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COUNTERFEIT DRUGS

The Challenge of counterfeit Drugs in Indian Market

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ABSTARCT:

A worldwide issue, counterfeit medications have led to potentially fatal consequences, monetary losses for both manufacturers and consumers, and a decline in public confidence in the healthcare system. In developing countries, where the general public has easy access to these drugs, the problem is more serious. It is imperative that this issue be resolved right away and that measures be taken to restrict its availability and widespread use. Even though India has taken some proactive steps to combat the issue of inferior or dangerous medications in order to safeguard and advance public health, much more work needs to be done.

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

INTRODUCTION:

One-third of the global population lacks access to essential medications, particularly in developing countries like India. This has led to a growing market for counterfeit drugs, a concern highlighted by the World Health Organization in 1985.

The global counterfeiting of medications has escalated, with over 10% of global medications being fake, and in some countries, over 50% of the drug supply. India is a prime example, with developing nations like China and India being the largest offenders. The issue is not only affecting victims but also suppliers.

India is the primary source of 75% of fake medications, according to the European Commission. The majority of bogus drugs in Nigerian markets originate from India. Counterfeit medications are pharmaceutical products manufactured and sold to misrepresent their origin, validity, or efficacy. They may contain excessive active substances, be incorrectly processed, or contain compounds not listed on the label. Most counterfeited medicines are new, expensive lifestyle medications, such as hormones, steroids, erectile dysfunction tablets, and antihistamines.

In developing nations, counterfeit medications are common, especially for serious illnesses including HIV/AIDS, TB, cancer, malaria, and antibiotics. People continue to buy counterfeit items because of their low cost, accessibility, and market availability, even if the Indian government provides free generic medications. When used with antibiotics, this results in treatment failure and raises antimicrobial resistance. The problem has spread to vitamin supplements, cough syrups, and painkillers. Frequently, counterfeit goods from nations like China, India, and the United Arab Emirates are seized by European customs officers.

India, the world's biggest supplier of generic drugs, has turned into a major location for fake and counterfeit drugs, especially in Gujarat, Bihar, West Bengal, and Uttar Pradesh. This is comparable to parasite resistance associated with drugs based on artemisinin, which frequently contain toxic substances or subtherapeutic concentrations of the active pharmaceutical ingredient (API). Research indicates that subtherapeutic quantities of the active ingredient or hazardous compounds are frequently included in low-quality counterfeit drugs, which are also common in Asia and Africa.

Black marketers create counterfeit items, while inadequate infrastructure, unscrupulous production practices, and inexperience result in subpar medications. SFFC medications have the potential to result in treatment failure or even death. SFFC drugs are defined by the International Medical Goods Anti-Counterfeiting Task Force of the World Health Organization as pharmaceuticals that are purposefully and fraudulently mislabeled with wrong ingredients, no active ingredients, too much or insufficient active ingredients, or phony packaging. Each country has its own definition of low-quality medications.

In India, medications are categorized as low quality under the Drug and Cosmetic Act of 1940. The Central medications Standard Control Organization (CDSCO) assigns A, B, and C classifications to mislabeled, counterfeit, or contaminated goods. This classification is essential for evaluating quality and is especially helpful in developing countries, especially in Southeast Asia and Africa, where counterfeiting of antimalarial drugs is common.

There have been reports of counterfeit antiretroviral drugs in Africa, including more than 35 counterfeit Nimulid, a drug made by Panacea Biotech. Approximately 8% of drugs brought into the Philippines were fake. In the UK, Lipitor did not include adequate API in 2006. 60% of antimalarial Mefloquine pills in Cambodia contained the less costly but ineffective sulphadoxine-pyrimethamine, either in counterfeit or damaged form.

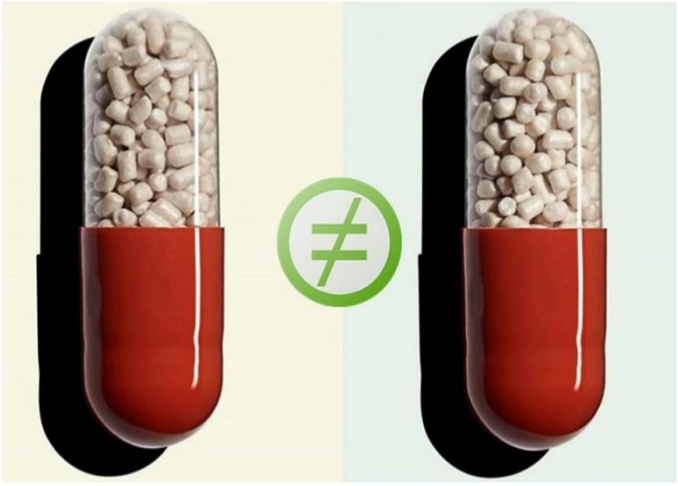
With more than 35 counterfeit versions of the Panacea Biotech drug Nimulid on the market, counterfeit antiretroviral drugs are becoming a bigger problem in Africa. Eight percent of imported drugs in the Philippines were fake. Sulphadoxine-pyrimethamine was present in 60% of Mefloquine pills in Cambodia in 2006, and UK Lipitor lacked sufficient API.

