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A Comprehensive Study of the Issue of Fake Drugs in the Indian Market

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ABSTRACT
India has grown to be a significant manufacturer and exporter of pharmaceuticals; the quality of these products and the regulatory environment in the nation are important to both India and the rest of the world. This review's goal was to investigate how blockchain technology might be used to provide a fresh defense against counterfeit drugs. By establishing a transparent and secure health data network, the proposed method aims to efficiently identify and stop the distribution and use of fake medications.Numerous factors, such as the high cost of pharmaceuticals, limited access to healthcare, and a general lack of public understanding, have been connected to the sale of fake and counterfeit medications in India. A report indicates that between 12 and 25 percent of the medications given in India are thought to be counterfeit. India is one of the world's leading producers of fake and counterfeit pharmaceuticals, and it also has a considerable market for them.
Drug counterfeiting must be actively opposed since it poses a harm to society. Although laws, regulatory monitoring, and recurring sample testing to confirm the veracity of label claims are required to enforce country-specific requirements to detect medicine counterfeiting, these regulations vary. Drug counterfeiting has become a worldwide problem. It is impossible for any country to prevent the pharmaceutical sector from selling counterfeit drugs.
Keywords: Counterfeit Drugs, Indian Market, Pharmaceutical industry, Fake medications.

I. INTRODUCTION

The poor therapeutic efficacy of counterfeit or faulty drugs is the primary cause of many deaths. Drug resistance may also result from some of these counterfeit drugs because they were made with inferior ingredients. The industry that makes these dangerous drugs consequently poses a serious risk to public health.Less than 1% to more than 50% of drugs in some developing nations are fake or of lower quality.[1] Poorer countries, such as India and many African nations, are particularly impacted by this problem because attempts to reform the pharmaceutical industry have primarily focused on counterfeit drugs while neglecting inferior pharmaceuticals.Until governments and corporations dramatically cut back on the use of subpar pharmaceuticals in developing nations, there remains a serious human health danger. Pharmaceutical markets are frequently protected by strong and well-supported institutional frameworks in developed nations. Standards bodies mandate acceptable manufacturing practices, while customs authorities guard against the importation of fake goods.These organizations have the strong support of the legal and judicial systems.

A definition of "spurious drugs" can be found in section 17-B of The Drug and Cosmetic Act 1940 and Rules 1945, a significant piece of Indian law that regulates the manufacture, distribution, and use of pharmaceutical compositions.[2]

If a different drug's registered name is used for its production;

It may be misleading if it mimics, substitutes, or looks like another medication in a way that is likely to deceive; if the name of a person or business claiming to be the drug's manufacturer appears on the label or container, but this person or business is either a fake or nonexistent; if it has been partially or completely replaced by another medication or substance; or if it purports to be a product from a manufacturer.

The World Health Organization (WHO) states that a medication is a counterfeit if it is intentionally and dishonestly mislabeled with respect to its identity and/or origin.Counterfeit medications are products with the necessary components but fake packaging, the wrong contents, no active ingredients, or insufficient active ingredients.

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Both branded and generic items are susceptible to counterfeiting. In other cases, drugs that are rejected by manufacturers or authorities may be sold in markets and may be considered counterfeits accordingly.[4]This also applies to drugs that have been repackaged with a fake expiration date after their supply has run out.

In less developed countries, the medications used to treat critical illnesses like HIV/AIDS, malaria, and tuberculosis are usually counterfeit. In developed countries, counterfeiters tend to target more costly and modern pharmaceuticals, including hormones, steroids, anticancer treatments, and psychiatric drugs. 5. The review's goal is to raise awareness of counterfeit medications and the pharmaceutical industry's production of these goods. I recommend a strategy that can effectively monitor counterfeiting.

Pharmaceutical counterfeiting: a worldwide situation

Drug traffickers and criminals have long made their home in the pharmaceutical industry. Large quantities of counterfeit drugs are produced by them and distributed via illicit channels, such as the dark web. The COVID-19 pandemic has expanded the production of counterfeit medications and exacerbated the illegal drug trade due to disruptions, a lack of company resilience, a shortage of skilled resources, and the quick exploitation of technologies.[6]The healthcare business is severely impacted financially by the consequences of illegal and counterfeit pharmaceuticals for supply chain partners. This trade also lowers the health sector's profitability and its ability to finance pharmaceutical research and innovation for economic expansion.To accurately estimate the market's size, four potential scenarios are evaluated, each of which is connected to projected global markets for counterfeit medications of $100 billion, $200 billion, $300 billion, and $431 billion, respectively. Continuous innovation is setting the standard for improving digital drug traceability through the use of blockchain-based applications and advanced manufacturing technology.[7] Material traceability in continuous manufacturing systems is one of the significant aspects of traceability that are being systematically observed and investigated.[8] In the current competitive economic climate of the pharmaceutical industry, traceability is crucial as a crucial differentiator.[9] It improves supply chain operations by cutting waste, preventing counterfeiting, and lowering targeted recalls. It also increases security, resilience, visibility, synchronization, and flexibility.

