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Review Article

Counterfeit Drugs: Detection And Prevention Strategies

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ABSTRACT

Counterfeit drugs pose a severe global public health threat, compromising patient safety, undermining the pharmaceutical industry, and damaging national reputations. These illicit products range from medicines with incorrect or absent active ingredients to those with falsified packaging, expired, relabelled products, and adulterated formulations. The World Health Organization (WHO), the US Food and Drug Administration (USFDA), and the Central Drugs Standard Control Organization (CDSCO) define counterfeit and falsified medicines based on their misrepresentation of identity, source, or composition. This review consolidates global and Indian perspectives on the scale, distribution, and impact of counterfeit pharmaceuticals, highlighting that prevalence is highest in regions with weak regulatory enforcement. Commonly counterfeited categories include anti-infectives, sexual health drugs, and cardiovascular medicines. The review discusses the socio-economic, regulatory, and logistical factors contributing to counterfeit proliferation, such as inadequate legal deterrence, post-GST distribution challenges in India, and increased demand during the COVID-19 pandemic. Detection strategies range from visual inspection and simple chemical tests to advanced spectroscopic (UV-Vis, Raman, NMR, XRD) and chromatographic (TLC, HPLC, LC-MS) methods. Prevention approaches emphasize serialization, blockchain integration with artificial intelligence, and overt/covert packaging technologies to enhance supply chain transparency. The paper underscores the need for harmonized global policies, technological interventions, and stakeholder collaboration to mitigate counterfeit drug circulation and safeguard public health.

INTRODUCTION

“One that is deliberately and fraudulently mislabelled to identity and /or source. It can apply to both branded and generic products, may include

products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients, or with fake packaging.” The definition of counterfeit drugs was established by the World Health Organization (WHO) in 1992.[1, 2]

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In 2011, the WHO proposed a new definition of substance, spurious, falsely labelled, falsified, and counterfeit” (SSFFC), considering public health impact. As per WHO 2019a, a counterfeit medicine is deliberately and fraudulently mislabelled concerning its identity and/or source.

Counterfeit products may include, as per (WHO, 2019b):

- Products made with inappropriate or inaccurate ingredients
- Products having insufficient or non-existent active components
- Products in counterfeit wrapping
- Drugs whose active components differ from those listed on the packet.
- Relabelling expired medication to increase its shelf life
- Products lacking the manufacturer’s name and address
- Expired products
- Medicines without an expiration date
- Products with an inaccurate amount of the declared active ingredient
- Products with a different number of contaminants.

As per the USFDA, counterfeit medicines/falsified medicines are described as they may be harmful to health because they are being passed off as authentic, may contain the wrong ingredients, contain too little or no active ingredient at all, or contain other harmful ingredients.^[3]As per CDSCO, Counterfeit drugs, which were categorised into

three types under the Drug and Cosmetic Act, 1940;

Spurious and Adulterated drugs: Drug formulations that are designed to look like another drug, particularly a well-known brand, to deceive the consumer and capitalize on the success of the original product are known as “spurious” or “imitation” drug products. The product may include the active substances or may not.

Adulterated medicines: These are those that include an adulterant or substituted product or are tainted with impurities, making them harmful to health.

Grossly substandard drugs: drugs manufactured by authorized producers that have been shown to have significant defects that lower the medication's egregious carelessness or manufacturing non-compliance with GMPs. The defects may broadly be as under:

- Active ingredient quantities that are less than 70% for products that are thermolabile and less than 5% of the allowed limits for products that are thermostable.
- Tablet/capsules failing in disintegration tests wherever prescribed.
- The active amounts of tablets and capsules that failed the dissolution test were less than 70% thermolabile products and less than 5% of the recommended limits for thermostable products.
- Liquid preparations that exhibit fungal growth.
- Parenteral preparation that exhibits excessive toxicity, pyrogen/endotoxin test failure, or sterility test.



- Vaccines that exhibit deficiencies in moisture content, toxicity, sterility, or efficacy.
- Any adulterant that makes the product harmful to health is present.