China has reported cases of fake drugs; from 1984 to 1999, 78% of 771 complaints came from underdeveloped countries. Nine hospitalizations and two fatalities resulted from the use of a conventional antidiabetic drug six times the authorized dosage in 2009. A hazardous ingredient found in antifreeze, paracetamol cough medication, killed 30 babies in India in 1998 and 89 in Haiti in 1995. Twenty countries submitted 46 complaints between 1999 and 2000.

According to the International Federation of Pharmaceutical Manufacturers Associations, counterfeit drugs make up 7% of the world's supply and are valued at about $30 billion. The US FDA is currently looking into four times as many cases of counterfeit drugs than it did in the 1990s. In Russia, the figure is predicted to be 12%, while in Ukraine, it may reach 40%.

The FDA warned about phony flu remedies in January 2006, mentioning a growing number of incidents in both developed and developing countries. One such medication was the prescription medication Oseltamivir.

Image: Counterfeit drugs



What can be done?

Around the world, counterfeit drugs are a leading source of disease, fatalities, and a drop in public confidence in healthcare providers and institutions. Compared to pharmacies, patent medicine stores, and street vendors, the public health sector—where around half of patients' prescriptions are purchased—is less susceptible to drug counterfeiting. The prevalence of fake drugs is rising even though governments, international organizations, and pharmaceutical companies work closely together. The World Health Organization offers recommendations for anti-counterfeit medication measures. Appropriate regulatory procedures, rigorous application, and cooperation among legislators, regulators, and consumers are the answers.

Since law enforcement is essential in stopping corrupt practices, the problem calls for extreme measures, such as apprehending and prosecuting individuals implicated. As suggested by the Mashelkar Committee (1993), the government should increase the number of regulatory officer jobs and enforce stringent surveillance, including suspicious and surprise checks at pharmacies.

The production and sale of counterfeit medications can be decreased with more regulatory officers. Because medications frequently involve special procedures, the public should inspect them before buying. False drugs can be identified with the use of modern techniques such as RFID, E-Pedigree, refractometer, Raman spectroscopy, isotopic characterization, tensiography, and near infrared spectroscopy. It is essential to educate the public about these techniques.

The creation of labels that are resistant to counterfeiting and the use of SMS text messages to confirm the legality of products are examples of recent developments in pharmaceutical technology. This American-developed device is being used in Ghana and Dia. Because their products are frequently distributed outside of regulated channels, pharmacies need to exercise caution when it comes to them. All patients should have access to generic medications, and efforts to encourage their wider usage should be encouraged.

In order to control the counterfeit drug industry, community leaders, legislators, drug controllers, and doctors are essential. Information about standard quality, counterfeit, adulterated, and misbranded pharmaceuticals should be made public by the government. Regular medication monitoring is also crucial. The market for counterfeit drugs can be controlled in India by setting up free drug quality testing facilities and examining imported drugs before they are sold. This will guarantee customer safety and benefit over-the-counter buyers.

An in-depth look at the problem of counterfeit drugs on the Indian market:

Because of their low therapeutic efficacy and potential for drug resistance, defective or counterfeit medications are responsible for a considerable number of fatalities. There is a significant risk to public health from the pharmaceutical business, which makes these harmful drugs. The percentage of inferior or fake drugs varies from less than 1% to more than 50% in underdeveloped countries. Due to regulatory efforts centered on counterfeit medications, this issue disproportionately affects poorer countries, like India and numerous African countries.

Because of their low therapeutic efficacy and potential for drug resistance, defective or counterfeit medications are the cause of many fatalities. These harmful medications are produced by the pharmaceutical business, which presents a serious risk to public health. The percentage of fake drugs in developing countries varies from less than 1% to more than 50%. Poorer nations like India and many African countries are disproportionately affected by this problem, while attempts to regulate the business center on counterfeit medications.

Because of their low therapeutic efficacy and potential for drug resistance, defective or counterfeit medications are the cause of many fatalities. With counterfeit drugs disproportionately harming poorer nations like India and several African countries, the pharmaceutical sector poses a serious threat to public health. The goal of reform initiatives is to combat counterfeit medications.

According to the World Health Organization (WHO), a counterfeit medication is one that is produced under a registered name, falsely mimics another medication, has the name of a fictitious or nonexistent manufacturer on the label, has been substituted with another medication or substance, or purports to be from a pharmaceutical company. These standards are essential for guaranteeing the effectiveness and safety of medications.

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Despite the necessity, counterfeit pharmaceuticals are not defined or mentioned in Indian drug regulations. Given that India is a significant producer and exporter of pharmaceuticals, the quality of pharmaceuticals made there and the regulatory frameworks are important to both India and the rest of the globe.

