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REVIEW ARTICLE

Tackling Counterfeit Drugs: The Challenges and Possibilities

Ranjana Pathak[1] · Vaibhav Gaur[2] · Himanshu Sankrityayan[2] · Jaideep Gogtay[2]

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Abstract
Drugs that have been manufactured or packaged fraudulently are referred to as counterfeit/fake/spurious/falsified drugs because they either lack active ingredients or have the incorrect dosages. Counterfeiting of drugs has become a global issue with which the whole world is grappling. The World Health Organization states the frightening figure in which almost 10.5% of the medications worldwide are either subpar or fake. Although developing and low-income countries are the targets of the large-scale drug counterfeiting activities, fake/substandard drugs are also making their way into developed nations including the USA, Canada, and European countries. Counterfeiting of drugs is leading to not only economic loss but is also playing its part in the morbidity and mortality of patients. The recent COVID-19 pandemic fuelled the demand for certain categories of medicines such as antipyretics, remdesivir, corticosteroids, vaccines, etc., thus increasing the demand and manufacture of subpar/fake medicines. This review articulates the current trends and global impact of drug counterfeiting, current and potential measures for its prevention and the role of different stakeholders in tackling the menace of drug counterfeiting.

Key Points

Drug counterfeiting is spreading globally at a disturbing rate.

Newer and improved steps are required to prevent the global drug counterfeiting.

Use of technology is paramount to tackle the drug counterfeiting issue.

The policymakers should work on appropriate laws in consultation with legal departments and ensure their strict enforcement to strike fear in drug counterfeiters.

1 Introduction

"Did you take your medicine?", asks a concerned mother.

"Did you complete your dose?", asks a diligent doctor.

The above are just some of the statements that are commonly heard when someone is ill. The presumption here is that whatever the ailment, medicine will either cure or prevent illness and/or make for a better quality of life. We all take medicines when we are sick; many also take health supplements such as nutraceuticals, vitamins, etc., to maintain our health. Over the years, medicine has played a key role in increasing the longevity of humans—today, our longevity and life expectancy has increased [1].

The World Health Organization (WHO) states that "health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity". The WHO further enunciates this to be a fundamental right without the distinction of race, religion, political beliefs, and economic or social condition [2].

Undoubtedly, everyone wants to live long and be healthy. While modern medicine has been a key contributor to improving health and longevity, unfortunately, the quality of medicines, has become open to question because of the huge disparity worldwide. With respect to medicine quality, each country's government plays a pivotal role in assuring and regulating health standards. As consumers, we expect the quality to be non-negotiable and a given; also, the consumer today is savvy and expects what he/she pays for as stated on the label. The reality, however, is not always on par with the above expectations. This review article hopes to serve as a spark to the reader to reflect on the above situation and hopefully call for action against this negative trend of—*bad medicine*, also known as spurious drugs or as counterfeit drugs.

✉ Ranjana Pathak
ranjanapathak@drreddys.com

[1] Present Address: Dr Reddy's Laboratory Ltd, Banjara Hills, 8-2-337, Road No. 3, Hyderabad, Telangana 500034, India

[2] Global Medical Affairs, Cipla Ltd, Mumbai, India

A counterfeit medication/drug is a medication or pharmaceutical item that is produced and sold with the intent of deceptively representing its origin, authenticity, or effectiveness. It may contain inappropriate quantities of active ingredients or none at all, it may be improperly processed within the body (e.g., absorption by the body), may contain ingredients, which may or may not be harmful, that are not mentioned on the label, or may be supplied with inaccurate or fake packaging and labelling. This also includes the drugs that are past their shelf-life but being sold with an altered date of expiry or manufacturing [3]. There are several examples of counterfeit medications where there is no active ingredient and no harmful drug, excessive active ingredient, less active ingredient, and/or drug mixed with microbial or chemical pollutants (Table 1). All can have varied impact on the consumer, ranging from no benefit at all from the drug to suboptimal effect or becoming resistant to the drugs (in case of anti-infectives), thereby leading to larger health issues later or even, at the worst, death.

