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Review Article

The Challenge of Counterfeit Drugs in Indian Market: A Comprehensive Review

Vikram Rameshrao Khangan[1], Rupali Hemant Tiple[2,*]

[1]Entrepreneur, Atlas Enterprises, Nagpur, Maharashtra, INDIA.
[2]Shree Babasaheb Gharfalkar, College of Pharmacy, Nachangaon, Pulgaon, Wardha, Maharashtra, INDIA.

ABSTRACT

India has become a major producer and exporter of medicines and drugs, the quality of pharmaceuticals produced here and the country's regulatory frameworks are crucial for both India and the rest of the globe. The objective of this review was to study the use of blockchain technology to offer a novel countermeasure against fake medications. The suggested approach seeks to effectively detect and prevent the distribution and consumption of counterfeit pharmaceuticals through the establishment of a transparent and secure health data network. The sale of fake and counterfeit medications in India has been linked to a number of causes, including the high cost of medications, restricted access to healthcare, and a general lack of public awareness. According to a survey, between 12 and 25% of all pharmaceuticals supplied in India are believed to be fake. India has a sizable market for spurious and counterfeit medications in addition to being one of the world's top producers of such products. Drug counterfeiting is a threat to society that needs to be vigorously combated. Different nations have different regulations to detect drug counterfeiting, but in order to enforce these; laws, regulatory monitoring and periodic sample testing to verify the accuracy of label claims are necessary. Drug counterfeiting is now a global issue. No nation has the ability to stop the sale of fake medications in its pharmaceutical industry.

Keywords: Counterfeit Drugs, Indian Market, Pharmaceutical industry, Fake medications.

Correspondence:
Dr. Rupali Hemant Tiple
Shree Babasaheb Gharfalkar College of Pharmacy, Nachangaon Pulgaon, Th Deoli, Wardha-442001, Maharashtra, INDIA.
Email: rupalihtiple@gmail.com

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INTRODUCTION

Many fatalities are caused by counterfeit or defective medications, mostly as a result of their poor therapeutic efficacy. Because they were produced using subpar methods, some of these phony medications may also cause drug resistance. The public's health is thus gravely threatened by the sector that produces these harmful pharmaceuticals. In certain underdeveloped countries, the percentage of pharmaceuticals that are counterfeit or of inferior quality varies from less than 1% to more than 50%.[1] Poorer nations, including India and many African countries, are especially affected by this issue because efforts to reform the pharmaceutical business have mostly targeted counterfeit drugs while ignoring subpar medications. There is still a serious risk to public health until governments and business drastically reduce the use of inferior medications in underdeveloped countries. In industrialized countries, pharmaceutical markets are often safeguarded by robust and well supported institutional frameworks. Standards organizations require sound manufacturing procedures, whereas customs agencies protect against the importation of counterfeit goods. The judicial and legal systems provide strong backing to these agencies.

A definition of "spurious drugs" can be found in section 17-B of The Drug and Cosmetic Act 1940 and Rules 1945, an important piece of legislation in India that governs the production, distribution, and quality of medications and formulations.[2]

If it is produced under a name that is registered to another drug;

If it imitates, replaces, or resembles another drug in a way that is likely to mislead; or

If the label or container bears the name of an individual or company claiming to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or

If it has been replaced entirely or partially by another drug or substance; or

If it claims to be a product from a manufacturer that it isn't actually a product of.

A medicine that is purposefully and fraudulently mislabeled with regard to its identification and/or source is considered a counterfeit, according to the (WHO) World Health Organization. Products having the right components but phony packaging,

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the incorrect ingredients, no active ingredients, or insufficient active ingredients are examples of counterfeit medicines. Counterfeiting can affect both branded and generic goods,[3] in other situations, pharmaceuticals that are rejected by authorities or manufacturers could be offered in markets and ought to be regarded as counterfeits.[4] The same is true for medications that have run out of stock but have been repackaged with a fictitious expiration date.

However, the phrase "counterfeit drugs" is not defined or mentioned in Indian drug regulations, despite the urgent need to include this term under their jurisdiction. Given that India has become a major producer and exporter of medicines and drugs, the quality of pharmaceuticals produced here and the country's regulatory frameworks are crucial for both India and the rest of the globe.

Medications needed to treat serious illnesses including HIV/AIDS, malaria, and tuberculosis is typically fake in underdeveloped nations. Counterfeiters in industrialized nations typically target more expensive and recent medications, such as anticancer drugs, hormones, steroids, and psychiatric medications.[5] The purpose of the review to create awareness about the fake drug and the pharmaceutical industry making such type of products in the market. and suggest the framework that can monitor the counterfeiting wisely.