In addition to suggesting a system for efficient monitoring of counterfeiting in developed countries, particularly in the production of expensive and more recent pharmaceuticals like hormones, steroids, and anticancer treatments, the review seeks to increase awareness of counterfeit medications in developing nations and the role played by the pharmaceutical industry in their production.

Drug counterfeiting-the global scenario:

The manufacturing and distribution of counterfeit drugs, especially via illicit channels like the dark web, is a serious problem for the pharmaceutical business. This trade has been made worse by the COVID-19 epidemic, which has disrupted operations and decreased corporate resilience. Economic growth and supply chain partners are impacted by the industry's large financial losses. There are four estimated market sizes for counterfeit medications, ranging from $100 billion to $431 billion. Through blockchain-based applications and cutting-edge manufacturing technologies, innovation is concentrating on enhancing digital pharmaceutical traceability.

By cutting down on waste, stopping counterfeiting, and lowering targeted recalls, blockchain technology can improve supply chain operations. This study focuses on material traceability in continuous manufacturing systems, as counterfeit medications make up 10% of the global pharmaceutical market. By detecting and stopping the use and distribution of these medications, a transparent health data network can guarantee patient safety and the legitimacy of the product. Blockchain technology improves accountability and transparency by bringing together multiple datasets and stakeholders. However, drug counterfeiting is a global issue, with 10% of medications in developing countries being counterfeit and 56% causing 3600 fatalities. Criminals all around the world utilize the dark web to buy illegal pharmaceuticals using cryptocurrencies, emphasizing the importance of addressing these concerns in order to improve accountability and transparency in the pharmaceutical industry.

In impoverished and undeveloped nations with low living standards and less regulated production, distribution, supply, and sale management, counterfeit medications are common. Some nations lack cyber rules to keep an eye on illicit drug trafficking, and strangers use virtual private networks (VPNs) to conceal their identities online. In the UK, a four-person cell was found guilty of cocaine trafficking.

In developing nations with low living standards and less regulated production, distribution, supply, and sale management, counterfeit medications are common. Some nations lack internet legislation to oversee illicit drug trade, and VPNs are used to conceal identities.

The most prevalent kinds of fake drugs are antibiotics and antimicrobials, which accounted for 28% of the worldwide market in 2012. Antibiotics made up 36% of all counterfeit medications seized by customs between 2014 and 2016. Beta-lactams, anti-folates, antiretroviral, antimalarial, and necessary drugs are among the other often counterfeited drugs. There have been reports of counterfeit trimethoprim-sulfamethoxazole, tetracyclines, ampicillin, and amoxicillin in 29 different countries.

Antibiotics and antimicrobials were among the counterfeit drugs that made up 28% of the global market in 2012 and 36% of all drugs seized between 2014 and 2016. Beta-lactams, anti-folates, antiretroviral, antimalarial, and critical pharmaceuticals are among the other counterfeit drugs that have been reported in 29 countries.

According to statistics from 29 nations, counterfeit pharmaceuticals, including antibiotics and antimicrobials, made up 28% of the global market in 2012 and 36% of drugs seized between 2014 and 2016.

In Tanzania, Uganda, Nigeria, and the Democratic Republic of the Congo, reports of counterfeit drugs have surfaced. Only 24% and 25% of 336,000 antimalarial medications in 49,500 hospitals were deemed to be quality-assured in a 2009–2015 assessment. Non-quality-assured medications were uncommon in public settings and primarily found in private sector establishments.

Despite foreign aid, outliers like Zambia and the Democratic Republic of the Congo have significant rates of non-quality-assured pharmaceuticals in their public sectors. In contrast to other nations where access to non-quality-assured medications is restricted because of international aid and procurement procedures that follow international quality-assurance norms, this is because of supply chain management and procurement issues.

In 2006, it was discovered that 75% of counterfeit medications were of Indian ancestry, and 54% of them came from India. Subpar or fake generic medication copies are frequently produced by Indian producers and might find their way into the global pharmaceutical supply chain. Twenty-five percent of the medications offered in Mandalay pharmacies in Myanmar were counterfeit or of low quality, and 75.8% of the medications were from India.

The mix of well-known manufacturers and unlicensed production facilities in India makes the country's pharmaceutical business complex and challenging to monitor and control.31 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 selling of fake and counterfeit drugs in India.

Drug counterfeiting in India

India's pharmaceutical industry is a highly knowledge-based industry that is growing quickly and making a substantial economic contribution to the nation. India's pharmaceutical sector is the fourth largest in the world in terms of output quantities, and over half of its exports go to countries with stringent restrictions. India exported $14.6 billion worth of drugs in the fiscal year that concluded on March 31, 2012, which is equivalent to around 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.

