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

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ABSTRACT :

India has grown to be a significant manufacturer and exporter of pharmaceutical ;regulatory frame word and the calibre of pharmaceuticals produced here are vital for both India and the rest of the world. This review's goal was block chain technology might be used to provide a unique defence against counterfeit drugs . by creating a transparent and secure health data network , the proposed strategy aims to efficiently identify and stop the distribution and use of fake medication . numerous factors, such as the high cost of pharmaceutical, limited access to healthcare , and a general lack of public understanding , have been connected to the sale and fake and counterfeit medication in India.

Keywords: Counterfeit Drugs, Indian market, Pharmaceutical industry, Fake medication.

Introduction:

One of the world's most pressing public health concerns is counterfeit medications, which account for an estimated 10–30% of pharmaceuticals in developing countries (fig. 1).Two India, one of the world's largest producers of pharmaceuticals, must both protect its domestic market and maintain its reputation as a reliable global supplier of pharmaceuticals. The World Health Organisation (WHO) classifies products that are "deliberately and fraudulently mislabelled with respect to identity and/or source" as counterfeit drugs.3 Because these products may contain the incorrect substances, incorrect dosages, or no active ingredients at all, they pose a major risk to the health of their consumers.

India's pharmaceutical business, estimated to be worth $50 billion, accounts for about 20% of global generic drug exports. 4 Because of its significance, India's approach to fighting counterfeit drugs is particularly crucial.This article places India's efforts in t he context of the global pharmaceutical counterfeiting landscape and examines whether the nation is tackling this important issue at the right pace. It also examines the current regulatory framework, technological interventions, and enforcement mechanisms.The wo rldwide reach of the issueThe problem of counterfeit drugs extends far beyond India and impacts countries at all economic levels. This deal also reduces the profitability of the health sector and its capacity to fund pharmaceutical innovation and research for econo mic expansion.7 Every scenario is assessed and linked to the anticipated worldwide counterfeit

pharmaceutical markets with relative values of $100 billion, $200 billion, $300 billion, and $431 billion to precisely gauge the marei t's size.The use of sophisticated manufacturing technology and blockchainbased applications to improve digital pharmaceutical trace ability is being driven by ongoing innovation.

Important facets of traceability are being closelymonitored and studied, such as material traceability in continuous manufacturing sy stems.8Traceability is a key distinction in the pharmaceutical industry's present competitive economic environment.

By reducing waste, stopping counterfeiting, and minimising targeted recalls, it optimises supply chain processes and boosts synchro nisation, adaptability, visibility, resilience, and security.

From a different perspective, the dark web is used by criminals worldwide since it allows them to covertly purchase any illegal or re stricted substance using cryptocurrencies.TwelveBoth the vendor and the consumer are strangers who conceal their identities online by using a VPN.

Although they are found everywhere, some nations and areas are more frequently linked to the manufacture and sale of illegal medic ations.Southeast Asia, which includes nations like Cambodia and Myanmar, has been recognised as a key supply of counterfeit and f alsified drugs despite not being a large producer of pharmaceuticalsThe issue transcends national boundaries and impacts regional ar eas; the Mekong is particularly problematic.22For international tourists to Southeast Asia, fake and counterfeit medications and anti malarials pose special risks and problems, especially when travelling to areas where malaria is endemic.A study conducted out betw een 2009 and 2015 on roughly 336,000 antimalarial medications in 49,500 medical facilities in eight African nations indicated that, on average, only 24% .

India's drug counterfeiting:

The pharmaceutical sector in India is a rapidly expanding, highly knowledgebased sector that significantly boosts the country's econ omy.In terms of production quantities, India's pharmaceutical industry is ranked fourth in the world, and more than half of its export

s are shipped to nations with severe regulations.Drug exports from India totalled $14.6 billion, or around Rs. 82,730 crore, during th e iscal year that concluded on March 31, 201.One of the best examples of a developing country with a strong pharmaceutical industr y and an effective drug regulation system is India.A survey indicates that 1225% of all medications supplied in India are thought to be counterfeit. The market for fake and substandard pharmaceuticals is substantial in India.

India's position on illegal substances :

With 10% of worldwide production, India's pharmaceutical sector is the third largest in the world by volume.
India leads the globe in producing generic medications and vaccines, which it supplies to more than 200 nations.
The country that produces the most of these counterfeit medications for export is India.The majority of recovered counterfeit medica tions can be traced back to their nation of origin, with China and India being the primary sources, according to several publications. A 2017 WHO examination found that 2030% of Indian pharmaceuticals were counterfeit.To gather this information, samples from a round the country were gathered and analysed.