The history of drug counterfeiting dates back to centuries and is considered as one of the oldest crimes in human history. Several centuries ago, there are mentions regarding a supply of counterfeit antimalarials, including cinchona in the early 1600s and quinine in the 1800s [4]. Since then, the problem of fake and substandard drugs has continued to grow unchecked. The ever-growing problem of drug counterfeiting was first scrutinised at a global level by the WHO. The WHO established a clearinghouse to gather information and inform governments about the nature and scope of counterfeiting in reply to a suggestion put forth by the Conference of Experts on the Rational Use of Drugs (Nairobi, 25–29 November 1985). In response to this decision, the International Federation of Pharmaceutical Manufacturers and Associations and the WHO jointly hosted the first global conference on fake medications from 1 to 3 April 1992 in Geneva. The WHO further launched a project on counterfeit drugs in 1995 with financial aid from Japan. Further, in 2006, the International Medical Products Anti-Counterfeiting Taskforce was established by the WHO, and it has since become the primary vehicle for the organisation's efforts to combat fake drugs [5]. This review is aimed at dissecting the problem of drug counterfeiting across the globe.

2 Global Impact of Counterfeit Medicines: Economic and Health Impact

In 2017, the WHO estimated that 10.5% of the medications worldwide is either subpar or fake. As per a report, the incidence of counterfeit medicines was around 13.6% in low- and middle-income countries (LMICs). The anticipated financial consequences in this context could be as high as $200 billion [6]. The whole world is dealing with the impact of a rise in counterfeit medicines, as indicated in Fig. 1. Drug counterfeiting also has a major financial impact. Every drug therapy incurs costs, either for the individual paying cash (which is the only choice for the majority of the poor in developing nations) or for the insurer/government that pays for the medications. In a survey carried out by WHO and Health Action International to gauge the number of days a poor daily wage earner might require buying medicines for a common treatment. Unfortunately, the cost of affording a standard treatment of malaria or other bacterial infections was several days of wages [7]. Furthermore, the global impact of counterfeit medicines is not only limited to the financial aspects but also could be called a crime against humanity wherein life-saving medicines are turned into the equivalent of life-taking poisons. According to the WHO, around 1 million people die each year because of fake medications. The majority of whom live in Africa, where it is estimated that 200,000 individuals pass away each year as a result of fraudulent antimalarial medications [8]. One of the prime dangers of using counterfeit or substandard drugs is the development of resistance. Antibiotic resistance has emerged as a major global issue and if a patient is taking a substandard antibiotic, the outcome is bound to be an increase in antibiotic resistance. Similarly, substandard antimalarials may lead to an increase in resistant *Plasmodium falciparum* and *P. vivax* strains [9]. Although the prevalence of counterfeit medicines is higher in the LMICs, it has also

Table 1 Possible types of drug counterfeiting with examples

S. no.	Type of counterfeiting	Example	References
1.	No active drug + no harmful substance	a. Vials of PROCRIT® (epoetin) were found to contain nothing but Miami city tap water b. Remdesivir ampoules filled with normal saline	[51]
2.	Excessive (concentrated) active drug	Concentrated onabotulinumtoxin A (Botox®) not meant for human application	[31]
3.	Wrong active drug	Sibutramine instead of orlistat in GSK's Alli®	[31]
4.	Drug contaminated with microbes, toxins and harmful chemicals	a. Fake inhalers for the treatment of paediatric cystic fibrosis were found to contain contaminated bacteria b. Counterfeit cough syrup that was mixed with ethylene glycol (i.e., antifreeze)	[31]