Executed in-process controls, or inappropriate storage or transportation circumstances for medicines. Examples of some such defects are as under:

- Broken or chipped tablets
- Spots, discoloration, or uneven coating are present
- The formulation's color changes
- Net content varies little
- Weight variation failures in formulations
- Formulations that don't reach the color test.
- Individual instances of foreign materials being present
- Labelling errors include Redline, Schedule H, Rx, NRx, XRx, and nomenclature errors, color, caution, etc.^[4]

3.1 GLOBAL INFORMATION ON COUNTERFEIT DRUGS:

The easy spreading of counterfeit drugs in those countries that have weak enforcement bodies and poorly regulated manufacturing, importation,

distribution, supply, and sale of drugs. ^[5]The majority of websites offering prescription-only medication for sale were not compliant with either federal or state laws, or with the industry standards which as recently reported by the National Association of Board of Pharmacy (NABP).^[6]The counterfeit drugs can lead to drug resistance, treatment failures, and loss of public confidence in medicine and public health.^[7] As per a published article in 2006, it is found that 15% of drugs sold worldwide are Counterfeit.^[8], which has serious public health and safety implications, with 50% in parts of Asia and African countries.^[9]According to the 2017 WHO estimate, 10.5% of medications are either counterfeit or of poor quality worldwide. In lower-middle-income countries, 13.6% of medicines are substandard or falsified.^[10] The FDA estimated that 10% medications worldwide are counterfeit, while the WHO estimates that 6% of them are. ^[11]The Pharmaceutical Security Institute claims that cases from about seven different parts of the world have been examined. Among 4,405 instances of pharmaceutical criminality, the institute discovered that the overall percent increase was +26%. After North America, Asia comes in at number two.^[12]Additionally, the worldwide effects of medications extend beyond their being considered a crime against humanity, since they are transformed into the equivalent of deadly poisons. The WHO estimates that counterfeit drugs cause about one million deaths annually. Most of whom reside in Africa, where it is believed that 200,000 people die annually as a result of taking fake anti-malarial drugs.^[13]



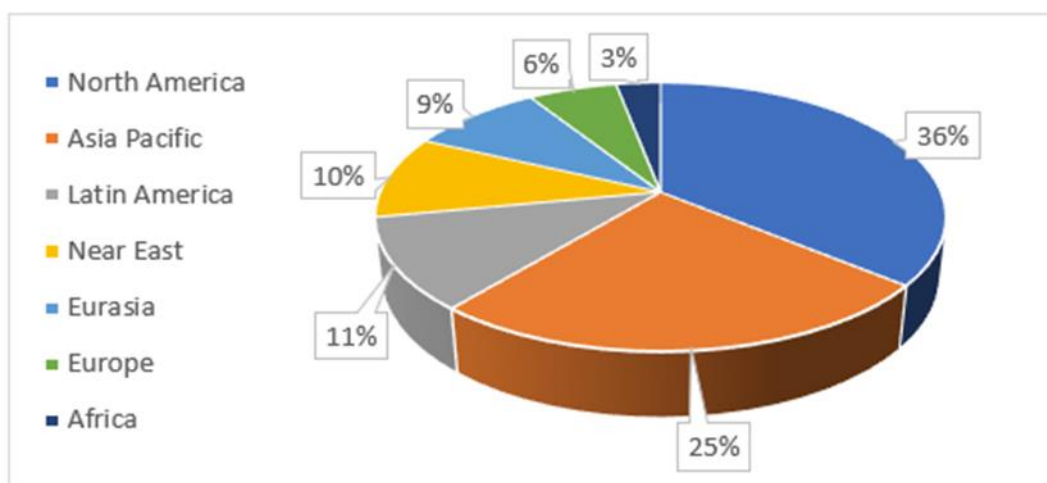


Fig.1: Representing the % of counterfeiting incident data with respect to seven regions of the world