Drug counterfeiting-the global scenario

Criminals and drug traffickers have always found a home in the pharmaceutical sector. They manufacture vast amounts of fake medications and sell them through illegal networks, including the dark web. Due to disruptions, limited company resilience, a lack of competent resources, and the rapid misuse of technologies, the COVID-19 pandemic has made the illicit drug trade worse and increased the manufacture of counterfeit drugs.[6] For supply chain partners, the negative economic effects of illegal and counterfeit medications have a substantial negative financial impact on the healthcare industry. Additionally, this trade reduces the health sector's profitability and its capacity to fund pharmaceutical innovation and research for economic growth.[7] Four possible scenarios are assessed, each of which is linked to anticipated worldwide counterfeit medication markets of $100 billion, $200 billion, $300 billion, and $431 billion, respectively, in order to precisely quantify the size of the market. Advanced manufacturing technologies and blockchain-based apps are being used to improve digital drug traceability, with ongoing innovation leading the way. Important facets of traceability are being methodically monitored and studied, such as material traceability in continuous manufacturing systems.[8] Traceability is essential as a key distinction in the pharmaceutical industry's present competitive economic environment.[9] By reducing waste, stopping counterfeiting, and reducing targeted recalls, it enhances supply chain operations and improves synchronization, adaptability, visibility, resilience, and security.

The World Health Organization estimates that 10% of the worldwide pharmaceutical market is made up of counterfeit pharmaceuticals, which constitute a serious threat to patient safety and public health. This study suggest the use of blockchain technology to offer a novel countermeasure against fake medications. The suggested approach seeks to effectively detect and prevent the distribution and consumption of counterfeit pharmaceuticals through the establishment of a transparent and secure health data network. A reliable and strong pharmaceutical supply chain can be established by utilizing blockchain technology, which makes it possible to track medications from production to patient consumption. This hinders the continued circulation of counterfeit medications while also making it easier to identify them right away. Participants in the drug supply chain can confirm the legitimacy of pharmaceutical items and guarantee patient safety by incorporating blockchain technology. Moreover, by combining many databases and stakeholders, blockchain technology improves accountability and transparency.

The global situation with regard to drug counterfeiting is not very good.[10] Increased drug resistance, potential death risks from critical illness medications, and similar effects are the results. 10% of pharmaceuticals in impoverished and underdeveloped nations are allegedly fabricated, according to WHO data research.[11] on the negative health effects of consuming counterfeit medications together with a geographic summary found that more than 56% of 48 occurrences involving approximately 3600 reported deaths are originated in underdeveloped nations. From an alternative perspective, the dark web is widely used by criminals around the world since it allows them to purchase all illegal and prohibited substances covertly using cryptocurrencies.[12] The seller and the customer are strangers who conceal their identities online using a VPN. Certain nations lack cyber laws to keep an eye on the online trade of illicit drugs.[13] Following a three-year investigation, a four-person group was found guilty of drug trafficking on the dark web in the UK. In developing and underdeveloped nations, where manufacturing, distribution, supply, and sale management are less regulated and living standards are low, counterfeit medications are more readily available.[14]

The use of digital technologies, such as computers, wearables, mobile phones, softwares, and apps, is known as a "digital intervention." By offering a number of services, implementing these digital solutions has improved and eased our lives.[15] In addition, for a digital system to be accepted or adopted in our life, it must be technically possible, effective, efficient, and achieve user satisfaction.[16] Thus, it is crucial to maintain a healthy balance between human needs, perceptions, behaviors, and digital intervention functionalities. In order to maintain a favorable relationship with a system's productivity, human resources, and capital management, digital interventions are thought to be a

more cost-effective approach that takes less people and physical space to implement.[17]

Antibiotics and antimicrobials are the most common types of falsified and counterfeit pharmaceuticals; in 2012, they accounted for 28% of the global market for such products.[18] Over the years, this percentage has gone increasing; from 2014 to 2016, 36% of all counterfeit medications seized by customs worldwide were antibiotics.[19] According to a 2020 research, beta-lactams, anti-folates, antiretrovirals, antimalarials and other vital medicaments were most frequently counterfeited.[20] Counterfeiting was reported with Amoxicillin in 29 countries, those of Ampicillin in 17, those of Tetracyclines in 11, and those of Trimethoprim-Sulfamethoxazole in 10 countries.[20] This is in accordance with past research that discovered that the most often faked and counterfeited drugs were early generation antibiotics, such as Tetracyclines and Penicillins.[21]

Although they are found all throughout the world, certain nations and areas are more frequently linked to the manufacture and sale of illegal medications. Southeast Asia, which includes nations like Myanmar and Cambodia, is not a big producer of pharmaceuticals, but it has been noted as a major supplier of fake and falsified pharmaceuticals. The issue transcends national boundaries and affects regional areas, with the Mekong being of particular concern.[22] Foreign visitors to Southeast Asia encounter particular difficulties and hazards associated with fake and counterfeit antimalarials and antibiotics, especially when traveling to areas where malaria is endemic.[23]

