimated that at least 1 percent of all drugs in circulation are counterfeit. Authorities confiscated 4 million counterfeit tablets in 2015 in Germany alone. (Fighting-Counterfeit Pharmaceuticals) [3]

Third World countries and others:

Initially it was perceived by the World health Organization that this issue belongs to third-world countries and general perception was also the same. Subsequent findings show that counterfeit drug issues exist globally to a larger extent, and it is a truly global challenge involving both richer and poorer regions of the world. Majority of counterfeit drugs are supplied in developing or poor countries like south Asia and Africa, the proportion of fake pharmaceuticals can rise to 70 percent. Roughly one-third of the world’s countries lack effective drug regulatory agencies, making them easy prey for counterfeiters and criminals. The absence of anti-counterfeiting measures, policies and technologies exposes millions of people to potentially lethal chemicals, contaminations and undermines the growth strategies of companies looking for new markets. More ominously,

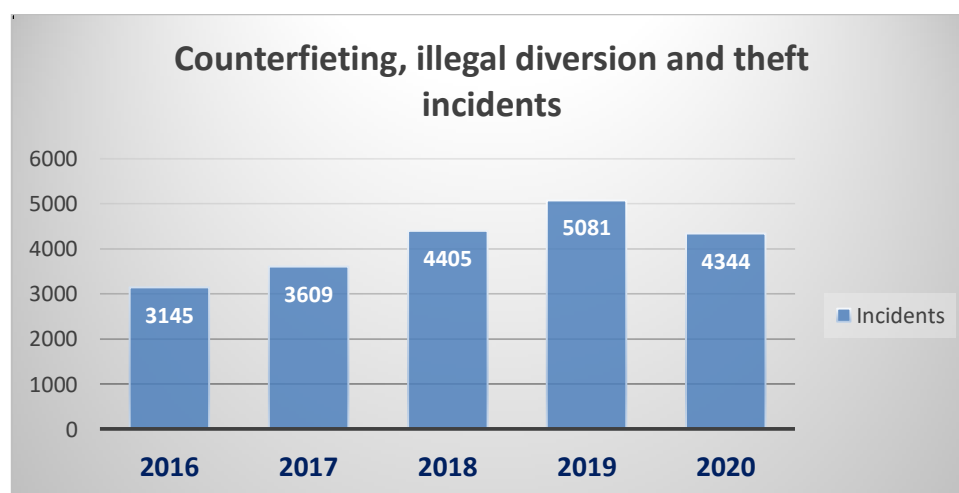
counterfeiters are moving beyond their traditional focus on “lifestyle” drugs, such as remedies for baldness and erectile dysfunction. Research shows that more than half the counterfeit pharmaceuticals sold today are fraudulent versions of treatments for such life-threatening conditions as malaria, tuberculosis, HIV/AIDS, and even cancer. Many instances counterfeit drugs make viruses more drug resistant due to uncontrolled ingredients and substances. Even in developed countries, there are possibilities that people could buy lifesaving drugs from local pharmacies which were previously returned and if the manufacturer didn’t verify the authenticity of the product, then it could be potentially fake. (Sylvester Senyo Ofori-Parku, 2022) [5]

The Pharmaceutical Security Institute’s data on incidents of counterfeiting show that illicit trafficking of medicines in 137 countries increased by 38%, from 3146 in 2016 to 4344 in 2020. The 2020 data involves 2451 different drugs across all therapeutic categories. North America ranked number one among regions with the highest incidents of counterfeit medicine seizures in 2020 (32%), followed by Asia Pacific (23%), Latin America, Eurasia, Near East, Europe, and Africa (3%), in that order. (psi-inc.org, 2022) [7]