Counterfeit drugs pose a major risk to public health and patient safety, accounting for 10% of the global pharmaceutical market, according to WHO estimates. Blockchain technology is proposed in this study as a new defense against counterfeit drugs. By establishing a transparent and secure health data network, the proposed method aims to efficiently identify and stop the distribution and use of fake medications.Blockchain technology, which allows tracking of pharmaceuticals from production to patient consumption, can be used to create a robust and dependable pharmaceutical supply chain. This makes it easy to spot fake drugs quickly and prevents them from continuing to be distributed. By using blockchain technology, medicinal supply chain participants may ensure patient safety and validate the authenticity of pharmaceutical products. Furthermore, blockchain technology increases openness and accountability by integrating numerous datasets and stakeholders.

The state of drug counterfeiting around the world is not good.[10] The outcomes include increased drug resistance, possible mortality risks from critical illness drugs, and similar consequences. WHO data research claims that 10% of medications in developing and disadvantaged countries are fake.[11] A geographic review of the detrimental health impacts of ingesting fake drugs revealed that over 56% of 48 incidents, which resulted in about 3600 recorded fatalities, started in developing countries. On the other hand, because it enables them to secretly buy any unlawful or restricted substance using cryptocurrency, the dark web is extensively utilized by criminals worldwide.Both the buyer and the vendor are strangers who use a VPN to hide their identities online. Cyber laws are necessary to monitor the illicit drug trade online in some countries.[13] After three years of investigation, a four-person group was convicted of drug trafficking in the UK via the dark web. The availability of counterfeit drugs is higher in emerging and undeveloped countries with low living standards and less regulation of manufacturing, distribution, supply, and sale management.[14]

The term "digital intervention" refers to the employment of digital technology, including wearables, computers, smartphones, software, and applications. The use of these digital technologies has enhanced and simplified our lives by providing a multitude of services.[15] Furthermore, a digital system needs to be successful, efficient, and user-satisfying in order to be accepted or embraced in

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our daily lives.[16] Therefore, it is essential to preserve a healthy balance between digital intervention functionalities and human requirements, perceptions, and behaviors. To sustain a positive relationship with a system's capital management, human resources, and productivity, digital interventions are believed to be a more economical strategy that requires fewer personnel and physical space to execute.[17]Pharmaceuticals that are most frequently falsified or counterfeit are antibiotics and antimicrobials, which made up 28% of the global market in 2012.[18] The ratio has been rising over time; between 2014 and 2016, antibiotics accounted for 36% of all counterfeit drugs that customs officials recovered globally.[19]Beta-lactams, anti-folates, antiretrovirals, antimalarials, and other essential medications were the most commonly counterfeited, per a 2020 study.[20] Amoxicillin counterfeiting was documented in 29 nations, ampicillin counterfeiting in 17, tetracycline counterfeiting in 11, and trimethoprim-sulfamethoxazole counterfeiting in 10.[20]According to earlier studies, early-generation antibiotics like tetracyclines and penicillins were the most often counterfeited and copied medications.[21]

Despite their global presence, some countries and regions are more commonly associated with the production and distribution of illicit drugs. Although Southeast Asia, which includes countries like Myanmar and Cambodia, does not produce many pharmaceuticals, it is known to be a significant supplier of counterfeit and phony medications. The problem impacts regional areas and crosses national borders, with the Mekong being of special concern.[22] Antimalarials and medications that are fake or counterfeit present unique challenges and risks for foreign tourists visiting Southeast Asia, particularly when visiting regions where malaria is endemic.[23]

There is a significant need for antiretrovirals, antibiotics, and antimalarials since infectious diseases are so common in Sub-Saharan Africa. This has led to the widespread availability of counterfeit and forged versions of these medications.[24] Numerous instances of fake medications have been reported in Tanzania, Uganda, Nigeria, and the Democratic Republic of the Congo (DRC).[25]

An average of only 24% of Artemisinin-based Combination Treatment (ACT) medications were quality-assured, while 25% were not, according to a 2009–2015 study on about 336,000 antimalarial drugs in 49,500 medical facilities across eight African countries. The majority of the non-quality-assured drugs were sold in private sector establishments, and they were uncommon (less than 10%) in public sector settings.However, some countries stood out from the rest. For example, Zambia had 85% of these medications in public sector settings, while the Democratic Republic of the Congo (DRC) had 39% of non-quality-assured medications in public sector settings. Zambia's public sector still has a sizable percentage of non-quality-assured pharmaceuticals, even with the involvement of foreign contributors. This may have something to do with supply chain management and drug procurement issues.The public sector's supply of non-quality-assured medications is decreased in other circumstances, such as when international aid and procurement practices, which frequently adhere to international quality-assurance standards, are implemented.[26]