GSK GlaxoSmithKline

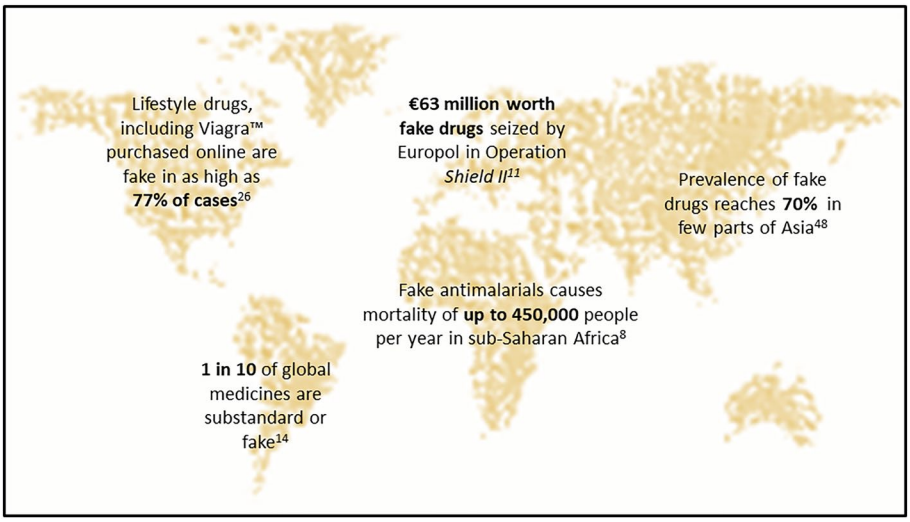

Fig. 1 Drug counterfeiting highlights across the globe

entered the global supply chain. In October 2018, the Medicines and Healthcare products Regulatory Agency (MHRA) and its partners in the UK, through Interpol's worldwide Operation Pangea assault on fake pharmaceuticals and medical equipment, discovered more than 3 million medicines and medical devices in the UK supply chain that were part of a fraudulent medication business worth £9 million [10].

In a recent Operation Shield II by Europol, more than 25 million units of medicines were seized with a value of around €63 million. Earlier in 2009, within only two months, the European Union (EU) confiscated 34 million counterfeit pills, including those containing sildenafil citrate (Viagra™), chemotherapeutic medicines and antibiotics [11].

Asia, specifically India, leads in the production of counterfeit medicines with approximately 35–75% of fake medicines being produced in India [12]. However, as per the reports of the Pharmaceutical Security Institute (PSI), a not-for-profit, membership organisation, the maximum percentage of counterfeit drugs seized was higher in North America followed by Asia-Pacific (Fig. 2)

Recently, in September 2022, the WHO flagged four substandard cough syrup brands from Maiden Pharma, India, as they were reportedly linked to the deaths of 66 children in Gambia in western Africa. The product was later found to possess excessive levels of diethylene glycol and ethylene glycol as contaminants [13]. This is not a singular case of death due to counterfeit or substandard medicines. Previously, many such cases have come to light where falsified or substandard medicine led to deaths and disabilities. The data collected by the PSI show that over the course of the last 5 years, there has been a gradual increase in cases of drug counterfeiting (Fig. 3).

Overall, such cases of drug counterfeiting will ultimately reduce the credibility of healthcare stakeholders/systems/

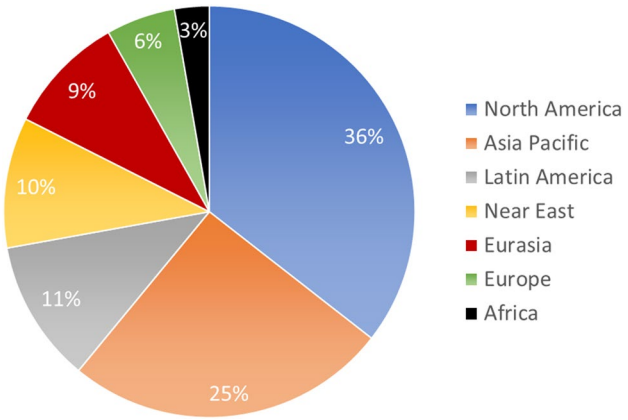

Fig. 2 A pie chart representing the percentage of counterfeiting incident data with respect to seven regions of the world

pharmaceutical companies and the trust of common people will be lost.

2.1 Extent of Counterfeiting of Drugs in Developing Countries

Developing nations are home to a sizable part of the counterfeit drugs being circulated in the world. As per the data from WHO, every 1 in 10 medicinal products in developing countries is counterfeit or spurious [14]. The growth in this business 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 enforcement capability in developing nations. Additionally, customers 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-retroviral