In the operation Shield II by Europol, over 25 million units of medications worth around €63 million were seized. In just two months earlier in 2009, the European Union seized 34 million fake tablets, including antibiotics, chemotherapy drugs, and Sildenafil citrate.[14] As per a published article in 2019-20, over thirty percent of medications sold are fake. Typically, 10-30% of the total market share in underdeveloped countries is a fair estimate. The Soviet Republics have 20% of the market for counterfeit medications, which puts them in the category of developing nations.[15] The WHO estimates that 25% of medications taken in developing nations may be fake because production costs are 40% lower there than in other nations, and 40% of the pharmaceutical market is thought to be controlled by counterfeit and illegally marketed medications to a published article in 2023.[16] With estimated global sales, the pharmaceutical industry is worth billions of dollars. According to estimates, the global pharmaceutical market is expected to reach a value of over \$ 1.5 trillion USD by 2023. Over the next five years, it will continue to grow at a compound annual growth rate of 3-6%.[17] According to some studies, the yearly market for counterfeit medications is worth between US\$70 and \$200 billion.[18] According to a 2024 report

by the US Drug Enforcement Administration (DEA), potentially fatal amounts of fentanyl were found in six out of ten counterfeit pills that were seized nationwide. With the rise of dark web marketplaces and online pharmacies, it is now simpler than ever for people to inadvertently buy dangerous medications.[19] SINGAPORE: 50.4 million doses of illegal Pharmaceuticals valued at USD 65 million were seized in 90 countries as part of an INTERPOL-coordinated operation, underscoring the startling scope of the world's unauthorized and counterfeit medication trade. During operation Pangea XVII, which ran from December 2024 to May 2025, 769 people were apprehended and 123 criminal organizations were dismantled globally. In 17 years, history of operation, these are the most arrests and seizures. The following countries participated in operation Pangea XVII: Argentina, Armenia, Australia, Austria, Azerbaijan, Bahrain, Belarus, Benin, Bolivia, Bosnia and Herzegovina, Botswana, Brazil, Brunei, Bulgaria, Burkina Faso, Cambodia, Cameroon, Canada, Chile, China, Colombia, Comoros, Congo, Costa Rica, Curacao, Cyprus, Czech Rep., Democratic Rep. of Congo, Denmark, Dominican Rep., Ecuador, Ethiopia, Finland, France, Gabon, Georgia, Greece, Guyana, Hong Kong (China), India, Indonesia, Iran, Iraq, Ireland,

Jamaica, Kuwait, Laos, Latvia, Lebanon, Madagascar, Malaysia, Maldives, Mexico, Morocco, Mozambique, Myanmar, Netherlands, New Zealand, Northern Ireland (United Kingdom), Niger, Nigeria, Norway, Pakistan, Palestine, Paraguay, Peru, Philippines, Poland, Portugal, Qatar, Rep San Marino, Romania, Russia, Rwanda, Senegal, Serbia, South Africa, Singapore, Slovakia, Spain, Sri Lanka, St Lucia, Sweden, Thailand, Togo, Türkiye, Ukraine, United Kingdom, United States of America, Uruguay, Venezuela and Zimbabwe.[20].

3.2 INDIA'S STATUS ON COUNTERFEIT DRUGS:

The Indian pharmaceutical industry is the third biggest in the world when it comes to the amount of medicine produced, making up 10 percent of the global output. India exports medicines to over 200 countries and is the top producer of generic drugs and vaccines worldwide. However, it is also the largest country sending out fake medicines. Many reports show that most of the fake medicines found are linked back to India, with China coming next.[21] India made up the largest share, around 54% of the fake and counterfeit medicines found worldwide in 2006.[22] A more recent survey shows that 75% of them are of Indian origin.[23] A study by the World Health Organization in 2017 found that between 20-30% of medicines in India were fake, based on testing samples collected from 258 locations across the country.[21] India doesn't have strong enough rules for making and selling medicines, which helps fake drugs get into the market. Also, because there is not much punishment for those who make or sell fake medicines, and the penalty is much less than the money they can make, it makes the problem worse. Recently, new guidelines have been made to deal with fake medicines. These guidelines are based on the Drugs and Cosmetics (Amendment) Act