The majority of the fake and counterfeit drugs found worldwide in 2006 (54%) were produced in India.[27] 75% of them are of Indian descent, per a more recent survey.[28] Most illicit manufacturers in India produce subpar or counterfeit generic medicine copies, which can then enter the global pharmaceutical supply chain.[29] A research on counterfeit drugs in Myanmar found that 20.5% of the drugs offered in Mandalay pharmacies were either fake or of poor quality, while 75.8% of the drugs were of Indian origin.[30] India has a complex pharmaceutical business with a mix of well-known manufacturers and unlicensed manufacturing facilities, making it challenging to monitor and control.[31] The high cost of pharmaceuticals, limited access to healthcare, and a general lack of public understanding are some of the factors that have been connected to the sale of counterfeit and phony drugs in India.[32]

Indian drug counterfeiting

India's highly knowledge-based pharmaceutical industry is growing quickly and making a substantial economic contribution to the nation. India has the fourth-largest pharmaceutical industry in the world in terms of output volumes, and over half of its exports are to countries with stringent restrictions. India exported $14.6 billion worth of drugs in the fiscal year that ended on March 31, 2012, or roughly Rs. 82, 730 crore. One of the best examples of a developing country with a strong pharmaceutical industry and an effective drug regulation system is India.Between 12 and 25 percent of all drugs delivered in India are thought to be counterfeit, per a report. India is one of the

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world's leading producers of such products and has a substantial market for fake and counterfeit pharmaceuticals (IMPACT). In India, the health ministry believes that 5% of pharmaceuticals are counterfeit and 0.3% are erroneous. New Delhi's "Bhagirath palace" Chandni Chowk is thought to be the epicenter of India's drug traffic in fake and counterfeit items.Fake drugs make about 20% of India's 40,000 crore pharmaceutical industry. Previously restricted to pricy and uncommon drugs like Viagra, this has recently expanded to include cough syrups, painkillers, and vitamin supplements.[33] A major location for the manufacture of fake and counterfeit drugs is India, which is the world's largest manufacturer of generic pharmaceuticals. Bihar, West Bengal, Uttar Pradesh, and Gujarat have the highest local market rates of fake and counterfeit drugs in India.[33] The primary countries from which European customs authorities confiscate counterfeit goods are China, India, and the United Arab Emirates.[34]

India's position on fake pharmaceuticals

India has the third largest pharmaceutical industry globally in terms of volume, accounting for 10% of worldwide production. India exports to more than 200 countries and is the world's top producer of generic drugs and vaccines. In terms of exporting these fake drugs, India is also the nation that makes the most of them. According to multiple sources, India is the main supplier of counterfeit drugs that are found, followed by China, and most of them are tracked back to their original location. Twenty to thirty percent of Indian medications were discovered to be fake, per a 2017 WHO investigation.Samples were collected and examined from all over the nation to compile this data. Because India lacks the regulations required to regulate the manufacture and sale of pharmaceuticals, those found guilty receive light sentences compared to their earnings and no serious legal action is taken against them, which encourages the creation of fake drugs. Medication samples that are found to be fraudulent or non-standard may result in ten years in prison, according to the Drugs and Cosmetics (Amendment) Act.Guidelines have therefore lately been developed for the handling of these samples. The use of these drugs is also having an increasing influence on people, hence steps must be taken to prevent the manufacture of counterfeit drugs. The number of drug-related deaths is only estimated; a precise number is not known because the majority of emerging markets lack efficient methods for determining the quantity of counterfeit medications available on the market. Consequently, counterfeit medications unintentionally become available in the marketplace where they are sold, putting the drug users at risk.[35]

Internet/online pharmacies and counterfeit pharmaceuticals

A study in The Lancet claims that the rise of online pharmacies has contributed to the globalization of counterfeit drugs. The WHO claims that nearly half of drugs sold online are fake. These statistics are appalling to patients, governments, and pharmaceutical companies alike.[36] In the USA, the National Association of Boards of Pharmacy (NABP) polled 10,000 online pharmacies and found that 9938 of them disobeyed both federal and state regulations as well as NABP's requirements for pharmacy practice and patient safety. This is not exclusive to developing countries.A separate survey of UK physicians found that 25% of patients who report adverse drug reactions purchased the medication online.[37] A study was conducted to ascertain what percentage of Viagra sold online is authentic. Reports indicate that the majority of online ViagraTM transactions were fraudulent. In as many as 77% of orders, fake ViagraTM was sent through websites that claimed to sell the genuine drug; these copies typically originated outside of the United States and had just 30–50% of the active pharmacological ingredient listed on the label.

With FDA permission, "generic Viagra" was advertised on 91% of the tested websites.[38] Research on the non-medical use of prescription pharmaceuticals outside of the United States of America in five European nations (Denmark, Germany, the United Kingdom, Spain, and Sweden) found that sedatives (2.7%), opioids (4.1%), and stimulants (7.6%) were commonly bought online without a prescription under a doctor's supervision.[39] To combat the growing menace of trafficking in counterfeit drugs through rogue online pharmacies, strict measures must be put in place.To control the purchase of medications online, collaboration between state, federal, and international authorities is required, as well as between patients and healthcare providers.