Following data shows that

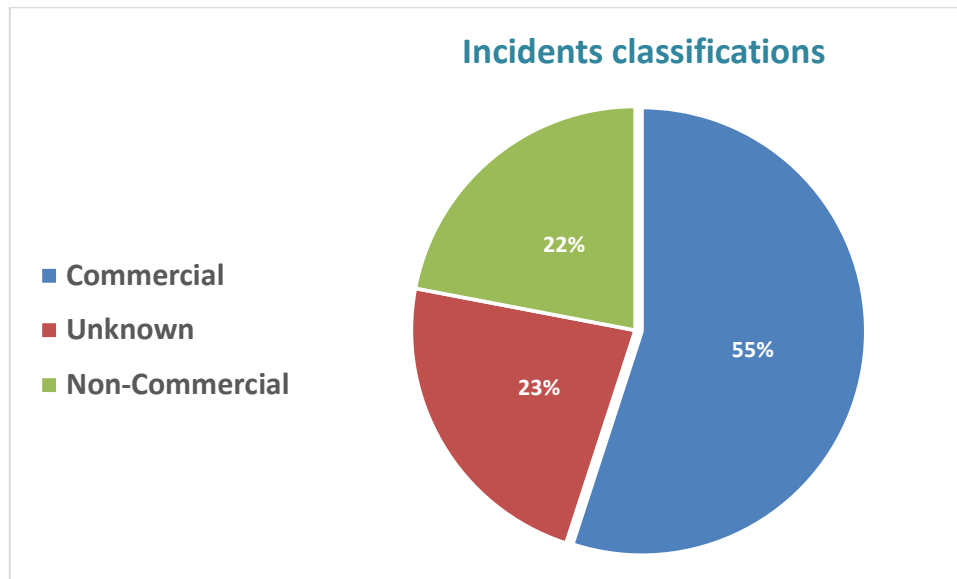
- 4,344 pharmaceutical crime incidents in CY 2020.
- Incidents decreased by fifteen percent (-15%) from CY 2019, the first annual decline in the past ten years.
- The decrease in new incidents can be attributed to the impact of the global pandemic. (psi-inc.org, 2022) [7]



The PSI institute further found that:

- 276 counterfeiting incidents involved either customs seizures or police/health inspector raids

- Seizures decreased by twenty-two percent (-22%) over the prior year.
- Commercial seizures represented fifty-five percent (55%) of the total.
- Twenty-two percent (22%) of the seizures were non-commercial. (psi-inc.org, 2022) [7]



IV. DISCUSSION AND CONCLUSION

Counterfeit medicines are an enormous global health challenge that can be curtailed through laws and regulations, drug seizures, or anti-counterfeiting technologies. The US is a significant market for counterfeit medicines and addressing the demand-side of the challenge is critical. There is an urgent need to execute anti-counterfeit medicines campaigns with tailored messages that tap into consumers' ethical norms, social beliefs, and safety needs. In the United States of America, the Food and Drug Administration (FDA) recommends purchasing medicine only from state licensed pharmacies. As per FDA, the online drug market is a potential threat to expose counterfeit drugs to US consumers. FDA is continuously defining and implementing key provisions of the Drug Supply Chain Security Act (DSCSA). These provisions establish a unique identifier in each drug unit which creates effective traceability in the supply chain. It also mandates the use of tamper proof technology in drug packages to mitigate the risk of adulterating drugs in the market. This will enhance FDA's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. (FDA – Counterfeit medicine) [6]

The European Union enforced their directive "Commission Delegated Regulation (EU) 2016/161" in 2019. Under this directive they made compliance that any prescribed drug supplied in European union member countries must have a unique identifier printed in each unit with 2D barcode. Every unique identifier data printed in each unit, must be uploaded into the European union centralized database. Every supply chain partner's system is connected to an EU centralized database, so they need to verify every physical unit. If a European centralized database does not verify the unit's printed identifier data, then it raises alerts and pharmacies are not allowed to dispense or sell this drug to patients. (Commission Delegated Regulation – 2016/11) [11]

In recent years many similar steps have been taken by Governments and regulatory bodies to prevent counterfeit and suspect products from circulate in the market. New drug traceability technologies and more secure packaging methods are becoming challenges for criminals and counterfeit manufacturers to supply illicit drugs in markets.

V. DECLARATION

Competing Interests.

There are no conflicts of interest that are relevant to this study for the authors of this manuscript.

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