Due to the high prevalence of infectious diseases in the Sub-Saharan African region, there is a substantial need for antiretrovirals, antibiotics, and antimalarials. Consequently, fake and forged versions of these drugs have been widely available.[24] There have been multiple reports of counterfeit drugs in countries including Tanzania, Uganda, the Democratic Republic of the Congo (DRC), and Nigeria.[25]

In eight African countries, a study conducted between 2009 and 2015 on approximately 336,000 antimalarial medications in 49,500 medical facilities revealed that, on average, only 24% of Artemisinin-based Combination Treatment (ACT) medications were quality-assured, while 25% were not. It was found that the non-quality-assured medications were rare (<10%) in public sector settings and were primarily sold in private sector establishments. Nevertheless, there were also noteworthy outliers, such as Zambia, where 85% of such pharmaceuticals were found in public sector settings, and the Democratic Republic of the Congo (DRC), where 39% of non-quality-assured drugs were found in the public sector. Despite the presence of international donors, there is still a comparatively large share of non-quality-assured medications in Zambia's public sector. This can be linked to difficulties in drug procurement and supply chain management. This is in contrast to other situations where international aid and procurement procedures that often follow global quality-assurance norms lead to reduced public sector availability of non-quality-assured pharmaceuticals.[26]

India produced the bulk (54%) of the fake and counterfeit medications that were detected globally in 2006.[27] According to a more current survey, 75% of them do have Indian origin.[28] The majority of illegal producers in India create inferior or fake generic drug copies, which can subsequently find their way into the world's pharmaceutical supply chain.[29] 75.8% of the medications being sold in Mandalay pharmacies were of Indian origin, and 20.5% of those medications were either subpar or fabricated, according to a study on counterfeit medications in Myanmar.[30] India has a complicated pharmaceutical industry that is difficult to oversee and manage because of its combination of well-known producers and unlicensed manufacturing facilities.[31] The sale of fake and counterfeit medications in India has been linked to a number of causes, including the high cost of medications, restricted access to healthcare, and a general lack of public awareness.[32]

Drug counterfeiting in India

The pharmaceutical sector in India is a highly knowledge-based sector that is expanding rapidly and contributing significantly to the country's economy. In terms of output volumes, India's pharmaceutical industry ranks fourth in the world and more than half of its exports go to regions with strict regulations. Drug exports from India reached a total of $14.6 billion (about Rs. 82, 730 crore) in the fiscal year ending on March 31, 2012. India is a prime example of a developing nation with a robust pharmaceutical sector and an efficient drug regulatory framework. According to a survey, between 12 and 25% of all pharmaceuticals supplied in India are believed to be fake. India has a sizable market for spurious and counterfeit medications in addition to being one of the world's top producers of such products (IMPACT). According to estimates from the health ministry, 0.3% of medications in India are spurious and 5% are counterfeit. "Bhagirath palace" Chandni Chowk, New Delhi, is reputed to be the center of India's drug trade in spurious and counterfeit goods. In India, the 40,000 crore pharma sector is made up of 20% fake pharmaceuticals. What was a once limited to expensive and unusual medication like Viagra has now spread to cough syrups, pain relievers, and vitamin supplements.[33] India, the world's biggest producer of generic pharmaceuticals, has emerged as a hub for the production of phony and counterfeit medications. In India, Bihar, West Bengal, Uttar Pradesh, and Gujarat have the highest rates of counterfeit and spurious drug cases in the local market.[33] The United Arab Emirates, China, and India are the main origin nations of counterfeit goods that European customs agencies seize.[34]

India's status on counterfeit drugs

With 10% of global production, the pharmaceutical sector in India is the third largest in the world by volume. India leads

the globe in producing vaccinations and generic medications, exporting to more than 200 nations. When it comes to the export of these phony medications, India is also the country that produces the most of them. As per several reports, the majority of the counterfeit medications that are apprehended are traced back to their origin, with India being the primary source, followed by China. According to a 2017 WHO investigation, 20-30% of Indian pharmaceuticals were found to be counterfeit. This information was gathered through sample collection and examination from around the country. India lacks the necessary laws governing the production and distribution of pharmaceuticals, and the fact that those found guilty face minimal punishments relative to their profits and no significant legal action is taken against them which further contributes to the development of counterfeit medications. The medications and Cosmetics (Amendment) Act stipulates that samples of medications that are deemed fake or non-standard may result in 10 years in prison. As a result, guidelines have recently been devised for handling these samples. The number of individuals impacted by the usage of these medications is rising as well, and action must be made to stop the production of fake medications. Since most emerging markets lack effective means of detecting the amount of counterfeit drugs on the market, the number of deaths from these drugs is only estimated; an exact figure is unavailable. As a result, fake medicines inadvertently find their ways into the marketplace where these counterfeit drugs are sold, endangering the users of the drugs.[35]