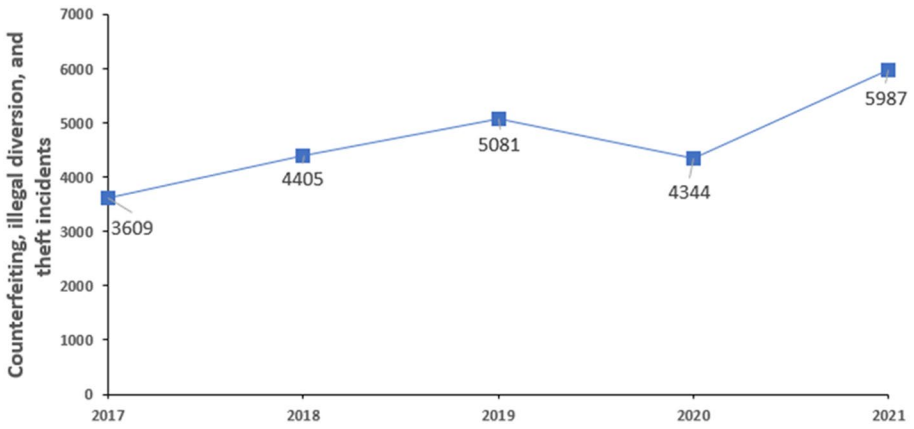

Fig. 3 The yearly totals for year 2017 to 2021 demonstrated as a line graph for the last 5 years from the collected data on counterfeiting, illegal diversion, and theft incidents

medications, antimalarials, and antibiotics, which are frequently 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 meningitis vaccine, etc. Furthermore, India accounts for 35% of the counterfeits produced, Nigeria produces about 23% and Pakistan accounts for 13.3% [15, 16].

3 Impact of COVID-19 on Counterfeiting of Medicines

The recent COVID-19 pandemic that wreaked havoc throughout the world proved to be advantageous for the illegal counterfeit medicine market that is already posing a big challenge across the globe. This was due to a staggering increase in the number of COVID-19 cases, leading to high demand for different drugs, protective gear and kits and disruption in the supply chains, aided by the inadequate regulatory capacity of law enforcement personnel [17, 18].

As soon as there were talks of vaccine development to counter the ill-effects of COVID-19, the WHO issued a warning regarding the risk of phony vaccine shots. Jürgen Stock, general secretary of Interpol, called vaccine as the liquid gold in 2021 and stated that counterfeiters would certainly target the vaccine supply chains. This concern was validated by different reports regarding the seizure and arrest of people in connection with the sale and distribution of fake COVID-19 vaccines in different parts of the world. Reports emerged that the Pfizer vaccines were sold for as high as $1000 in Mexico and Poland [19]. In southern Africa, Interpol confiscated vaccines, fake medicines, masks, and phony COVID-19 test certificates worth $3.5 million. Another report claims that the illegal market for drugs has increased by more than 400% at the end of 2021 [19]. It provides the counterfeiters with an opportunity to cash in on the fast-growing demand for vaccines for different diseases including COVID-19, which would be hard to prevent.

Counterfeiting is not limited to vaccines alone. Counterfeited versions of basic necessities required during the COVID-19 pandemic, such as face masks, PPE kits, N95 masks, gloves, sanitisers and diagnostic kits, along with medicines such as antivirals, chloroquine, paracetamol, and vitamin C were also abundant in the market [20]. COVID-19 stretched the healthcare system of even the developed countries to breaking point. The drugs that were supposedly effective in COVID-19 such as hydroxychloroquine (HCQ) were in acute short supply in most countries, including the USA. Initially, due to a shortage, India banned the export of HCQ, which was later lifted when India exported 50 million HCQ tablets to the USA [21]. The shortage was such that regular users of HCQ for arthritis and lupus were struggling to find a source. Several cases in India were registered for the falsification and selling of remdesivir where empty remdesivir vials were filled with liquid paracetamol or even saline. In India, falsified batches of remdesivir were also found circulating in the market. Dexamethasone was another drug that was found to be counterfeited in high amounts during COVID-19 by Indian regulatory agencies. A report stated that the prevalence of substandard dexamethasone ranged between 3.14 and 32.2% in LMICs [22].

COVID-19 also played an important role in the surge of counterfeit medicines by disrupting the global supply chain. The main reason for such disruption was the export bans and border shut-down of countries producing the bulk of active pharmaceutical ingredients and raw materials, including China and India. Consequently, the countries dependent on these supplies faced shortages during the outbreak, thus greatly enabling counterfeiters to expand their market in such countries [23].

