

# Study of Counterfeit Drug in Pharmaceutical Market

Saurabh S. Swami<sup>1</sup>, Shubham U. Tikait<sup>2</sup>, Vinayak A. Katekar<sup>3</sup>,  
Swati P. Deshmukh<sup>4</sup>

<sup>1</sup> Department of Pharmacy, Shraddha Institute of Pharmacy, Washim, Maharashtra, India.

<sup>2</sup> Department of pharmaceuticals, Shraddha Institute of Pharmacy, Washim Maharashtra, India.

<sup>3</sup> Department of Quality Assurance, Shraddha Institute of Pharmacy, Washim Maharashtra, India.

<sup>4</sup> Department of Pharmacology, Shraddha Institute of Pharmacy, Washim Maharashtra, India.

## Abstract

Counterfeiting is an ever-growing issue intensified by the increasing ease of access via e-commerce activities. The amalgamation of misinformation-driven panic, economic distress, and public health emergency contributes to the challenges related to the accessibility and supply of better and essential quality medicinal products, leading to price volatility, uncertainty, quality of issues, and drug shortages. The adoption of state-of-the-art technologies paves the way for the digital transformation of the pharmaceutical industry, incorporating blockchain technology augments the safety of drugs, with early detection of falsified drugs, thereby leading to minimized mortality rate and improved safety. Blockchain-based architectures enable the systems to offer a platform that is substantially better in addressing the changing need for pharmaceutical data privacy, data storage quality assurance, and material traceability. This paper discusses the different technologies in the counterfeiting of drugs, with the prime focus on blockchain technology. It emphasizes on the strategic decisions and models adopted by the key players in their supply chain process to make these an efficacious one. The article also focuses on the relevant information regarding blockchain architectures and the challenges being faced in the implementation of this technology in combating counterfeiting in the pharmaceutical industry.

**Keywords:** Blockchain, Counterfeiting, Drugs, Pharmaceutical, Technology.

## INTRODUCTION:

Drugs are used to cure or treat disease, relieve symptoms, ease pain, prevent disease or symptoms, eliminate or reduce symptoms and to slow the disease process. Fake means something that is not genuine but is presented as or appears to be genuine to make or produce something and claim it is genuine when it is not. Shelf life is the time taken for the preparation to become unfit for use either through chemical degradation of the active ingredient or physical deterioration of the preparation during storage. It can also be defined as the period a drug or product will remain satisfactory when stored under expected or directed storage conditions ordered by the manufacturer. Shelf life or expiry date of a drug is usually a maximum of five years. Counterfeit is something made for a dishonest purpose, an act deliberately designed to deceive.

The World Health Organization defines counterfeit drugs as one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting of commercial

products is an age old practice which flourishes in many countries and is motivated mainly by the huge profits to be made. Trade in counterfeit drugs appears to be widespread. Internationally, affecting both developed and developing countries. The spread of counterfeit drugs is generally more pronounced in those countries where the manufacture, importation, distribution, supply and sale of drugs are less regulated and enforcement may be weak. Counterfeiting can apply to both branded and generic products and counterfeit medicines may include products with the correct ingredients but fake packaging with the wrong ingredients, without active ingredients or with insufficient active ingredients. Counterfeit medicinal drugs include those with less or none of the stated active ingredients with added sometimes hazardous, adulterated, substituted ingredients, completely misrepresented or sold with a false brand name otherwise legitimate drugs that have passed their date of expiry are sometimes remarked with false date low quality. A counterfeit medication or pharmaceutical product is produced or sold with the intent to deceptively represent its origin authenticity or effectiveness. A counterfeit drug may contain inappropriate quantities of active ingredients or none may be improperly processed within the body for example absorption by the body, or may contain ingredients that are not on the label. Several technologies may prove helpful in combating the counterfeit drug problem. Fake drugs otherwise called counterfeit drugs are unfit for usage and human consumption and therefore constitute hazard to good health. Drug counterfeiting is a growing danger and not only in developing countries where it can account for up to 40% of the market. Some counterfeiting is difficult to detect, investigate, quantify or stop. The quantity of counterfeit medication is difficult to determine. Counterfeiting occurs throughout the world, although there are claims it is more common in some developing Countries with weak regulatory or enforcement Regimens. A counterfeit drug may look like the genuine Version of medication.