Counterfeit medications and internet/ online pharmacies

Globalization of fake medications has been attributed to the growth of internet pharmacies, according to a paper published in The Lancet. According to the WHO, almost 50% of medications marketed online are bogus. For governments, pharmaceutical corporations, and patients alike, these are horrifying statistics.[36] This is not exclusive to underdeveloped nations; in the USA, the National Association of Boards of Pharmacy (NABP) surveyed 10,000 internet pharmacies and discovered that 9938 of them disregarded US state and federal laws as well as NABP patient safety and pharmacy practice requirements. According to a different poll conducted among UK doctors, 25% of patients who report a medication's side effects bought it online.[37] To determine what proportion of online Viagra is real, a study was done. According to reported data, the bulk of internet purchases of Viagra™ were fake. Fake Viagra™ was supplied via websites purporting to sell the real medication in as many as 77% of orders; the fakes usually came from non-American locations and had just 30-50% of the active pharmacological ingredient stated on the label. The study's conclusions show that none of the 22 websites that were examined needed a health check to be performed before a purchase could be made and all of them did not request a prescription before making a purchase as required by law. Furthermore, despite the fact that these medications lack FDA approval, 91% of the websites that were tested made the claim to sell "generic Viagra".[38] Research conducted outside of the United States of America in five European countries (Denmark, Germany, UK, Spain, and Sweden) on the non-medical use of prescription pharmaceuticals discovered that stimulants (7.6%), opioids (4.1%), and sedatives (2.7%) were frequently purchased online without a prescription under the guidance of a physician.[39]

Strict steps must be implemented to stop the growing threat of counterfeit drug trafficking through rogue internet pharmacies. Cooperation between international, national, and state authorities as well as between patients and medical professionals is necessary to regulate the purchase of drugs online.

Impact of COVID-19 on counterfeiting of medicines

The illicit market for counterfeit medicines, which is already a major concern worldwide, has benefited from the recent COVID-19 outbreak that caused havoc throughout the world. This resulted from an alarming rise of COVID-19 instances, which in turn caused a surge in demand for various medications, protective equipment, and kits. Additionally, the limited regulatory capacity of law enforcement personnel contributed to supply chain disruptions.[40]

The WHO warned of the dangers of fake vaccine doses as soon as discussions about developing a vaccine to counteract the negative effects of COVID-19 began. The general secretary of Interpol, Jürgen Stock, described vaccines as the "liquid gold" in 2021 and predicted that supply chains for vaccines will undoubtedly become a target for counterfeiters. Several accounts of people being detained and arrested in connection with the sale and distribution of counterfeit COVID-19 vaccinations around the globe confirmed this worry. There have been rumors that Pfizer vaccinations were offered for as much as $1000 in Poland and Mexico.[41] Interpol seized $3.5 million worth of fraudulent COVID-19 test certificates, masks, vaccines, and medications in southern Africa. By the end of 2021, the illegal drug market was expected to have grown by almost 400%, according to another report.[41] It gives counterfeiters a chance to profit from the rapidly increasing need for vaccinations against many illnesses, including the difficult-to-prevent COVID-19 virus. Vaccines are not the only item that can be counterfeited. Face masks, PPE kits, N95 masks, gloves, sanitizers, and diagnostic kits were among the many counterfeit items that were widely available in the market, along with medications like antivirals, chloroquine, paracetamol, and vitamin C.[42] Even in developed nations, COVID-19 overtaxed their healthcare systems to the breaking point. Medications like hydroxychloroquine (HCQ), which were thought to be beneficial against COVID-19, were severely limited in most nations, including the USA. India first prohibited the export of HCQ due to a scarcity; however, this ban was eventually reversed after India shipped 50 million HCQ tablets to the United States.[43] Due to the severe shortage, people who regularly used HCQ for lupus

and arthritis were having trouble finding a supplier. Remdesivir was falsified and sold in multiple incidents in India, where empty vials of the medication were replaced with saline or even liquid paracetamol.

It was also discovered that counterfeit batches of Remdesivir were selling in India. Another medication that Indian regulatory authorities discovered to be heavily counterfeited during COVID-19 was Dexamethasone. According to a report, the percentage of low-quality Dexamethasone in LMICs varied from 3.14 to 32.2%.[44] Because COVID-19 interrupted the worldwide supply chain, it also contributed significantly to the rise in fake medications. The export restrictions and border closures of nations like China and India, which produce the majority of active pharmaceutical components and raw materials, were the primary causes of this disruption. Due to shortages in the nations reliant on these goods during the outbreak, counterfeiters were able to significantly increase their market share in that nations.[45]