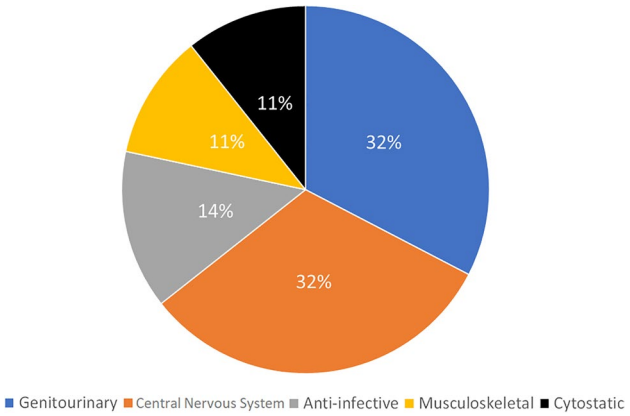

Fig. 4 Counterfeiting incidents shown according to the different therapeutic categories including the top five categories in the year 2021. Data from https://www.psi-inc.org/therapeutic-categories

4 Categories of Drugs Being Counterfeited

Drugs belonging to different therapeutic categories are counterfeited across the globe. Different reports corroborate that the anti-infective drug category, which consists of antibiotics, antivirals, antifungals, antimalarials, etc., makes up the bulk of drugs being counterfeited, with the percentage ranging anywhere from 10% to as high as 50% [24]. Further, in this category, antibiotics are the most falsified anti-infective with a staggering 28% share of the entire global counterfeit medicines market [25].

This is followed by genitourinary drugs, especially drugs for male sexual health, including counterfeit phosphodiesterase-5 inhibitors (PDE5i). Unfortunately, a study conducted by the global security department of Pfizer for its blockbuster PDE5i, Viagra, showed that 77% of the tablets ordered online were counterfeit [26].

Cardiovascular drugs are the next most counterfeited medicines with 11.6% penetration in legitimate supply chains [27]. As per the data presented in the SEVEN study conducted in 10 sub-Saharan countries, there was a high prevalence of inferior-quality cardiovascular drugs, with almost one in every six samples failing to meet the required standards [28].

The Pharmaceutical Security Institute has provided an approximation of the counterfeited drugs seized during 2021 (Fig. 4).

5 Role of Various Stakeholders in Protecting Against Counterfeiting of Drugs

5.1 Role of the Consumers and Pharmacists

Pharmacists as well as end consumers are vital players in the war against drug counterfeiting. They are the individuals who are in direct contact with the drug suppliers. It thus becomes essential to ensure that pharmacists and patients are aware of the problem of counterfeiting and the ways to identify genuine medicines from counterfeit medicines. A patient must buy the medicines from a trusted source and avoid using shady online pharmacies since reports suggest that most counterfeit products are sold via untrusted online pharmacies. The patient must immediately contact the pharmacist or the doctor if he/she notices any discrepancy in the appearance, taste, or effect of the consumed drug. Pharmacists must ensure that they are buying their medicines from a trustworthy source that has been approved by the respective drug regulatory agencies. Pharmacists are advised to keep records of products to ascertain the traceability of the medicine or medical device. This becomes necessary for patient safety. Another important task for the pharmacist is to notify the relevant authorities regarding any suspicious or confirmed case of drug counterfeiting [29, 30].

5.2 Role of the Pharmaceutical Companies

As per available reports, pharmaceutical companies lose almost $200 billion annually to drug counterfeiting [31].

Pharmaceutical companies spend many years and huge budgets to research and develop innovator and generic drugs. Randomized controlled trials ensure rigid safety measures are taken. Therefore, the loss of income to pharmaceutical companies is but one of the consequences of drug counterfeiting.

In order to prevent the same, companies need to prevent counterfeiting at the source, such as the wholesalers, distributors, the pharmacist community, and regulatory agencies. Pfizer alone has 103 counterfeited medicines being sold in 116 countries [32].

Their blockbuster drug Viagra™ (used in erectile dysfunction), is the topmost counterfeited drug. Lipitor (atorvastatin) is another Pfizer drug that is highly counterfeited.

Drug manufacturing companies and/or packagers, regulatory bodies, primary and end consumers have the collective responsibility of preventing falsification of drugs. There are certain steps that could be put into practice to fight this menace of drug counterfeiting. First and foremost, companies could focus on raising awareness amongst the pharmacists, doctors, and the end consumers. Pfizer has launched a counterfeit awareness campaign to detect, disrupt and deter leading producers and sellers of their drug imitations [33].

Companies should focus on drug supply chain integrity. The companies should ensure that their supply chain is not susceptible to penetration by the counterfeiters. A specific team must be formed within the company, which will be responsible for monitoring the sanctity of the supply chain to protect the products at manufacturing sites, warehouses, during shipment, and at the end customer level [34]. This

process must be audited in sufficient detail to ensure supply chain security.