A report indicates that 12–25% of all medications provided in India are thought to be counterfeit. In addition to being one of the world's leading producers of fake and counterfeit pharmaceuticals, India also has a substantial market for these goods (IMPACT). The health ministry believes that 5% of Indian drugs are counterfeit and 0.3% are fake. Chandni Chowk, New Delhi, is known as the "Bhagirath palace" and is thought to be the epicenter of India's drug traffic in fake and counterfeit items. Twenty percent of the 40,000 crore pharmaceutical industry in India consists of counterfeit drugs. What was formerly restricted to costly and uncommon drugs like Viagra has now expanded to include vitamin supplements, cough syrups, and painkillers.
The world's largest manufacturer of generic drugs, India, has become a center for the manufacture of fake and counterfeit drugs. The states with the greatest rates of fake and counterfeit medication cases in the Indian market include Gujarat, West Bengal, Uttar Pradesh, and Bihar. The main nations from which European customs authorities confiscate counterfeit products are China, India, and the United Arab Emirates. India's position on fake medications

With 10% of global production, the pharmaceutical sector:

Vaccines and generic drugs are produced worldwide and exported to more than 200 countries. The nation that produces the most of these fake drugs is India, which also exports the most of them. Many studies state that the majority of the recovered counterfeit drugs can be traced back to their nation of origin, with China and India being the main suppliers. A 2017 WHO examination indicated that 20 to 30 percent of Indian medications were counterfeit. This data was acquired by collecting and analyzing samples from all throughout the nation.

In addition to the fact that individuals found guilty get light sentences in comparison to their earnings and no serious legal action is taken against them, India lacks the regulations that are required to regulate the manufacture and distribution of medicines, which further encourages the creation of fake drugs. According to the Medicine and Cosmetics (Amendment) Act, medication samples that are found to be fraudulent or out of the ordinary carry a ten-year jail sentence. Guidelines for processing these samples have therefore lately been developed. Action must be taken to curb the creation of counterfeit pharmaceuticals because the number of people affected by their use is also increasing.

The number of fatalities from counterfeit pharmaceuticals is only approximated; a precise number is not known since the majority of emerging countries lack efficient methods for determining the quantity of these products on the market. As a consequence, counterfeit medications unintentionally make their way into the market where they are marketed, putting the drug users at risk.

Counterfeit medications and internet/ online pharmacies:

According to a study in The Lancet, the rise of online pharmacies has been linked to the globalization of counterfeit drugs. Nearly half of drugs sold online are fake, according to the WHO. These are alarming figures for patients, governments, and pharmaceutical companies. This is not exclusive to developing countries; in the United States, the National Association of Boards of Pharmacy (NABP) polled 10,000 online pharmacies and found that 9938 of them ignored federal and state regulations in the United States as well as NABP's criteria for pharmacy practice and patient safety. According to a different UK doctor study, 25% of individuals who experienced negative effects purchased their prescription drugs online. To determine the proportion of genuine Viagra offered online, a research was conducted. The majority of online ViagraTM orders were fraudulent, according to research that has been revealed.

Up to 77% of orders for fake ViagraTM came from websites that claimed to provide the actual drug; these fakes often originated outside of the United States and included just 30–50% of the active pharmacological ingredient listed on the label. The study's findings indicate that none of the 22 websites under investigation required a health examination prior to a purchase, and none of them requested a prescription before completing a purchase as required by law.

Furthermore, 91% of the examined websites claimed to sell "generic Viagra" even though the FDA has not approved these drugs. Studies on the non-medical use of prescription drugs 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 often bought online without a prescription under a doctor's supervision. To combat the rising menace of trafficking in counterfeit drugs through rogue online pharmacies, strict measures must be put in place. Regulating online medication purchases requires collaboration between state, federal, and international agencies as well as between patients and drug medical specialists.

Impact of COVID-19 on counterfeiting:

The recent COVID-19 epidemic, which wreaked devastation throughout the world, has boosted the illegal market for counterfeit medications, which is already a huge threat. This was brought about by a startling increase of COVID-19 cases, which in turn led to a spike in demand for different drugs, safety gear, and kits. Disruptions to the supply chain were also caused by law enforcement officials' limited regulatory ability.

As soon as talks started to create a vaccine to combat the harmful effects of COVID-19, the WHO issued a warning about the hazards of false vaccination doses. In 2021, Interpol General Secretary Jürgen Stock called vaccines the "liquid gold" and said that vaccination supply chains will surely become a target for counterfeiters. This concern was supported by many reports of persons being arrested and incarcerated in relation to the global sale and distribution of fake COVID-19 vaccines. There have been reports that Pfizer vaccines were sold in Mexico and Poland for up to $1000.

In southern Africa, Interpol confiscated counterfeit COVID-19 test certificates, masks, vaccinations, and drugs valued at $3.5 million. Another estimate predicted that the illegal drug market will have expanded by over 400% by the end of 2021. The constantly growing demand for vaccines against a variety of diseases, including the hard-to-prevent COVID-19 virus, presents counterfeiters with an opportunity to make money. Not just vaccines are susceptible to counterfeiting. Along with drugs like antivirals, chloroquine, paracetamol, and vitamin C, the market was rife with counterfeit products, including face masks, PPE kits, N95 masks, gloves, sanitizers, and diagnostic kits.