Reasons for growth

A number of factors, including the expanding pharmaceutical industry, lax pharmaceutical regulation, high drug costs, value-added tax, prescription drugs written without registration, low public awareness, lax enforcement of laws, and flexibility in the current legal system, have contributed to the drug counterfeiting industry's boom in India. In India, the drug counterfeiting industry is immensely profitable. Because of its reputation as a low-cost manufacturing hub, counterfeiters now have easier access to India. Despite not having to pay the enormous expenditures of research and development that legitimate businesses do, counterfeiters are nonetheless able to make large profits. Drug counterfeit detection is a difficult and expensive process. Customers are unable to distinguish between a genuine product and a fake one, and occasionally even prescribing physicians are in the same situation. For instance, there's no need to worry about a phony product if a patient eats the fake and heals on their own. Drug counterfeiters are becoming more and more skilled at their illicit trade by utilizing cutting-edge technological tools. Researchers recently looked at the frequency of inactive chemicals in fake Artesunate, an anti-malarial drug. What they found was that counterfeiters were much better at using sophisticated printing techniques like holograms between 2001 and 2005. When there is a gap between the supply and demand for pharmaceuticals, criminals often turn to producing and selling fake or spurious drugs as an alternative to real medications in order to benefit from their crimes. Additionally, people who misuse medications frequently create a demand for them, which may come from counterfeit sources. For instance, there is now a market for fake medications that include steroids because of weight supplementation. These medications are frequently sold in black markets or through unapproved channels at exorbitant costs. Many exporting nations do not regulate drugs produced for domestic use to the same quality as those made for export by the home country. Furthermore, drugs are occasionally exported through Free Trade Zones (FTZs), which make drug control difficult and lead to repackaging and relabeling. Even in highly controlled markets, counterfeiters have greater opportunity to get illegal medications into the supply chain through this kind of negligent trade system. The foundation of drug regulation is comprised of laws and regulations. It takes a capable national drug regulatory body with the resources it needs to regulate the production, import, distribution, and sale of pharmaceuticals in the nation. According to a WHO assessment, roughly 20% of the 191 member states have sophisticated drug laws and regulations. 30% either have very little or no drug control in place, or have very little that is practically functional, while 50% are enforcing drug regulation at various levels. The spread of counterfeit medications in legitimate distribution channels is caused by uncontrolled drug importation, manufacturing, and distribution, which is encouraged by insufficient, ineffective, or weak drug regulatory oversight.[46]

Role of IPR

The Indian pharmaceutical sector has seen changes since it joined the World Trade Organization (WTO) and agreed to apply TRIPS (Trade Related Aspects of Intellectual Property Rights). Globally, there have been significant changes to the intellectual property rules that affect the pharmaceutical business in India. The patents legislation of 1970 gives the Indian generic pharmaceutical market a spurt in expansion. Because of the age of process patents, India emerged as a major player in the production, marketing, and distribution of medicines, including patented drugs, between 1970 and 2005.[47] Thus, India emerged as the global leader in the supply of APIs (active pharmaceutical ingredients) and generic medications.[48] The liberal procedural patent environment brought about significant changes to the Indian pharmaceutical business by lowering the cost of pharmaceuticals and making them freely available. Local Indian companies began to replicate their medicine production procedures by creating their own and obtaining patents for them. At the time, Indian businesses were also allowed to export their counterfeit goods to other nations that recognized international patents. The pharmaceutical sector entered a new age of product patents on January 1, 2005, when Indian pharmaceutical companies were required to install a TRIPS compliant patent system. This meant that they could no longer produce or market copyrighted pharmaceuticals without obtaining a license from the patent owners. In this new age of product patents, the generic pharmaceutical sector in India, which had thrived on process patents, was no longer permitted to do so. This statute restricted the Indian pharmaceutical industry's ability to produce generic medications, but it also made funding for the discovery and development of novel medications easier to come by. In the Indian pharmaceutical industry, this age is marked by a rising tendency in public participation, awareness,

patenting, and patent enforcement. About 30% of trademark and patent applications and grants in India go to Pharma.[49]

Role of the consumers and pharmacists

End users and pharmacists are important allies in the fight against drug counterfeiting. These are the people who communicate directly with the drug suppliers. Therefore, it is crucial to make sure that patients and pharmacists are informed about the issue of counterfeiting as well as how to distinguish real medications from fake ones. Since reports indicate that the majority of counterfeit goods are marketed through unreliable online pharmacies, patients should purchase their medications from reputable suppliers and refrain from utilizing dubious online pharmacies. If the patient detects any differences in the appearance, flavor, or impact of the medication they have taken, they must get in touch with the pharmacist or the doctor right once. It is imperative for pharmacists to verify that the sources of their medications are reliable and have been authorized by the relevant drug regulatory bodies. It is recommended that pharmacists maintain product records in order to determine the medicine's or medical device's traceability. The safety of the patient makes this necessary. Notifying the appropriate authorities of any suspicious or confirmed incidence of drug counterfeiting is another crucial duty for the pharmacist.[50]

Role of the pharmaceutical companies

Pharmaceutical businesses lose over $200 billion a year due to medicine counterfeiting, according to reports that are currently accessible.[51] Pharmaceutical corporations invest enormous resources and years of time into the development of novel medication. RCTs guarantee that strict safety protocols are followed. Thus, one of the effects of drug counterfeiting is the loss of revenue to pharmaceutical businesses.