COVID-19's effects on medication counterfeiting

The current COVID-19 pandemic, which has wreaked devastation around the globe, has helped the illegal market for fake medications, which is already a significant threat.An alarming increase of COVID-19 cases led to this, which in

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turn increased demand for a range of drugs, kits, and protective gear. The restricted ability of law enforcement officials to regulate also had a role in supply chain interruptions.[40]The WHO issued a warning about the risks of counterfeit vaccination doses as soon as talks to create a vaccine to mitigate the adverse effects of COVID-19 started. Vaccine supply networks will surely become a target for counterfeiters, according to Jürgen Stock, general secretary of Interpol, who referred to vaccinations as the "liquid gold" in 2021. Numerous reports of individuals being arrested and incarcerated in relation to the global sale and distribution of fake COVID-19 vaccines validated this concern. There have been claims that Mexico and Poland were selling Pfizer vaccines for up to $1000.[41] Fraudulent COVID-19 test certificates, masks, vaccines, and drugs totaling $3.5 million were found in southern Africa by Interpol. According to another research, the illegal drug industry was predicted to have expanded by about 400% by the end of 2021.[41]It provides counterfeiters with an opportunity to benefit from the quickly rising demand for vaccines against a variety of diseases, including the hard-to-prevent COVID-19 virus. There are other products that can be faked besides vaccines. The market was filled with counterfeit goods, including face masks, PPE kits, N95 masks, gloves, sanitizers, and diagnostic kits, in addition to prescription drugs including vitamin C, antivirals, chloroquine, and paracetamol.[42] COVID-19 put an extreme strain on healthcare systems, even in industrialized countries. Drugs like hydroxychloroquine (HCQ), which were believed to be effective against COVID-19, were highly restricted in the majority of countries, including the United States. India initially forbade the export of HCQ because of a shortage, but after sending 50 million HCQ pills to the US, the ban was later lifted.[43] Finding a provider was difficult for those who frequently used HCQ for lupus and arthritis because of the acute shortage. Several instances of Remdesivir being sold in India involved the substitution of saline or even liquid paracetamol for the drug's empty bottles.

Additionally, it was found that Remdesivir was being sold in India in fake batches. Dexamethasone was another drug that Indian regulatory authorities found to be widely counterfeit during COVID-19. A study found that the range of low-quality dexamethasone in LMICs was 3.14 to 32.2%. 44. Because COVID-19 disrupted the global supply chain, it also had a major role in the increase in counterfeit drugs.This interruption was mostly caused by export restrictions and border closures in countries like China and India, which generate the majority of raw materials and active pharmaceutical components. During the outbreak, counterfeiters were able to greatly expand their market share in the countries that depended on these items because to shortages in those countries.[45]

Causes of growth

Numerous factors have contributed to the growth of the drug counterfeiting industry in India, including the growing pharmaceutical sector, lax pharmaceutical regulation, high drug costs, value-added tax, prescription drugs written without registration, low public awareness, lax law enforcement, and flexibility in the current legal system. The drug-counterfeiting business in India is very lucrative.The reputation of India as a hub for low-cost manufacturing has made it easier for counterfeiters to enter the country. Counterfeiters are able to generate substantial profits even though they are exempt from the high R&D costs associated with legitimate enterprises. Drug counterfeit detection is a costly and challenging procedure. Consumers are unable to discern between authentic and counterfeit products, and sometimes even doctors who prescribe them are in this predicament.If a patient consumes the fake and recovers on their own, for example, there is no need to be concerned about a bogus product. Drug counterfeiters are increasing in number.
using state-of-the-art technical tools to become proficient in their illegal activity. Researchers recently examined the prevalence of inactive ingredients in counterfeit anti-malarial medication Artesunate. Between 2001 and 2005, they discovered that counterfeiters had significantly improved their use of complex printing methods, such as holograms. Criminals frequently produce and sell counterfeit or fake drugs as an alternative to genuine medications when there is a discrepancy between the supply and demand for pharmaceuticals. This allows them to profit from their crimes.

Furthermore, drug abusers usually generate demand for drugs, which may originate from illegal sources. For example, due to weight supplements, a market for counterfeit drugs containing steroids has emerged. These drugs are usually sold for astronomical prices on illegal markets or through unregulated channels.Drugs produced domestically are not always regulated to the same standards as those produced for export by the host country in many exporting nations.

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Additionally, narcotics are sometimes exported through Free Trade Zones (FTZs), which complicates drug management and encourages relabeling and repackaging. This type of careless trade system gives counterfeiters a better chance of getting illegal drugs into the supply chain, even in marketplaces with strict controls.Regulations and legislation are the cornerstone of drug control. The nation's pharmaceutical manufacture, import, distribution, and sale must be regulated by a competent national drug regulatory authority that has the resources necessary. A WHO evaluation estimates that 20% of the 191 member states have complex drug laws and regulations.