COVID-19 pushed healthcare systems to their limits, even in industrialized countries. Most countries, including the USA, had very few medications like hydroxychloroquine (HCQ), which were believed to be effective against COVID-19. India first banned the export of HCQ because of a shortage, but after sending 50 million HCQ pills to the US, the prohibition was later lifted. People who often used HCQ for lupus arthritis were having trouble finding a provider because of the acute scarcity. Remdesivir was fabricated

and sold in many cases in India, where the drug was sold in empty vials and replaced with saline or even liquid paracetamol.

Remdesivir:Counterfeiting Of Anti-Covid Medicines

Additionally, it was found that Remdesivir was being sold in India in fake batches. During COVID-19, Indian regulatory officials also found that dexamethasone was a drug that was widely counterfeited. The percentage of low-quality dexamethasone in LMICs ranged from 3.14 to 32.2%, citing a study. COVID-19 also had a major role in the increase of counterfeit drugs since it disrupted the global supply chain. The main reasons for this interruption were the export limits and border closures of countries like China and India, which manufacture the bulk of raw materials and active pharmaceutical components. During the epidemic, counterfeiters were able to greatly expand their market share in the countries that depended on these items because of shortages in those countries.

Causes of growth:

The growth of the medication counterfeiting business in India has been attributed to a variety of causes, including the rising pharmaceutical sector, loose pharmaceutical regulation, high drug costs, value-added tax, prescription, pharmaceuticals written without registration, poor public knowledge, lax enforcement of laws, and flexibility in the present legal system. The medication counterfeiting business is quite lucrative in India. India is now more easily accessible to counterfeiters due to its status as a hub for low-cost manufacturing. Counterfeiters are able to generate significant profits even though they are not required to make the same massive investments in research and development as real enterprises.

The procedure of detecting drug counterfeiting is costly and challenging. Consumers cannot tell the difference between a real product and a phony, and sometimes even doctors who prescribe it are in the same predicament. For example, if a patient consumes the fake and recovers on their own, there is no reason to be concerned about a fake product. Drug counterfeiters are become more skilled at their illicit trade with the use of advanced technical tools. The frequency of inactive compounds in counterfeit Artesunate, an anti-malarial medication, was recently examined by researchers.

They discovered that between 2001 and 2005, counterfeiters significantly improved their use of advanced printing methods, such as holograms. When there is a shortage of medicines, criminals often manufacture and sell fake or counterfeit pills instead of real medications in order to benefit from their crimes. Furthermore, drug abusers often generate demand for drugs, which may originate from illegal sources. For example, weight supplementation has led to the emergence of a market for counterfeit drugs that include steroids. These drugs are commonly offered for sale at astronomical prices in illegal marketplaces or through unregulated methods. Many exporting countries do not control domestically manufactured medications to the same standards as domestically produced drugs for export. Additionally, Free Trade Zones (FTZs) are sometimes used to export pharmaceuticals, which complicates drug regulation and encourages repackaging and relabeling.

Through this type of careless trading system, counterfeiters have a better chance of introducing illicit pharmaceuticals into the supply chain, even in areas with strict regulations. 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 to do so. A WHO evaluation estimates that about 20% of the 191 member nations 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 useful. 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 oversite.

Role of IPR:

Since India joined the World Trade Organization (WTO) and committed to implementing TRIPS (Trade Related Aspects of Intellectual Property Rights), the country's pharmaceutical industry has undergone changes. Significant changes have been made to the intellectual property laws that impact India's pharmaceutical industry on a global scale. The Indian generic pharmaceutical business is seeing rapid growth thanks to the 1970 patent legislation. Between 1970 and 2005, India became a significant player in the manufacturing, distribution, and marketing of pharmaceuticals, including patented medications, because to the age of process patents.

As a result, India became the world's largest supplier of generic drugs and active pharmaceutical ingredients, or APIs. By reducing the cost of drugs and granting them unrestricted access, the liberal procedural patent environment significantly altered the Indian pharmaceutical industry. By developing their own and securing patents for them, local Indian businesses started to copy their methods for producing medications. Indian companies were also permitted to export their fake goods to other countries that accepted international patents at the time. When Indian pharmaceutical firms had to put in place a patent structure that complied with TRIPS.

The pharmaceutical sector began a new era of product patents on January 1, 2005. As a result, they were unable to manufacture or distribute medications protected by copyright without a license from the patent holders. The Indian generic pharmaceutical industry, which had prospered on process patents, was no longer allowed to do so in this new era of product patents. Although this law limited the Indian pharmaceutical industry's capacity to manufacture generic drugs, it also made it simpler to get funds for the research and development of new drugs. Public engagement, awareness, patenting, and patent enforcement are all on the rise in the Indian pharmaceutical business. Pharmacists in India receive over 30% of all trademark and patent applications and awards.