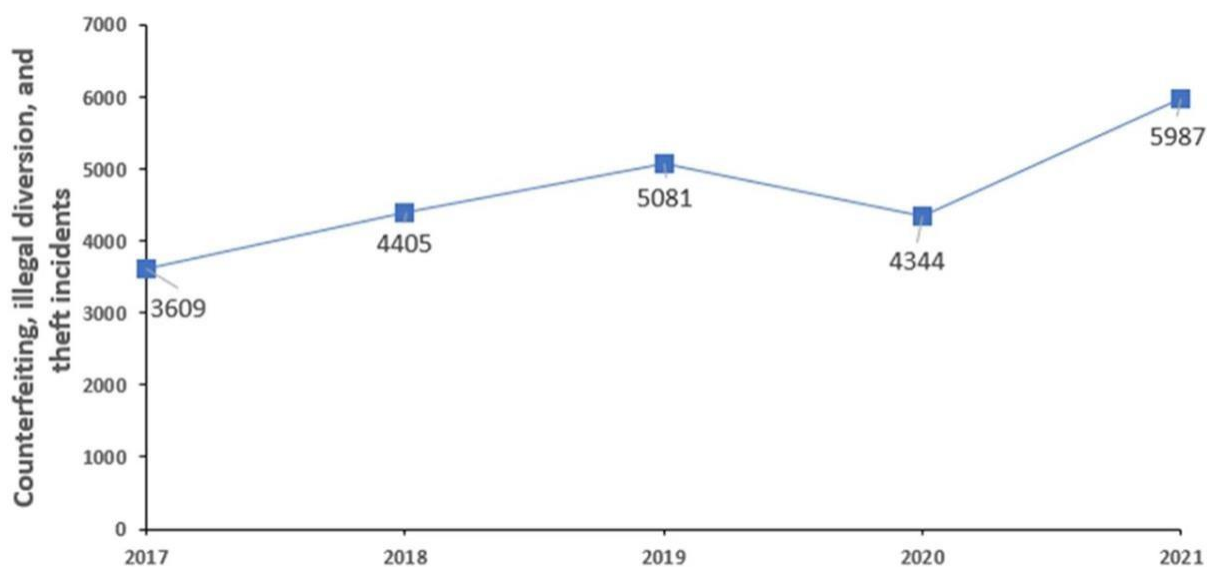
#### **IMPLICATIONS OF COUNTERFEIT DRUGS:**

- The problem of fake drugs is very important in medicine because of the associated health risks. Obviously, counterfeit drugs have adverse health, economic and social implications. Its negative impact on the society is more than that of either narcotic agents or the combined effects of malaria, HIV/AIDS and armed robbery .
- Fake drugs have led to therapeutic. Failures, antibiotic resistance, toxic effects and even deaths. whole essence of manufacturing pharmaceutical products is to ensure the well- being of the human body or to provide cure for diseases without endangering any organ. Tissue or system of the patient. The reverse becomes the case where the product counterfeit or substandard because the drug will complicate the patient's health situation.
- Fake drugs has embarrassed our Healthcare providers and eroded the confidence of the public in our healthcare delivery system. The situation became so bad that even when patients were treated with genuine antibiotics, they no longer respond due to resistance induced by previous intake of fake antibiotics. Fake drugs are now making their way from the black market directly to pharmacies where legitimate drugs are being sold and even communities also pay as these fake drugs result in increased demand for health care and more invasive interventions to treat illness that could be treated early on with Medications.
- Drug counterfeiting has led to enormous economic loss and appears to be increasing annually. According to the WHO, about 32 billion US dollars were lost to drug counterfeiting business in 2004. This increased to 40 billion US dollars in 2006 and is projected to reach 75 billion US dollars in 2010. Many pharmaceutical companies are deprived of their rightful profits due to the unjust competition from this brutal crime and have even resulted in the collapse of some of the companies. For instance many multinational companies divested and left Nigeria out of frustration. E.g. Boehringer, ICI, Sandoz, Merck, Boots etc .

- The image of the country is at stake as the country becomes rated as one of the countries with the highest incidence of fake/ counterfeit drugs. During an epidemic of meningitis involving 41,000 cases in Niger in 1995, the country was promised a donation of 88,000 vaccine doses from Nigeria, with Pasteur Mérieux and Smith Kline as Beecham as Manufacturers. In fact the vaccines were found to have been replaced on the way with spurious copies containing no active ingredient but with labeling meticulously copied from the original. About 2, 500 people died in the country following the administration of the counterfeited vaccines to some 60, 000 people .