Companies need to stop counterfeiting at the source, which includes regulatory agencies, wholesalers, distributors, and the community of pharmacists, in order to avoid the same. Just Pfizer confirmed fake versions of 104 medications in 116 different countries.[52]

The most commonly counterfeited medication is their popular erectile dysfunction medication, Viagra™. Another commonly counterfeited Pfizer medication is Lipitor (Atorvastatin). It is the joint obligation of pharmaceutical production firms, packagers, regulatory agencies, and primary and end users to stop medicine falsification. There are certain actions that could be taken to combat the threat of drug counterfeiting. Firstly, businesses should concentrate on increasing awareness among physicians, pharmacists, and final consumers. To identify, impede, and discourage top manufacturers and retailers of their drug imitations, Pfizer has initiated a campaign to raise awareness about counterfeit goods.[53] Integrity of the medicinal supply chain should be a priority for businesses. Businesses need to make sure that counterfeiters cannot get access to their supply chain. To safeguard the items at manufacturing facilities, warehouses, during shipping, and at the point of consumer interaction, a dedicated team needs to be established within the organization.[54] In order to guarantee supply chain security; this process needs to be examined thoroughly. The companies have the option to employ clever packaging that incorporates QR codes with Artificial Intelligence (AI) built in it. Additionally, common digital tags that provide a medicine with a unique identity include Near-Field Communication (NFC) and Radiofrequency Identification (RFID). These IDs contain data on the product and enable a feature called track-and-trace that helps pharmaceutical businesses see their products at every stage of the supply chain.[54]

Regulations in India

Under the Drug and Cosmetics Act 1940 and Rules 1945, counterfeit drugs are considered illegal in India.

- Guidelines for handling drug samples that are deemed bogus or substandard quality have been announced, along with harsher sanctions.
- A reward program for those who come forward to expose fraud in the pharmaceutical, cosmetic, and medical device industries.
- Protocol for Establishing the Track and Trace System for Exporting Medicine Formulations.[55]

Deficiency in Indian regulation

- A study conducted by the WHO found that 10% of pharmaceuticals are fake. Prior to 2013, there were numerous cases that went undetected, but after 2013, 1500 cases have been documented. Thus, a barcoding system should be in place for drugs exported from the nation, according the Director-General of Foreign Trade's (DGFT) regulation.
- It is mandatory for the makers to upload the drug product's information to the central system so that it may be tracked.
- Consequently, the primary shortcoming in Indian rules pertaining to goods exportation is the requirement for barcodes to be placed so that product tracking is possible.[56]

Techniques to prevent counterfeit medicines

There are numerous methods on the market to stop drugs from being counterfeited. However, since drug counterfeiting has been on the rise, two strategies that can be applied in the pharmaceutical industry have been covered here. These strategies have the potential to significantly alter the way that drug counterfeiting is prevented. The Indian healthcare industry ought to implement this method as well.[57]

Serialization and adoption of Blockchain technology are more helpful.

Comparison of regulatory requirements of different countries with India for counterfeited medicines

Table 1 compares the laws governing counterfeit medications in India with those in other nations, including the USA, Europe, and Canada.[58]

Effects of counterfeit drugs

There are several negative impacts of counterfeit pharmaceuticals on a population's economic and health conditions. There are several situations in which using fake medications might be harmful to one's health.

Scenario 1: There are no hazardous or active chemicals in the counterfeit medication. In this instance, the patient is not injured by the fake medication directly; rather, the delay in seeking care causes the patient's illness to worsen. Additionally, the ineffectiveness of the counterfeit medication may lead to an incorrect diagnosis of antibiotic resistance.

Scenario 2: The fake medication contains hazardous chemicals but no active ingredient. Here, the patient may experience unanticipated adverse medication reactions that could result in death or morbidity.

Scenario 3: The fake medication has the incorrect active ingredient: In this case, the patient would be unknowingly using a different medication in place of the one that was prescribed.

Scenario 4: The fake medication contains the required active ingredients along with additional substances, but in incorrect amounts. Both the patient's morbidity and the likelihood of developing antibiotic resistance may rise as a result of this.