India's lack of legislation controlling the production and sale of pharmaceuticals, the fact that those found guilty incur minor fines re lative to their earnings, and the absence of significant legal action against them all contribute to the growth of counterfeit drugs.
The Medications and Cosmetics (Amendment) Act stipulates that samples of pharmaceuticals that are discovered to be nonstandard or counterfeit may be sentenced to ten years in prison. Guidelines for managing these samples have therefore just been developed. Additionally, the number of people affected by the use of these drugs is growing.

Pharmaceutical counterfeiting and Internet pharmacies :

A study that was published in The Lancet claims that the internationalisation of fake medications has been connected to the growth o f online pharmacies.The WHO estimates that nearly half of medications marketed online are counterfeit.These numbers are concerni ng for patients, governments, and pharmaceutical businesses.36. According to the National Association of Boards Pharmacy (NABP), 9938 out of 10,000 online pharmacies in the United States disregarded both NABP patient safety and pharmacy practice guideline s and US state and federal legislation.This issue is not limited to underdeveloped nations.According to a different survey, 25% of pe ople who report prescription side effects bought their medications online.Counterfeiters have a chance to profit from the ever-increasing demand for vaccinations against various diseases, especially the difficult-to-prevent COVID-19 virus.

Vaccines are not the only products that can be counterfeited.Face masks, PPE kits, N95 masks, gloves, sanitisers, and diagnostic kits were among the counterfeit products available on the market, along with medications like antivirals, chloroquine, paracetamol, and vitamin C.42. Even in wealthy nations, COVID19 overloaded healthcare systems.Drugs like hydroxychloroquine (HCQ), which wer e successful against COVID19, are subject to rigorous regulations in the majority of nations, including the USA.Due to a shortage, I ndia initially forbade the export of HCQ; however, this ban was later lifted after India sent 50 million HCQ tablets to the US.Anothe r medication that Indian regulatory authorities discovered to be regularly counterfeited during COVID-19 was dexamethasone.

Motives for expansion :

Numerous factors, including the expansion of the 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 curen t legal system, have contributed to the growth of the drug counterfeiting industry in IndiaIn India, drug counterfeiting is a tremendou sly profitable industry.India's prominence as a low-cost manufacturing powerhouse has made it more accessible to counterfeiters. Despite not having to pay the hefty expenses of research and development that legitimate businesses do, counterfeiters are nonethele ss able to generate substantial profits.Drug counterfeit detection is an expensive and difficult process.Customers can't tell the differe nce between real and fake products.They found that between 2001 and 2005, counterfeiters became far more skilled at using intricat e printing techniques like holograms.When there is a gap between the supply and demand for pharmaceuticals, criminals often turn t o making and distributing phoney or spurious drugs as a substitute for legal treatments in order to benefit from their crimes. Additionally, drug abusers frequently create a, which may come from phoney source

IPR's function :

The Indian pharmaceutical sector has seen changes since it joined the World Trade Organisation (WTO) and agreed to apply TRIPS (Trade Related Aspects of Intellectual Property Rights).Significant global changes to intellectual property rules have an impact on In dia's pharmaceutical sector. Because of the 1970 patent law, the generic pharmaceutical industry in India is expanding quickly. Due to the era of process patents, India rose to prominence in the production, marketing, and distribution of pharmaceuticals, includi ng protected goods, between 1970 and 2005.47. Consequently, India emerged as the world's leading provider of APIs (active pharma

ceutical ingredients) and generic medications.48. The liberal procedural patent environment in India brought about significant impro vements.

Local Indian companies began to imitate their pharmaceutical production techniques by creating their own and obtaining patents for them.Additionally, Indian businesses were allowed to export their counterfeit goods to nations that at the time recognised internation al patents.The pharmaceutical sector started a new age of product patents on January 1, 2005, when Indian pharmaceutical companie s were required to adopt a TRIPS compliant patent regime. This meant that they could no longer produce or market copyright-protected medications without a licence from the patent owners.In this new era of product patents, the Indian generic pharmaceutical business, which had thrived on process patents, was prohibited.This rule restricted the Indian pharmaceutical industry's ability to pr oduce generic medications.

Customers' and chemists' roles :

In the fight against drug counterfeiting, chemists and end users are essential allies.They are the ones who have direct communication with the drug suppliers.Therefore, it is crucial to make sure that patients and chemists understand the issue of counterfeiting and ho w to distinguish between authentic and fake medications.Since statistics indicates that the majority of counterfeit goods are markete d through dubious online pharmacies, patients should purchase their prescriptions from reliable suppliers and refrain from utilising d ubious online pharmacies.If the patient notices any changes in the flavour, appearance, or effect of the medication they have taken, t hey must notify the physician or chemist right away.