The companies could also utilise intelligent packaging with artificial intelligence (AI)-embedded quick-response (QR) codes. Also, common digital tags, such as radiofrequency identification (RFID) and near-field communication (NFC), can give a drug a distinct identity. These identities carry information about the product, and they facilitate a track-and-trace element that aids drug companies in gaining product visibility throughout the supply chain [34].

5.3 Role of the Regulators

It is the responsibility of the regulators in different countries to ensure that their people are receiving genuine medicines. The International Medical Products Anti-Counterfeiting Taskforce was established by the WHO in 2006 with the objective of bringing together pertinent parties such as national governments, the pharmaceutical sector, non-governmental organisations (NGOs), and law enforcement organisations such as Interpol to combat the spread of counterfeit medicines [35].

The European Parliament and European Council released the Falsified Medical Directive (FMD) to fight against the spread of drug counterfeiting. The FMD 2011/62/EU requires marketing authorisation holders and manufacturers to put in place a system to prevent falsified medicines from entering the legal supply chain. It also aims to improve patient safety. The FMD directive recommends the placement of safety features, including a unique identifier and an anti-tampering device, on the packaging of specific medicinal products for human use. Additionally, the FMD offers a tool to help with security while purchasing medications online [36, 37].

The United States Food and Drug Administration (US-FDA) has a Drug Supply Chain Security Act (DSCSA) in place to prevent the circulation of counterfeit medications. The act describes how to implement electronic tracing that is compatible at the packaging level to identify and track specific prescription medications as they are supplied in the USA. This improves the FDA's capacity to assist in preventing consumer exposure to medications that might be fake, stolen, tainted, or otherwise hazardous. Furthermore, the FDA conducts an electronic evaluation of each imported shipment of a product subject to FDA regulation [38]. The FDA has requirements for quality, safety and efficacy that imported medications must adhere to. Other FDA initiatives to counter the penetration of drug counterfeiters in the supply chain include BeSafeRx and Know Your Source [39].

India, is home to the maximum number of drug counterfeiting cases. The Indian government formed a task force to tackle the issue of drug counterfeiting. The task force ultimately reached the conclusion that for track and trace to be effective, the following two systems must be put into place concurrently: first, a unique identification number for each primary pack to allow consumers to identify the medicine; and second, a 2-D bar coding that incorporates all product information for quick data retrieval at each stage of the supply chain [40]. Based on the recommendations of the task force, India has already implemented the suggestion of including a unique identification number and a bar code on each drug pack. One can also verify the authenticity by sending the unique code behind the bottle or package to the Drug Technical Advisory Board's (DTAB) number via SMS. The DTAB should respond with an authentication message from the medicine's manufacturer.

Despite all these regulations by different countries, the threat of drug counterfeiting continues to increase in developing countries, particularly in Africa. Hence, there is a pressing need for global regulatory authorities to come together to devise a strategy to prevent drug counterfeiting internationally.

6 Current Technology and Modern Technologies to Prevent Drug Counterfeiting

As counterfeiters' tactics evolve, there is a dire need for more sophisticated anti-counterfeiting technology.

6.1 Overt, Covert and Track-and-Trace Technology

Currently, different technologies such as overt, covert, and track-and-trace technologies are being employed to tackle drug counterfeiting. Packaging can be verified using visual representations employing overt (visible) technology without the need for sophisticated equipment or specialised knowledge. In order to swiftly assess packaging, this technique uses optically uneven elements such as colour-shift inks or holograms on drug packaging. Colour-shift inks use various colour combinations in which certain colours may be seen at different angles. Holograms are also very effective tools against drug counterfeiting. They can be made further airtight by additional security features such a micro or nano texts, scrambled or hidden images, ultraviolet (UV)-sensitive or other specialised inks, etc., thus making them extremely difficult to copy. The track-and-trace system refers to the procedure of giving each stock unit a special identification number during manufacturing that stays with it throughout the supply chain until consumption. Further, a special pack coding connects and enables access to the exact information on a safe repository [41, 42].

Apart from the above technologies, companies are also focusing on using covert technologies, including RFID labels on the packages as well as special UV inks that are

unnoticeable to normal eyes but can be seen under UV rays. In fact, a combination of the various overt and covert techniques can be a valuable deterrent to prevent drug counterfeiting [43]. The same has been undertaken by a few pharma giants such as Pfizer, GlaxoSmithKline and Johnson and Johnson for their top counterfeited and valuable brands.