A high frequency of fake medications would also make the public lose faith in the healthcare system.[59]

Economic effects of counterfeit drugs

The economic impact of counterfeit medications is a result of increased morbidity, adverse drug responses, and drug resistance. Not only is there a rise in illness but also in death, which can result in lost economic opportunities. The selling of fake pharmaceuticals will hurt the sale of real drugs, which will hurt businesses that have spent money on drug quality, research, and development. This could also discourage businesses from making R and D investments and discourage international investment. The government also loses a great deal of tax income. In addition, significant sums of money need to be spent on developing technologies that can identify fake pharmaceuticals and safeguarding the drug supply chain. As previously mentioned the sale of counterfeit medications may result in the exclusion of Indian businesses from other nations and further fines.[59]

Counterfeit drugs and pharmacovigilance

Programs for pharmacovigilance depend on unprompted reporting of Adverse Drug Reactions (ADRs) and the subsequent investigation of their causation. These programs are predicated on the idea that the suspected medication formulation contains all of the right constituents in the prescribed amounts as stated on the label. A significant incidence of fake medications would change conclusions drawn from causality analysis, such as the improper assignment of ADRs to particular active components. In order to prevent patients from losing critically important medications, caution must be exercised in avoiding being "over vigilant." Programs for pharmacovigilance must take the likelihood of

Table 1: Comparing India's restrictions with those of other nations regarding fake medical products.

Sl. No.	Parameters	USA	Europe	Canada	India
1	Authority	United States food and drug administration	European medicine agency	Health Canada	Central drugs standard control organization
2	Market of counterfeit drugs	1.82 trillion USD by the year 2020 (0.2% market).	Europe reporting around 347 crime per year (0.2% market).	$1.1 million(2005)	Upto 20% of total drug sold in Indian market is counterfeit.
3	Guidelines	Standards for Securing the Drug Supply Chain Title II of the Drug Quality and Security Act (DQSA), the Drug Supply Chain Security Act (DSCSA).	Falsified medicines directive(FMD) (2011/62/EU) Commission delegated regulation (EU 2016/161) - Impact by Brexit.	Health Products and Food Branch Inspectorate Policy on Counterfeit Health Products.	Drug and Cosmetics Act 1940 and Rules 1945. Samples of Drugs Declared Spurious or Not of Standard Quality (Amendment) Act, 2008.
4	Examples of counterfeit	- Botox - Avastin - Cialis tablet	- Clopidogrel - Carvedilol - Ciprfloxin	- Rofact® (Rifampicin) - Amlodipine	- Primaquine Tablet I.P. 2.5 mg - Onset (Ondansetron Injection I.P.).

counterfeit medications into account when making assessments. Employees involved in pharmacovigilance, in particular, need to be aware of counterfeit medications when they see unusual or unexpected adverse effects. The source (the internet, a dealer, a pharmacy, etc.,) must be questioned, and if there are any doubts, they must be indicated in the report along with the reasons why. But it would be hard to keep track of every prescription drug issued.[60]

CONCLUSION

Drug counterfeiting is a threat to society that needs to be vigorously combated. Different nations have different regulations to deter drug counterfeiting, but in order to enforce these laws, regulatory monitoring and periodic sample testing to verify the accuracy of label claims are necessary. Drug counterfeiters in India might face penalties under criminal laws such as the Indian Penal Code, 1860, and the Drugs and Cosmetics Act, 1940, as well as prohibitions under intellectual property laws such as the Trademark Act, 1999 and the Patents Act, 1970. This overview describes each stratum's function and pertinent data in preventing medicine counterfeiting. The assessment advises health care providers to inform primary and end users on the distinctions between real and counterfeit drugs, and it also advises end users to be proactive in identifying and reporting any changes in the medications they take. In order to stop manufacturers from adding fake medications to the supply chain, it addresses how crucial it is for supply chain management to evolve and be transparent.

In order to stop the growing number of medication fabrication instances, the review concluded by discussing the necessity for governments and international organizations to establish pertinent national and international rules and ensure that they are closely adhered to. Further research should also be done to find out the precise number of counterfeit drugs that are purchased through legitimate prescriptions as opposed to those that are purchased from unreliable internet pharmacies. A positive step in the fight against counterfeiting is when different national governments mandate the adoption of modern technologies. To create a coherent strategy that can successfully stop medicine counterfeiting, governments, pharmaceutical companies, and regulatory agencies must actively collaborate with one another.

SUGGESTIONS AND RECOMMENDATIONS

Drug counterfeiting is now a global issue. No nation has the ability to stop the sale of fake medications in its pharmaceutical industry. Collaboration between law enforcement, manufacturers, suppliers, and law providers at the national, regional, and worldwide levels is necessary to combat the counterfeiting or falsification of medications. It is imperative that medical experts and other health care providers inform patients about the existence of counterfeit medications and teach them how to recognize them. Because of this, a lot of pharmaceutical businesses use holograms, which allow customers to verify the validity of the drug by looking at the holographic. However, these days, counterfeit drug producers may also replicate the holograms. Consequently, it is imperative that the manufacturer also upgrades its technology.