Fifty percent enforce drug regulation at different levels, whereas thirty percent have either little or no drug control in place or very little that is realistically functional.Uncontrolled drug imports, production, and distribution—which are facilitated by inadequate, ineffectual, or weak drug regulatory oversight—are the root cause of the growth of counterfeit drugs through legal distribution channels. [46]

The function of IPR

Changes have occurred in the Indian pharmaceutical industry after the country joined the World Trade Organization (WTO) and decided to implement TRIPS (Trade Related Aspects of Intellectual Property Rights). Globally, the laws governing intellectual property have undergone substantial modifications that have an impact on India's pharmaceutical industry. The 1970 patent law has accelerated the growth of the Indian generic drug industry. India became a significant player in the manufacturing, distribution, and marketing of pharmaceuticals, including patented medications, between 1970 and 2005 due to the age of process patents.[47]

India became the world's largest supplier of generic drugs and APIs (active pharmaceutical ingredients) as a result.[48] The Indian pharmaceutical industry saw substantial changes as a result of the liberal procedural patent environment, which reduced the cost of medications and made them widely accessible. Local Indian businesses started to copy their methods for producing medications by developing their own and securing patents for them. Businesses in India were permitted to export their fake goods to countries that accepted international patents at the time.On January 1, 2005, Indian pharmaceutical companies were mandated to implement a patent system that complied with TRIPS, ushering in a new era of product patents. This implied that they needed a license from the patent owners in order to manufacture or sell medications that were protected by copyright. In this era of product patents, India's generic pharmaceutical industry, which had prospered on process patents, was no longer allowed to do so.Although this law limited the Indian pharmaceutical industry's capacity to manufacture generic drugs, it also made it simpler to obtain funds for the research and development of new drugs. A growing trend in public involvement, awareness, patenting, and patent enforcement characterizes this era in the Indian pharmaceutical sector. In India, pharmaceutical companies account for around 30% of trademark and patent applications and grants.[49]

The role of pharmacists and consumers

In the battle against medicine counterfeiting, end consumers and pharmacists are crucial allies. These individuals have direct contact with the medication suppliers. Ensuring that patients and pharmacists are aware of the problem of counterfeiting and how to tell the difference between genuine and phony pharmaceuticals is therefore essential. Patients should buy their drugs from trustworthy vendors and avoid using questionable online pharmacies, since reports suggest that most counterfeit items are sold through these untrustworthy internet pharmacies.If the patient notices any changes in the way the drug looks, tastes, or affects them, they need to contact the doctor or pharmacist immediately. Pharmacists must confirm the legitimacy of the sources of their medications and that they have been approved by the appropriate drug regulatory agencies. Pharmacists are advised to keep product records in order to ascertain the traceability of medications or medical devices.For the patient's safety, this is essential. The pharmacist also has a critical responsibility to report any suspected or verified instances of drug counterfeiting to the proper authorities.[50]

The function of pharmaceutical firms

There are now available reports that show pharmaceutical companies lose more than $200 billion annually as a result of medicine counterfeiting.[51] Pharmaceutical companies devote years of effort and substantial resources to the creation of new medications. RCTs ensure adherence to stringent safety procedures. Thus, pharmaceutical companies losing money is one consequence of drug counterfeiting.

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To prevent the same, businesses must fight counterfeiting at its source, which includes regulatory bodies, distributors, wholesalers, and the pharmacy community. Only Pfizer verified that 104 drugs in 116 different nations were counterfeit.[52]

Viagra, a well-known drug for erectile dysfunction, is the most frequently counterfeited drug. The Pfizer drug Lipitor (atorvastatin) is another one that is frequently counterfeited. To prevent medicine falsification, pharmaceutical manufacturing companies, packagers, regulatory bodies, and primary and end consumers have a shared responsibility. Combating the threat of drug counterfeiting could involve a few different strategies.

First, companies should focus on raising awareness among ultimate consumers, pharmacists, and doctors. Pfizer has launched an awareness-raising campaign to highlight counterfeit goods in an effort to identify, thwart, and deter leading manufacturers and retailers of their medication imitations.[53] The integrity of the pharmaceutical supply chain ought to be a top concern for companies. Companies must make sure that their supply chain is out of reach for counterfeiters. A specialized staff must be formed within the company to protect the goods at warehouses, manufacturing plants, during shipment, and at the point of customer contact.[54] To ensure supply chain security, this procedure must be carefully considered.The businesses can use smart packaging that integrates artificial intelligence (AI) into QR codes. Furthermore, Near-Field Communication (NFC) and Radiofrequency Identification (RFID) are popular digital tags that give a medication a distinct identity. Pharmaceutical companies can view their products at every point in the supply chain thanks to a feature called track-and-trace, which is made possible by these IDs, which also carry product data.[54]

Regulations in India

Drug counterfeiting is prohibited in India by the Drug and Cosmetics Act 1940 and Rules 1945.