Role of the consumers and pharmacists:

Pharmacists and end users are crucial allies in the battle against medication counterfeiting. They are the ones who speak with the medication suppliers directly. As a result, it is essential to ensure that pharmacists and patients are aware of the problem of counterfeiting and how to tell the difference between genuine and counterfeit pharmaceuticals. Patients should get their prescriptions from dependable vendors and avoid using questionable internet pharmacies, since reports suggest that most counterfeit items are sold through these companies.

If the patient observes any changes in the look, taste, or action of the drug, they must get in touch with the doctor or pharmacist very once. Pharmacists must confirm that the suppliers of their drugs are trustworthy and approved by the appropriate drug regulatory agencies. To ascertain the traceability of a medication or medical equipment, pharmacists are advised to keep product records. This is required for the patient's safety. Another crucial responsibility for pharmacists is to report any suspected or verified instances of medication counterfeiting to the proper authorities.

Pharmaceutical companies lose more than $200 billion annually as a result of drug counterfeiting, according to reports that are currently available.51 Pharmaceutical companies devote years and a great deal of resources to the creation of new drugs. RCTs ensure that stringent safety procedures are adhered to. Consequently, medication counterfeiting causes pharmaceutical businesses to lose money. To prevent the same, businesses must fight counterfeiting at its source, which includes regulatory bodies, distributors, wholesalers, and the pharmacy community. ViagraTM, a popular therapy for erectile dysfunction that Pfizer has only verified in 116 countries, is the most often counterfeited drug. Lipitor (atorvastatin) is another Pfizer drug that is frequently counterfeited.

Stopping drug falsification is a shared responsibility of pharmaceutical manufacturing companies, packagers, regulatory bodies, and primary and end consumers. The problem posed by drug counterfeiting might be addressed in a few ways. First and foremost, companies should focus on raising awareness among doctors, pharmacists, and end users. In an effort to identify, thwart, and deter the top makers and merchants of their medication imitations, Pfizer has started a campaign to increase public awareness about counterfeit goods. Businesses should place a high premium on maintaining the integrity of the pharmaceutical supply chain. Companies must ensure that their supply chain is inaccessible to counterfeiters.

A specialized team must be formed inside the company to protect the goods at production sites, storage facilities, during transportation, and at the point of customer contact.54 This procedure must be carefully investigated in order to ensure supply chain security. Businesses may choose to use intelligent packaging that integrates artificial intelligence (AI) with QR codes. Other popular digital tags that give a medication a unique identification are Radiofrequency Identification (RFID) and Near-Field Communication (NFC). Pharmaceutical businesses can view their products all the way through the supply chain thanks to a function called track-and-trace that is made possible by these IDs. Product information is contained in these IDs. Indian regulations

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

• More severe penalties and guidelines for handling drug samples of questionable or subpar quality have been announced.

• 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.

Techniques to prevent counterfeit medicines:

There are several strategies available to prevent the counterfeiting of pharmaceuticals. However, two tactics that can be used in the pharmaceutical business have been discussed here since medicine counterfeiting has been increasing. The method that drug counterfeiting is prevented might be drastically changed by these tactics. This approach should be used by the Indian healthcare sector as well. Block chain adoption and serialization are more beneficial.

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 nation, including the USA, Europe, and Canada.

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

Sr.No.	Parameters	USA	Europe	Canada	India
1.	Authority	United States food and drug administrati -on	European medicine agency	Health Canada	Central drugs standard control organisati -on
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 drugs sold in Indian market is counterfe- it
3.	Guidelines	Standards for Securing the Drug Quality and Security Act (DQSA),the Drug Supply Security Act (DSCSA)	Falsified medicines directive (FMD) (2011/62/EU)Commissio n delegated regulation (EU2016/161) - Impact by Brexit	Health Products and Food Branch Inspectorate Policy on Counterfeit Health Products	Drugs and Cosmetics Act 1940 and Rules 1945. Samples of Drugs Declared Spurious or not of Standard Quality (Amendm ent)Act, 2008
4.	Examples of counterfeit	-Botox -Avastin -Cialis tablet	- Clopidogrel - Carvedilol - Ciprfloxin	-Rofact (Rifampicin) -Amlodipine	- Primaquin e Tablet I.P.2.5mg -Onset (Ondanset on Injection I.P.)

Examples of counterfeit: Fake botox indentification.

Effects of counterfeit drugs:

The economic and health situations of a population are negatively impacted by counterfeit medications in a number of ways. The use of counterfeit pharmaceuticals may be detrimental to one's health in a number of circumstances. Scenario 1: There are no dangerous or active ingredients in the fake drug. In this case, the phony drug does not directly harm the patient; rather, the patient's ailment worsens as a result of the delay in obtaining help. Furthermore, the ineffectiveness of the fake drug might lead to an inaccurate diagnosis of antibiotic resistance. Scenario 2: The counterfeit drug has no active ingredient but includes dangerous compounds. In this case, the patient can have unexpected negative drug responses that could cause morbidity or death.
Scenario 3: The incorrect active component is included in the counterfeit drug. In this case, the patient would be unaware that they were taking a different prescription than what was recommended. Scenario 4: The counterfeit drug has the necessary active components as well as other chemicals, but in the wrong proportions. Consequently, there may be an increase in the patient's morbidity and risk of antibiotic resistance. Furthermore, the proliferation of fake drugs may erode public confidence in the healthcare system.