Today's Challenges and Smart Solutions

Our goals are to pinpoint the legal underpinnings of Indian health care, describe the current state of public authorities' efforts to combat counterfeit and falsified medications, present data on medication counterfeiting, falsification and their detrimental effects on citizens' health, and identify the strategies for strengthening the legal framework governing the public relations industry. Therefore, the state, its authorized officials, and scientific perspectives on resolving the current situation should be concerned with the serious global issues for sake of end users which negatively impact on citizens' health and quality of life which "call into question the entire health care system, methods of activity, and legal influence of the state in this area." So as to provide Indian population with high-quality medicines requires the state, public administration organizations, and their representatives required to take actions to provide the individual's right of adequate health care and to safe, high-quality medical treatment at the national level, as stipulated by the Indian Constitution and other legislative acts. The health care system should benefit from having enough and high-quality medications, but the current issues with medication fabrication and counterfeiting also make it difficult for citizens to exercise their fundamental right to health protection. The state's national security is at risk due to the absence of efficient procedures and solutions to address medication counterfeiting and falsification. The Parliament must react more skillfully and sufficiently to the current level of legislative support for such a significant area of public relations in order to solve the current issue. The work of health management agencies needs to be improved in light of the issues that society is currently confronting. The state must implement a more systematic strategy to prohibit the promotion of medications and medical gadgets on television, radio, and other mass media, particularly when it comes to the elderly, who are the biggest users of pharmaceuticals. Many manufacturers are unable to invest much in research and development, which is the backbone of the pharmaceutical industry, as the internet undermines price differential across markets and competition from lower-cost goods squeezes earnings. Governments must therefore treat it as a national issue and take it into account when formulating their health care strategies. Given that India is cited as a significant supplier of fake medications, it is imperative that the government enact a zero-tolerance policy and put in place a complete solution that makes use of the infrastructure established for the unique identification system by appropriately enhancing it.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

ACT: Artemisinin-based combination treatment; **ADRs:** Adverse drug reactions; **AI:** Artificial intelligence; **APIs:** Active pharmaceutical ingredients; **COVID:** Coronavirus disease; **DGFT:** Director-General of Foreign Trade's; **DRC:** Democratic Republic of the Congo; **EU:** European Countries; **FDA:** Food and Drug Administration; **FMD:** Falsified medicines directive; **HCQ:** Hydroxychloroquine; **HIV/AIDS:** Human immunodeficiency virus/Acquired immunodeficiency syndrome; **IPR:** Intellectual Property Rights; **LMICs:** Low- and middle-income countries; **NABP:** National Association of Boards of Pharmacy; **NFC:** Near-field communication; **RFID:** Radiofrequency identification; **R and D:** Research and Development; **TRIPS:** Trade Related Aspects of Intellectual Property Rights; **UK:** United Kingdom; **USA:** United States of America; **WHO:** World Health Organization; **WTO:** World Trade Organization; **RCTs:** Randomized Controlled Trials; **VPN:** Virtual Private Network.

SUMMARY

India has become a major producer and exporter of medicines and drugs, the quality of pharmaceuticals produced here and the country's regulatory frameworks are crucial for both India and the rest of the globe. The objective was to suggest the use of blockchain technology to offer a novel countermeasure against fake medications. Criminals and drug traffickers have always found a home in the pharmaceutical sector. They manufacture vast amounts of fake medications and sell them through illegal networks, including the dark web. Due to disruptions, limited company resilience, a lack of competent resources, and the rapid misuse of technologies, the COVID-19 pandemic has made the illicit drug trade worse and increased the manufacture of counterfeit drugs. The pharmaceutical sector in India is a highly knowledge-based sector that is expanding rapidly and contributing significantly to the country's economy. India leads the globe in producing vaccinations and generic medications, exporting to more than 200 nations. When it comes to the export of these phony medications, India is also the country that produces the most of them. According to the WHO, almost 50% of medications marketed online are bogus. For governments, pharmaceutical corporations, and patients alike, these are horrifying statistics. A number of factors, including the expanding pharmaceutical industry, lax pharmaceutical regulation, high drug costs, value-added tax, prescription drugs written without registration, low public awareness, lax enforcement of laws, and flexibility in the current legal system, have contributed to the drug counterfeiting industry's boom in India. In the Indian pharmaceutical industry, this age is marked by a rising tendency in public participation, awareness, patenting, and patent enforcement. About 30% of trademark and patent applications and grants in India go to Pharma. It is recommended that pharmacists maintain product records in order to determine the medicine's or medical device's traceability. The safety of the patient makes this necessary. Notifying the appropriate authorities of any suspicious or confirmed incidence of drug counterfeiting is another crucial duty for the pharmacist. Companies need to stop counterfeiting at the source, which includes regulatory agencies, wholesalers, distributors, and the community of pharmacists, in order to avoid the same. However, since drug counterfeiting has been on the rise, two strategies that can be applied in the pharmaceutical industry have been covered here.

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