- More severe penalties have been issued, along with guidelines for dealing with drug samples that are judged to be fraudulent or of inferior quality.
- A reward scheme for anyone who come forward to reveal fraud in the medical device, cosmetic, and pharmaceutical sectors.
- Procedure for Putting in Place a Track and Trace System for Exporting Drug Formulations.[55]

Inadequate regulation in India

- A WHO investigation revealed that 10% of medications are fraudulent. A total of 1500 instances have been reported since 2013, however many cases before that year remained unreported. In accordance with the Director-General of Foreign Trade's (DGFT) order, a barcoding system ought to be implemented for pharmaceuticals exported from the country.
- The manufacturers must upload the drug product's data to the central system in order for it to be tracked.
- The necessity that barcodes be affixed in order to enable product monitoring is therefore the main flaw in Indian regulations relating to the export of products.[56]

Methods for avoiding counterfeit medications

Drug counterfeiting can be prevented using a variety of strategies available on the market. Nonetheless, given the recent surge in medicine counterfeiting, this article has discussed two tactics that the pharmaceutical sector can use. The methods used to stop drug counterfeiting could be drastically changed by these tactics. The Indian healthcare sector should also use this approach.[56] Adoption of Blockchain technology and serialization are more beneficial.

Impacts of counterfeit medications on the economy

The economic cost of counterfeit drugs stems from a rise in drug resistance, adverse drug reactions, and morbidity. Deaths and illnesses are on the rise, which can lead to missed business opportunities. Businesses who have invested in drug quality, research, and development will suffer as a result of the sale of counterfeit pharmaceuticals, which will undermine sales of genuine medications. Additionally, it may deter companies from investing in R&D and foreign investment.There is also a significant loss of tax revenue for the government.Significant financial resources must also be allocated to protecting the drug supply chain and creating systems that can recognize counterfeit medications. As was already mentioned, selling fake drugs could lead to additional fines and the exclusion of Indian companies from other countries.[59]

Drug fraud and pharmacovigilance

Unprompted reporting of adverse drug reactions (ADRs) and the subsequent analysis of their cause are essential components of pharmacovigilance programs. Based on the premise

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that the suspected pharmaceutical formulation has all the appropriate ingredients in the amounts indicated on the label, several processes are initiated. A high prevalence of counterfeit drugs would alter findings from causality analysis, such as incorrectly attributing adverse drug reactions to specific active ingredients.To keep patients from misplacing vital prescriptions, care must be taken to avoid becoming "over vigilant." When evaluating pharmacovigilance programs, the possibility of counterfeit drugs must be considered. Workers engaged in pharmacovigilance, in particular, must be alert for fake drugs when they see odd or unexpected side effects.The source (the internet, a dealer, a pharmacy, etc.) needs to be questioned, and any doubts should be mentioned in the report along with the justifications for them. However, it would be challenging to monitor each prescription medication that is given out.[60]

II. CONCLUSION

Drug counterfeiting poses a hazard to society and must be actively addressed. Although rules to prevent medicine counterfeiting vary by country, regulatory oversight and recurring sample testing to confirm the veracity of label claims are required to enforce these laws. In addition to being prohibited by intellectual property regulations like the Trademark Act of 1999 and the Patents Act of 1970, drug counterfeiters in India may also be subject to criminal penalties under the Indian Penal Code of 1860 and the Drugs and Cosmetics Act of 1940.In order to avoid drug counterfeiting, this overview explains the role of each stratum and relevant information. The evaluation suggests that healthcare providers educate primary and end users about the differences between authentic and fake pharmaceuticals. It also suggests that end users take the initiative to recognize and report any changes in the prescriptions they take. It highlights how important it is for supply chain management to change and become more open in order to prevent manufacturers from introducing counterfeit drugs into the market.

The study concluded with a discussion on the need for governments and international organizations to create important national and international regulations and make sure they are strictly followed in order to curb the rising number of drug fabrication cases. Additionally, more investigation is needed to determine the exact proportion of fake medications that are bought with valid prescriptions as opposed to those that are bought from dubious online pharmacies.When various national governments require the implementation of contemporary technologies, it is a positive step in the battle against counterfeiting. To effectively prevent medicine counterfeiting, governments, pharmaceutical companies, and regulatory agencies need to work together to develop a cohesive strategy.

REFERENCES

[1]. Bate R. Fatal pharmaceuticals: the Indian counterfeit drug market. Georgetown Journal of International Affairs. 2010:125-30.
[2]. Anon. The Drugs and Cosmetics Act, 1940. Act no. 23 of 1940. http://www.vakilno1. com/ba reacts/drugs and cosmetics act/drugsandcosmeticsact.htm.
[3]. World Health Organization. World Health Organization fact sheet 275. Revised 2006 February. http://www.who.int/mediacentre/factsheets/fs275/en/ (accessed Feb 2007)
[4]. Wertheimer AI, Chaney NM, Santella T. Counterfeit pharmaceuticals: current status and future projections. Journal of the American Pharmacists Association. 2003;43(6):710-8.
[5]. JA R. Fake antimalarials circulating in Cambodia. Bull Mekong Malaria For. 2000;7:62-8.
[6]. Billups M, Singh R. Systematic framework for implementation of material traceability into continuous pharmaceutical tablet manufacturing process. Journal of pharmaceutical innovation. 2020;15:51-65.
[7]. Kumar G. Critical success factors of adopting an enterprise system for pharmaceutical drug traceability. Universal Journal of Pharmacy and Pharmacology. 2023:3-10.
[8]. Gopal G, Suter-Crazzolara C, Toldo L, Eberhardt W. Digital transformation in healthcare-architectures of present and future information technologies. Clinical Chemistry and Laboratory Medicine (CCLM). 2019;57(3):328-35.
[9]. Kumar G. Securing pharmaceutical supply chain using digital drug serialization. World Journal of Advanced Engineering Technology and Sciences. 2023;10(1):015-20.
[10]. Nayyar GM, Breman JG, Mackey TK, Clark JP, Hajjou M, Littrell M, et al. Falsified and substandard drugs: stopping the pandemic. The American journal of tropical medicine and hygiene. 2019;100(5):1058.
[11]. Rahman MS, Yoshida N, Tsuboi H, Tomizu N, Endo J, Miyu O, et al. The health consequences of falsified medicines-a study of the published literature. Tropical Medicine and International Health. 2018;23(12):1294-303.