6.2 Blockchain Technology

The complexity of the global pharmaceutical supply chain makes it vulnerable for drug counterfeiters to take advantage of. Blockchain technology uses a decentralised peer-to-peer architecture for transaction processing with little potential for record-tampering. This would make it possible to maintain a permanent record of all transactions that will be accessible to all the parties involved and include details such as location, data, quality, and pricing. Implementation of blockchain technology in the supply chain will help to make it safe, transparent and decentralised, thus enabling savings in expenditure while ensuring the ability to tracking down doubtful areas and close any gaps in the supply chain of genuine drugs [44, 45].

Blockchain has a vital role to play in several areas such as healthcare, logistics, public service, supply chain management, etc. Hence, such technology should be explored further from the viewpoint of *fit for the purpose* in the health care industry, as it could be useful in the management of medical records, clinical trials, medical supply management and control of access to health care data [45].

7 Counterfeiting of Food Supplements Used for Improved Health and Wellbeing

Nowadays, customers are becoming more and more health conscious and this has led to increased demand for food (dietary) supplements many of which are 'natural'. They are now widely available and, against common assumption, safer and healthier than synthetic medications. These supplements are considered foods in the EU and are not subject to any safety reviews before going on sale. According to an EU report, yearly spending on dietary supplements is presently projected to exceed €7 billion and is steadily increasing [46]. The same trends are also seen in the USA and Asia. Food supplement counterfeiting is becoming a profitable business for drug counterfeiters. A very well-known example is of dietary supplements claiming to treat erectile dysfunction. Reports suggest that illegal PDE5i are present in many so-called 'natural supplements', which expose consumers to the same health hazards but with much less forewarning [47].

The counterfeit food supplement market has been boosted by patients who are embarrassed by/conscious of their health condition and want to make improvements or who are looking for less expensive substitutes for legal medications. The rise of online pharmacies has made it simple to purchase such supplements.

Food supplements, unfortunately, are not regulated in most countries; hence, they are easy to manufacture and distribute. The consumer is swayed by the advertisements for such products, which are sometimes endorsed by celebrities. The critical considerations in supplements would be cross-contamination, accuracy regarding product potency, purity of the source of input materials and, lastly, the claims that the manufacturer is making, if any.

8 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 pharma companies, governments and patients [48]. 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 [49].

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 [50].

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.

9 Conclusion and Significance

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.

This review outlines the role and information for each stratum in the prevention of drug counterfeiting. The review informs the end consumers to be proactive in recognising and reporting any difference in their medicines and health care professionals to educate and make the primary and end consumers aware of the differences between a genuine and fake drug. It discusses the importance of advancement and transparency in supply chain management for producers to prevent the addition of counterfeit drugs in supply chain. Last, the review discussed the need of policymakers and international organisations to set up relevant national and international guidelines and make sure that they are strictly followed to curb the rising cases of drug falsification. The author submits that it is absolutely essential to address this public menace with targeted intervention, i.e., repression for prevention is absolutely necessary. Preventing counterfeit goods from entering the supply chain is the first crucial step. If such a condition is not met, action must be taken to effectively detect any fake drugs in circulation. Additionally, the focus should be on close monitoring of the manufacturing and selling processes to building a transparent and safe supply chain on a worldwide scale. Moreover, future investigation should be carried out to obtain the actual data regarding the percentage of counterfeit medications that are bought through valid prescriptions versus those being bought via unverified online pharmacies. Mandating the use of newer technologies by various national governments is a welcome step in preventing counterfeiting. Active collaboration between nations, pharmaceutical companies and regulatory bodies is essential to formulate a cohesive plan to effectively prevent drug counterfeiting.

Declarations

Conflict of interest/competing interests Dr Ranjana Pathak is a permanent employee in Dr Reddy's Laboratory Ltd. and working as Global Head of Quality and Pharmacovigilance. She is also a management council member in Dr Reddy's Laboratory Ltd. Dr Vaibhav Gaur, Dr Himanshu Sankrityayan and Dr Jaideep Gogtay are permanent employees of Cipla Ltd. The authors declare no conflict of interest.

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Code availability Not applicable.

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