The pharmaceutical corporations' role :

Pharmaceutical businesses lose around $200 billion a year due to medicine counterfeiting, according to available data.51. Pharmace utical companies invest a lot of time and money in developing new medications.RCTs guarantee strict adherence to safety protocols. Therefore, medicine counterfeiting costs pharmaceutical businesses money.Businesses must combat counterfeiting from the source, which includes regulatory agencies, distributors, wholesalers, and the pharmacy community, in order to stop this
Pfizer alone has identified fake versions of 104 medications in 116 countries.

Indian regulations :

The Drug and Cosmetics Act 1940 and Rules 1945 forbid the sale of counterfeit drugs in India.
• Stricter criteria and penalties have been published for handling drug samples deemed to be fake or of low quality.
• An incentive program for those who report fraud in the pharmaceutical, cosmetic, and medical device industries.
• How pharmaceutical formulations are exported via the Track and Trace system.55Insufficient regulation in India
• A WHO study found that 10% of pharmaceuticals are fake.
Prior to 2013, many cases went undetected; however, since then, 1500 cases have been documented.
A barcoding system must be in place for pharmaceuticals exported from the nation, according to a directive from the Director-General of Foreign Trade (DGFT).

Counterfeit drugs have a lot of detrimental effects on a community's economic and health conditions.
There are several situations in which using fake medications could be harmful to one's health.
Scenario 1: There are no harmful or active chemicals in the counterfeit medication.
In this instance, rather than being directly injured by the phoney medicine, the patient's condition worsens as a result of the delay in obtaining medical assistance.Furthermore, the inefficiency of the fake drug could lead to an incorrect diagnosis of antibiotic resistan ce.The phoney medication contains hazardous substances but has no active ingredient.

In this situation, the patient may experience unanticipated adverse medication reactions that result in morbidity or even death.

Scenario 3: The phoney medication has the incorrect active component:
In this case, the patient would unintentionally be taking a different medication rather than the prescribed one.
Scenario 4: The phoney medication contains other molecules and the required active ingredients, but in the incorrect am ounts.Both the patient's morbidity and the chance of developing antibiotic resistance may rise as a result.
Furthermore, the public's trust in the healthcare system would be damaged by a high prevalence of fake medications.

The impact of fake medications on the economy :

The economic cost of counterfeit medications is caused by increased morbidity, adverse drug reactions, and drug resistance.
Disease and mortality rates are rising, which could result in lost commercial possibilities.The selling of fake drugs would hurt comp anies that have made investments in pharmaceutical quality, research, and development.This may also discourage businesses from m aking R&D and foreign investment investments.In addition, a substantial quantity of tax money is lost by the government.Large sum s of money must also be spent on developing technologies that can identify fake medications and safeguarding the drug supply chain

.DetailsIndia, Europe, Canada, and the United States1. StrengthThe European Agency for Medicine and the US Food and Drug Administration The Health of Canada The Central Organisation for Drug Standard Control

Three Guidelines
Guidelines for safeguarding the drug supply chain are provided by the Drug Supply Chain Security Act (DSCSA) and Title II of the Drug Quality and Security Act (DQSA).The impact of Brexit on the CommissionDelegated Regulation (EU 2016/161) and the Falsified Medicines Directive (FMD) (2011/62/EU).Examine the Food and Health Products Branch's policy against counterfeit health products.Drug and Cosmetics Act of 1940 and Rules of 1945.

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RESULTS :

Drug counterfeiting is a threat to society and needs to be aggressively combated.Different nations have different laws to stop drug counterfeiting, but in order to put these laws into effect, regulatory monitoring and frequent sample testing to verify the accuracy of label claims are necessary.Drug counterfeiters may face penalties under criminal laws such as the Indian Penal Code of 1860 and the Drugs and Cosmetics Act of 1940, as well as prohibitions under intellectual property laws such as the Trademark Act of 1999 and the Patents Act of 1970.This synopsis outlines each stratum's function and pertinent data in preventing pharmaceutical counterfeiting.The report recommends that health care providers inform primary and end users about the distinctions between genuine and counterfeit drugs.

India leads the globe in producing generic medications and vaccines, which it supplies to more than 200 nations.The country that produces the most of these counterfeit medications for export is India.The WHO estimates that nearly half of medications marketed online are counterfeit.These numbers are concerning for patients, governments, and pharmaceutical businesses.Numerous factors, including the expansion of the pharmaceutical industry, lax pharmaceutical regulation, high drug costs, valueadded tax, prescription drugs written without registration, low public awareness, lax enforcement of laws, and the flexibility of the current legal system, hav contributed to the growth of the drug counterfeiting industry in India.Trends in public awareness, involvement, patenting, and patet enforcement define this age in the Indian pharmaceutical industry.

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