International Journal of Pharmaceutical Research and Applications
Volume 10, Issue 3 May-June 2025, pp: 2241-2250 www.ijprajournal.com ISSN: 2456-4494

[12]. Degeneve C, Longhi J, Rossy Q. Analysing the digital transformation of the market for fake documents using a computational linguistic approach. Forensic Science International: Synergy. 2022;5:100287.
[13]. Chawki M. The Dark Web and the future of illicit drug markets. Journal of Transportation Security. 2022;15(3):173-91.
[14]. Islam MN, Inan TT. Exploring the fundamental factors of digital inequality in Bangladesh. Sage Open. 2021;11(2):21582440211021407.
[15]. Zaman A, Islam MN, Zaki T, Hossain MS. ICT intervention in the containment of the pandemic spread of COVID-19: An exploratory study. arXiv preprint arXiv:2004.09888. 2020 Apr 21.
[16]. UNICEF. Designing Digital Interventions for Lasting Impact: a Human-Centred Guide to Digital Health Deployments. Report, 2018.
[17]. Griffiths F, Lindenmeyer A, Powell J, Lowe P, Thorogood M. Why are health care interventions delivered over the internet? A systematic review of the published literature. Journal of medical Internet research. 2006;8(2):e498.
[18]. Delepierre A, Gayot A, Carpentier A. Update on counterfeit antibiotics worldwide; public health risks. Medecine et maladies infectieuses. 2012;42(6):247-55.
[19]. Illicit Trade (Ed.),Trade in counterfeit pharmaceutical products, OECD Publishing Paris (2020)
[20]. Kelesidis T, Falagas ME. Substandard/counterfeit antimicrobial drugs. Clinical microbiology reviews. 2015;28(2):443-64.
[21]. Wondemagegnehu E. Counterfeit and substandard drugs in Myanmar and Viet Nam. WHO Report. WHO/EDM/QSM. 1999;99.
[22]. Islam MR, Yoshida N, Kimura K, Uwatoko C, Rahman MS, Kumada S, Endo J, Ito K, Tanimoto T, Zin T, Tsuboi H. An investigation into the quality of medicines in Yangon, Myanmar. Pharmacy. 2018;6(3):96.
[23]. Nayyar GM, Breman JG, Newton PN, Herrington J. Poor-quality antimalarial drugs in southeast Asia and sub-Saharan Africa. The Lancet infectious diseases. 2012;12(6):488-96.
[24]. Atukunda EC, Anne F. An Evaluation of Factors Affecting Drug Quality: Evidence from the Antimalarial Market in Uganda.
[25]. Kamba PF, Ireeta ME, Balikuna S, Kaggwa B. Threats posed by stockpiles of expired pharmaceuticals in low-and middle-income countries: a Ugandan perspective. Bulletin of the world health organization. 2017;95(8):594.
[26]. Newton PN, Hanson K, Goodman C. Do anti-malarials in Africa meet quality standards? The market penetration of non quality-assured artemisinin combination therapy in eight African countries. Malaria journal. 2017;16:1-21.
[27]. Swaminath G. Faking it - I The Menace of Counterfeit Drugs. Indian J Psychiatry. 2008;50(4):238-40.
[28]. Verma S, Kumar R, Philip PJ. The business of counterfeit drugs in India: A critical evaluation. International Journal of Management and International Business Studies. 2014;4(2):141-8.
[29]. Shukla N, Sangal T. Generic drug industry in India: the counterfeit spin.
[30]. Sakuda M, Yoshida N, Takaoka T, Sanada T, Rahman MS, Tanimoto T, et al. Substandard and falsified medicines in Myanmar. Pharmacy. 2020;8(1):45.
[31]. Mamtashanti M, Rahul J, Kashyap T. A Review on Regulatory Requirements to Prevent Counterfeit Drugs in India. International Journal of Pharmaceutical Investigation. 2020;10(3).
[32]. Khan AN, Khar RK. Current scenario of spurious and substandard medicines in India: a systematic review. Indian journal of pharmaceutical sciences. 2015;77(1):2.
[33]. The alternative (2011), "Pharma secure: Fighting fake drugs in India", available at: http://thealternative.in/social-business/pharma-secure-fightingfake-drugs-in-india/
[34]. Reynolds L, McKee M. Organised crime and the efforts to combat it: a concern for public health. Globalization and health. 2010;6:1-3.
[35]. Times of India. Counterfeit medicines kill more people than terror: CBI chief. 2015. Available from:https://timesofindia.indiatimes.com/india/Counterfeit-medicines- kill-more-people-than-terror-CBI-chief/articleshow/47808588.cms.
[36]. Clark F. Rise in online pharmacies sees counterfeit drugs go global. The Lancet. 2015;386(10001):1327-8.
[37]. Novak SP, Håkansson A, Martinez-Raga J, Reimer J, Krotki K, Varughese S. Nonmedical use of prescription drugs in the European Union. BMC psychiatry. 2016;16:1-2.
[38]. Campbell N, Clark JP, Stecher VJ, Goldstein I. Internet-ordered viagra (sildenafil citrate) is rarely genuine. The journal of sexual medicine. 2012;9(11):2943-51.
[39]. Fincham JE. Negative consequences of the widespread and inappropriate easy access to purchasing prescription medications on the