### Extent of Counterfeiting of Drugs in Developing Countries:

Developing nations are home to a sizable part of the counter- feit drugs being circulated in the world. As per the data from WHO, every 1 in 10 medicinal products in developing coun- tries is counterfeit or spurious [14]. The growth in this busi ness of drug counterfeiting is a consequence of the scale and complexity of drug counterfeiters, which is being linked to the absence of competent regulation and a limited enforce- ment capability in developing nations. Additionally, custom- ers in underdeveloped nations are more inclined to look for these affordable alternatives due to the high cost and lack of availability of medications. The developing countries are in dire need of life-saving medications such as anti-retrovira



**Fig No.1 : the yearly total for year 2017 to 2021 demonstrated as a line graph for the last 5 year from the collected data on the counterfeiting ,illegal diversion and theft incidents.**

Medications, antimalarials, and antibiotics, which are fre- quently the main targets of drug counterfeiters. For example, a 2004 international study revealed that more than 53% of artesunate tablets sold in southeast Asia contained no active ingredient at all, with unimaginable repercussions for the region's efforts to combat malaria. Several previous reports such as 100 fatal cases of kidney damage in Haiti, two-thirds of the available antimalarials in Cambodia were found to be counterfeited, 2500 deaths in Niger due to counterfeit men- ingitis vaccine, etc. Furthermore, India accounts for 35% of the counterfeits produced, Nigeria produces about 23% and Pakistan accounts for 13.3% .

### **Counterfeit Medications and Internet/ Online Pharmacies:**

As per a report in The Lancet, rise in online pharmacies has led to the globalisation of counterfeit medicines. The WHO states that approximately 50% of the drugs sold via the internet are fake. These are terrifying numbers for pharmaceutical companies, governments and patients. This is not limited to developing countries; in the USA, a survey of 10,000 online pharmacies by the National Association of Boards of Pharmacy (NABP) found that 9938 online pharmacies did not adhere to NABP patient safety and pharmacy practice standards or US state and federal laws. Another survey done amongst physicians in the UK revealed that 25% of the patients reporting an adverse effect of a drug have purchased it from an online pharmacy.

A study was conducted to evaluate what percentage of online Viagra is genuine. Reported results show that the majority of the Viagra™ purchased online was counterfeit. In up to 77% of orders, fake Viagra™ had been supplied from websites claiming to sell the real drug; the fakes typically originated from non-American addresses and included only 30-50% of the active pharmaceutical ingredient claimed on the packaging label. As per the study findings, 100% of the 22 websites evaluated did not request a prescription before a purchase, as required by law, and none demanded that a health check be completed before a purchase could be made. In addition, 91% of the websites tested claimed to sell drugs known as 'generic Viagra despite these drugs not having FDA approval [26]. Apart from the USA, research on the non-medical use of prescription pharmaceuticals in five European nations (Denmark, Germany, UK, Spain, and Sweden), found that stimulants (7.6%), opioids (4.1%), and sedatives (2.7%) were often obtained via online pharmacies without the supervision of a doctor.

To prevent the expanding menace of the distribution of counterfeit drugs via rogue online pharmacies, strict measures need to be taken. Regulating the purchase of pharmaceuticals online requires cooperation between international, national and state entities as well as between patients and medical experts.

### **Conclusion and significance:**

Trade in counterfeit drugs appears to be widespread internationally and affects both developing and developed countries. The spread of counterfeit drugs is generally more pronounced in countries where the manufacture, importation, distribution, supply and sale of drugs are less regulated and enforcement may be weak. To achieve the goal of health for all, the menace of counterfeit drugs needs to be controlled. Counterfeit medicine poses a serious threat to public health and has taken a silent devastating toll on humanity due to the lack of reporting in some critically affected areas. In addition to past and present losses due to fake drugs the future of global health is at risk. Disease causing agents can develop resistance to genuine drugs.