Economic effects of counterfeit drugs:

Increased morbidity, negative drug reactions, and drug resistance are the causes of the economic effect of counterfeit pharmaceuticals. In addition, there is an increase in mortality, which might lead to missed business chances. Businesses who have invested in medicine quality, research, and development will suffer as a result of the sale of counterfeit medications. Additionally, this can deter companies from investing in research and development as well as foreign investment. A significant amount of tax revenue is also lost by the government. Large quantities of money must also be invested in protecting the drug supply chain and creating technology that can detect counterfeit medications. As previously mentioned the sale of counterfeit medications may result in the exclusion of Indian businesses from other nations and further fines.

Counterfeit drugs and pharmacovigilance:

Pharmacovigilance programs rely on the spontaneous reporting of adverse drug reactions (ADRs) and the subsequent analysis of their cause. The premise behind these programs is that the suspected medicine formulation has all the appropriate ingredients in the amounts indicated on the label. For instance, a large rise in counterfeit drugs might alter the inaccurate assignment of adverse drug reactions (ADRs) to certain active ingredients.

In order to keep patients from misplacing vital prescriptions, care must be taken to avoid being "hyper watchful." Pharmacovigilance programs must include the possibility of counterfeit drugs while conducting evaluations. When pharmacovigilance staff see odd or unexpected side effects, they should be especially alert for counterfeit drugs. It is necessary to question the source (the internet, a dealer, a pharmacy, etc.) and to provide any reservations in the report along with an explanation. However, it would be challenging to monitor all of the prescription medications that are dispensed.

CONCLUSION:

The menace of drug counterfeiting to society must be aggressively addressed. Regulations to prevent medicine counterfeiting vary by country, but they must be enforced by regulatory monitoring and recurring sample testing to confirm the veracity of label claims. In India, drug counterfeiters may be subject to bans under intellectual property laws including the Trademark Act of 1999 and the Patents Act of 1970, as well as criminal penalties under the Indian Penal Code of 1860 and the Drugs and Cosmetics Act of 1940. This summary explains the role of each stratum and relevant information in stopping the counterfeiting of medications.

In addition to advising end users to be proactive in recognizing and reporting any changes in their prescription regimen, the evaluation suggests that healthcare providers educate primary and end users on the differences between authentic and counterfeit pharmaceuticals. It discusses how important it is for supply chain management to change and be transparent in order to prevent manufacturers from introducing counterfeit drugs into the supply chain. The evaluation ended by addressing the need for governments and international organizations to create relevant national and international regulations and make sure they are strictly followed in order to curb the rising number of drug fabrication cases.

The exact percentage of counterfeit medications that are bought with valid prescriptions as opposed to those that are bought from dubious online pharmacies should also be determined by more investigation. Mandating the use of current technology by various national governments is a significant step in the battle against counterfeiting. Governments, pharmaceutical businesses, and regulatory agencies must work together to develop a cohesive approach that can effectively prevent the counterfeiting of medicines.

SUGGESTIONS AND RECOMMENDATIONS:

Today, medication counterfeiting is a global concern. No government has the authority to prohibit the selling of counterfeit pharmaceuticals in its pharmaceutical business. To prevent drug counterfeiting or falsification, law enforcement, manufacturers, suppliers, and legal providers must work together on a national, regional, and global scale. It is critical that medical professionals and other health care providers educate patients about the presence of counterfeit pharmaceuticals and teach them how to identify them. As a result, several pharmaceutical companies utilize holograms, which allow buyers to check the legitimacy of the medicine by gazing at the hologram. However, nowadays, counterfeit medication manufacturers may also reproduce the holograms. As a result, the producer must likewise modernize its technology.

Today’s Challenges and Smart Solutions:

Our objectives are to establish the legal foundations of Indian health care, describe the current condition of public authorities' attempts to combat counterfeit and falsified pharmaceuticals, offer statistics on medication counterfeiting and falsification, and their negative impacts on citizens' health, and suggest measures for enhancing the legislative framework controlling the public relations business. As a result, the state, its authorized authorities, and scientific viewpoints on fixing the current situation should be concerned with the significant global concerns for the sake of end users that negatively effects citizens' health and quality of life and "bring into question the whole health care system, methods of activity, and legal influence of the state in this field."