internet. American Health and Drug Benefits. 2021;14(1):22.
[40]. Ranney ML, Griffeth V, Jha AK. Critical supply shortages-the need for ventilators and personal protective equipment during the COVID-19 pandemic. New England Journal of Medicine. 2020;382(18):e41.
[41]. Srivastava K. Fake covid vaccines boost the black market for counterfeit medicines. bmj. 2021;375.
[42]. Ziavrou KS, Noguera S, Boumba VA. Trends in counterfeit drugs and pharmaceuticals before and during COVID-19 pandemic. Forensic Science International. 2022;338:111382.
[43]. India lifts export ban on hydroxychloroquine. 2020. https://www. thehi ndu. com/ news/ natio nal/ india- lifts- export- ban-onhydroxychl oroqu ine/ artic le318 06635. ece.
[44]. Borse NN, Cha J, Chase CG, Gaur R, Koduri CK, Kokai-Kun JF, et al. Responding to the surge of substandard and falsified health products triggered by the COVID-19 pandemic. Rockville, MD: United States Pharmacopeia (USP). 2021 May.
[45]. Mackey TK, Liang BA, York P, Kubic T. Counterfeit drug penetration into global legitimate medicine supply chains: a global assessment. The American journal of tropical medicine and hygiene. 2015;92(Suppl 6):59.
[46]. Reynolds L, McKee M. Organised crime and the efforts to combat it: a concern for public health. Globalization and health. 2010;6:1-3.
[47]. Chandran S, Roy A, Jain L. Implications of new patent regime on Indian pharmaceutical industry: Challenges and opportunities.
[48]. Nair, M.D. "TRIPS, WTO and IPR: Counterfeit Drugs", Journal of Intellectual Property Rights, 2010:15; 380-2.
[49]. Nair, "Impact of TRIPS on Indian pharmaceutical industry", Journal of Intellectual property rights. 2008:13; 32-441
[50]. Chambliss WG, Carroll WA, Kennedy D, Levine D, Moné MA, Ried LD, et al. Role of the pharmacist in preventing distribution of counterfeit medications. Journal of the American Pharmacists Association. 2012;52(2):195-9.
[51]. Blackstone EA, Joseph PF, Pociask S. The health and economic effects of counterfeit drugs. Am Health Drug Benefits. 2014;7(4):216.
[52]. Pfizer's Role In Combatting Fake Medicine. https://www.pfizer.com/ products/medic ine-safety/counterfeiting. 2023.
[53]. Counterfeit awareness campaign. https://www.pfizer.com/counterfeiting/ counter f eita wareness campaign. 2023
[54]. Three strategies to combat counterfeit drugs and other pharma supply chain threats. 2022. https:// health. econo micti mes. India times. com/ news/ pharma/ three- strategies- to-combat- counterfeit drugs-and- other- pharma-supply- chain.
[55]. Pharmaceutical Security Institute. 2020. Available from: http://www.psi-inc.org/cou nterfeitSituation.cfm.
[56]. Chokshi M. Mongi R, Wattal V. Indian council for research on international economic relations" Drug Quality and Safety Issues in India Working Paper 310. 2020.. Available from: https://icrier.org/pdf/Working_Paper_310.pdf.
[57]. El-Jardali F, Akl EA, Fadlallah R, Oliver S, Saleh N, El-Bawab L, Rizk R, Farha A, Hamra R. Interventions to combat or prevent drug counterfeiting: a systematic review. BMJ open. 2015;5(3):e006290.
[58]. Mamtashanti M, Rahul J, Kashyap T. A Review on Regulatory Requirements to Prevent Counterfeit Drugs in India. International Journal of Pharmaceutical Investigation. 2020;10(3).
[59]. Blackstone EA, Fuhr Jr JP, Pociask S. The health and economic effects of counterfeit drugs. American health and drug benefits. 2014;7(4):216.
[60]. Cobert BL. Manual of drug safety and pharmacovigilance.Jones and Bartlett Publishers, 2011 -Medical - 407 pages