Counterfeit drugs are a menace to society, one that must be countered actively. There are different laws in different countries to discourage drug counterfeiting, but this requires regulatory oversight and sporadic testing of samples to assess the accuracy of the label claims. India has provisions under intellectual property law (The Trademark Act, 1999 and The Patents Act, 1970) and criminal laws (The Indian Penal Code, 1860 and Drugs and Cosmetics Act, 1940) to punish the drug counterfeiters. Similarly, the USA has state and federal laws which make provision for imprisonment and financial penalty in cases of drug counterfeiting. Europe also levies high penalties and imprisonment in cases of drug falsification. Despite all these laws, the borderless trafficking of counterfeit medications is on all time high and is projected to increase even higher. Considering that the monitoring ambit of the regulators barely covers essential medicines, it would be a big stretch for them to enforce or conduct frequent surveillance audits. This is where the government plays a vital role in funding the health agencies to enable such surveillance.

**Reference:**

1. World Health Organization. Guidelines for the development of measures to combat counterfeit drugs. Available from: <http://www.who.int> [Accessed 2023 Oct 22].
2. World Health Organization. Fact sheet 272. Revised 2006 February. Available from: <http://www.who.int/mediacentre/factsheets/fs272> [Accessed 2023 Oct 22].
3. Juliet Y. Update on counterfeit drugs: a growing risk for public health. Bull Acad Nati Med. 2008;192(7):1423-34.
4. Akunyili D. Counterfeit medicines: a serious crime against humanity. Proceedings of the Director General of the National Agency for Food and Drug Administration and Control (NAFDAC); 2007. P. 1-7.
5. Akunyili D. Experience: implications, challenges, actions and recommendations; 2005. Available from: [siteresources.worldbank.org/INTAFRREGTOPHIVAIDS/...](http://siteresources.worldbank.org/INTAFRREGTOPHIVAIDS/) [Accessed 2015 Sep 8].
6. Chika A, Bello SO, Jimoh AO, Umar MT. The menace of fake drugs: consequences, causes and possible solutions. Res J Med Sci. 2011;5:257-61.
7. Sporoxil: combating counterfeit drugs with mobile phones; 2012. Available from:
8. [www.businesscalltoaction.org/.../sproxilcasestudy2.23.2012forweb17.pdf](http://www.businesscalltoaction.org/.../sproxilcasestudy2.23.2012forweb17.pdf) [Accessed 2015 Sep 8].
9. Summary of recommendations and concluding remarks; 2004. Available from: [www.unmillenniumproject.org/documents/TF5-medicines-Chapter4.pdf](http://www.unmillenniumproject.org/documents/TF5-medicines-Chapter4.pdf) [Accessed 2015 Sep 8]
10. The situation of medicine counterfeiting in Africa. Available from: [www.whpa.org/background/medicines\\_counterfeiting\\_in\\_africa\\_chiom](http://www.whpa.org/background/medicines_counterfeiting_in_africa_chiom) [Accessed 2015 Sep 24].
11. World Health Organization. 1 in 10 medical products in developing countries is substandard or falsified. 2017. Available from: <http://www.who.int/new/28-11-2017-1-in-10-medical-products-in-developing-countries-is-substandard-or-falsified>. Accessed 1 Mar 2023.
12. Francesca B, Germano A, Brusa P. Diffusion of counterfeit drugs in developing countries and stability of galenics stored for months under different conditions of temperature and relative humidity. CNSAT Med. 2012;1(2):173-84.
13. Kristina LM. Rx roulette: combatting counterfeit pharmaceuticals in developing nations. Manag Decis Econ. 2007;28(4-5):500-20.
14. Clark F. (2015) discusses the rise of online pharmacies and the global issue of counterfeit drugs, emphasizing the risks associated with purchasing medications over the internet.
15. Novak SP et al. (2016) examines the nonmedical use of prescription drugs in the European Union, highlighting trends and implications for public health.
16. Fincham JE addresses the negative consequences of easy access to prescription medications online, raising concerns about misuse and the impact on healthcare systems.
17. Ziavrou KS, Noguera S, Boumba VA. Trends in counterfeit drugs and pharmaceuticals before and during COVID-19 pandemic. Forensic Sci Int. 2022;338:111382.
18. Amusa M, Oluwade B. A historical background of some basic ICT tools used in counterfeit drug control. Afr J Comput. 2020;13(1):52-61.
19. Isah H. Information and communication technology in combating counterfeit drugs. Int J Eng Technol. 2012;2.
20. European Union. Unique device identification (UDI) system: Under The EU medical devices regulations, 2017/745 and 2017/746. European Union; 2020. P. 6.