To offer high-quality pharmaceuticals to the Indian people, the state, public administration organizations, and their representatives must take steps to ensure the individual's right to appropriate health care and safe, high-quality medical treatment at the national level, as outlined in the Indian Constitution and other legislative acts. The health-care system should benefit from an adequate supply of high-quality pharmaceuticals, but existing challenges with medication manufacture and counterfeiting make it impossible for individuals to enjoy their fundamental right to health protection. The state's national security is jeopardized owing to a lack of effective processes and methods to combat medicine counterfeiting and falsification.

To address the current situation, Parliament must respond more effectively and properly to the existing level of legislative support for such an important area of public relations.The work of health management organizations must be enhanced in view of the difficulties that society is now facing. The state must execute a more systematic plan to prevent the advertising of drugs and medical devices on television, radio, and other mass media, especially among the elderly, who are the most frequent consumers of pharmaceuticals.

Because the internet diminishes market price differentials and competition from lower-priced items reduces revenues, many manufacturers are unable to engage significantly in research and development, which is the backbone of the pharmaceutical sector. Governments must consequently approach it as a national issue and consider it when developing their health-care strategy. Given India's reputation as a major provider of counterfeit drugs, it is critical that the government execute a zero-tolerance policy and implement a comprehensive solution that takes use of the infrastructure developed for the unique identification system by effectively improving it.

SUMMARY:

India has emerged as a significant manufacturer and exporter of medicines and therapeutics; the quality of pharmaceuticals produced here, as well as the regulatory frameworks in place, are critical for both India and the rest of the world. The idea was to demonstrate that block-chain technology may be utilized as a new method to combat counterfeit drugs. Criminals and drug traffickers have always found a place in the pharmaceutical industry. They produce large quantities of counterfeit drugs and sell them through criminal networks, including the dark web. The COVID-19 pandemic has exacerbated the illicit drug trade and boosted the creation of counterfeit medications as a result of interruptions, poor firm resilience, a lack of qualified resources, and the fast abuse of technology.

The pharmaceutical business in India is a highly knowledge-based industry that is quickly increasing and making substantial contributions to the country's economy. India sells to over 200 countries and is the world leader in producing generic pharmaceuticals and vaccines. When it comes to the export of these bogus pharmaceuticals, India is also the leading producer. According to the WHO, over half of the pharmaceuticals sold online are fraudulent. These are appalling figures for governments, pharmaceutical companies, and patients.

The medication counterfeiting business in India has grown due to a variety of causes, including an rising pharmaceutical sector, inadequate pharmaceutical regulation, high drug costs, value-added tax, prescription pharmaceuticals written without registration, poor public awareness, lax law enforcement, and flexibility in the present legal system.

This era is distinguished by an increase in public engagement, awareness, patenting, and patent enforcement in the Indian pharmaceutical business. Pharma accounts for around 30% of trademark and patent award applications and grants in India. Pharmacists should keep product records to assess the traceability of medicines and medical devices. This is required to ensure the patient's safety. Another critical responsibility of the pharmacist is to notify the proper authorities of any suspected or proven cases of medication counterfeiting. To avoid counterfeiting, companies must eliminate it at the source, which involves regulatory bodies, wholesalers, distributors, and the pharmacy community. However, because medicine counterfeiting is on the rise, we have discussed two approaches that can be employed in the pharmaceutical sector.

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. WHO. WHO medicines strategy: countries at the core, 2004–2007.World Health Organization. 2008.

12. Bate R, Zhe Jin G, Mathur A. Does price reveal poor-quality drugs? Evidence from 17 countries. J Health Econ. 2011; 30:1150-63.

13. Gupta P, Singhal K, Pandey A. Counterfeit (Fake) Drugs & New Technologies to Identify it in India. Int J Pharm Sci Res. 3(11); 4057- 4064

14. Swaminath. Faking it - II: Countering and preventing counterfeiting of drugs. Indian J Psychiatry. 2009 Jan-Mar; 51(1): 9-11.

15. Bate R, Boateng K. Bad medicine in the market. Am. Enterprise Inst. Public Policy Res. 2007; 43:13-21.

16. Raufu A. India agrees to help Nigeria tackle the import of fake drugs. Br. Med. J. 2003; 326: 1234

17. WHO. Counterfeit medicines, Fact Sheet Revised. November 14, 2006. Available from URL:http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/index.html [Last accessed on 2015 April 5].

18. Chika A, Bello SO, Jimoh AO, Umar MT. The Menace of Fake Drugs: Consequences, Causes and Possible Solutions. Research Journal of Medical Sciences. 2011; 5(5):57-261.

19. PIB. Generic Medicines. Press Information Bureau of India. 2012. Available from URL: http://www.pib.nic.in/newsite/erelease.aspx?relid=89323 [Last accessed on 2015 April 5].

20. Gentry JW, Putrevu S, Shultz C, Commuri S. How now Ralph Lauren? The separation of brand and product in a counterfeit culture. Lincoln, Nebaraska. 2001.p. 258-65. Available from URL: http://www.acrwebsite.org/search/view-conference-proceedings.aspx?Id=8485 [Last accessed on 2015 April 5].