and include a penalty of up to 10 years in jail for those found guilty of making or selling fake medicines. More people are getting affected by fake medicines, and there is a need for stronger action to stop this. However, the number of people who die from fake drugs is only an estimate. Exact numbers are not known because fake medicines are not well detected in many developing countries. This makes it easier for fake drugs to get into the market and harm people who use them.[24] According to a study on counterfeit drugs in Myanmar, 75.8% of the drugs sold in Mandalay pharmacies came from India, and 20.5% of those drugs were either fake or of poor quality.[25] In the financial year ended March 31, 2012, India's drug exports totalled \$14.6 billion or roughly Rs. 82,730 crores. One of the best examples of a developing country with a strong pharmaceutical industry and an effective drug regulation system is India. 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 estimates that 5% of Indian drugs are counterfeit and 0.3% are fake. 20% of the 40,000 in are pharmaceutical industry in India consists of counterfeit drugs. The states with the largest local drug cases of counterfeit and substandard drugs in India include Gujarat, Uttar Pradesh, West Bengal, and Bihar.[26] The pharmaceutical sector has long struggled with concerns of fake or counterfeit medications, both globally and in India, but these problems have been worse since the outbreak. All Parties involved must cooperate to prevent problems like fake medications from undermining India's reputation as the "Pharmacy of the World." [27]

3.3 REGULATION IN INDIA[28]:

In India, the Drug and Cosmetics Act of 1940 and Rules 1945 apply to counterfeit medications.



There are now guidelines for handling drug samples that have been deemed shady or of substandard quality, along with harsher punishments.

In order to combat the threat of counterfeit or phony medications, cosmetics, and medical

equipment, there is a reward program for whistleblowers.

The process for putting the Track and Trace system into place for exporting medication formulations.

Table 1: Regulations of India at the Central and State levels for drugs.

Sr. No.	At the Central Level	At the State Level
1	Giving Approval to new drugs	Licensing of drug manufacturing establishments and sales premises
2	Permission to conduct clinical trials	Inspecting licensed premises
3	Laying down the standards for drugs, cosmetics, diagnostics, and devices, and updating the Indian Pharmacopoeia	Drawing samples for tests and monitoring the quality of drugs and cosmetics in the state.
4	Approving licenses as the Central License Approving Authority (CLAA) for the manufacture of drugs.	Taking appropriate action, like suspension or cancellation of licenses.

3.4 COMPARISON OF THE REGULATORY REQUIREMENTS OF DIFFERENT COUNTRIES WITH INDIA FOR COUNTERFEIT MEDICINES[2]:

Compares the laws governing counterfeit medications in India with those in other nations, including the USA, Europe, and Canada.

Table 2: Comparison of the regulatory requirements of different countries with India for counterfeited medicines

Sr. no.	Parameters	USA	Europe	Canada	India
1	Authority	United States food and drug administration	European Medicines Agency	Health Canada	Central Drugs Standard Control Organization
2	Market of counterfeit drugs	1.82 trillion USD by the year 2020 (0.2% market)	Europe reports around 347 crimes per year (0.2% market)	\$1.1 million (2005)	Up to 20% of total drugs sold in the Indian market are counterfeit.
3	Guidelines	Standards for Securing the Drug Supply Chain Title II of the Drug Quality and Security Act (DQSA), the Drug Supply Chain Security Act (DSCSA)	Falsified Medicines Directive (FMD) (2011/62/EU) Commission delegated regulation (EU 2016/161)- Impact of Brexit	Health Products and Food Branch Inspectorate Policy on Counterfeit Health Products	Drug and Cosmetics Act 1940 and Rules 1945. Samples of Drugs Declared Spurious or Not of Standard Quality (Amendment) Act, 2008

4	Examples of counterfeit	- Botox - Avastin - Cialis tablet	- Clopidogrel - Carvedilol	-Rofact® (rifampicin) - Amlodipine	-Primaquine Tablet I.P. 2.5 mg -Onset (Ondansetron Injection I.P.)
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3.5 CATEGORIES OF DRUGS BEING COUNTERFEIT:

All over the world, counterfeit medication from various therapeutic categories is produced. Various data confirm that the majority of counterfeit pharmaceuticals are in the anti-infective drug category, which includes antibiotics, antivirals, antifungals, anti-malarial, etc. The percentage of counterfeit drugs varies from 10%-50%.[9] Additionally, with a startling 28% market share in counterfeit medications

worldwide, antibiotics are the most counterfeit anti-infective in this category.[29] Drugs for male sexual health, such as fake phosphodiesterase-5 inhibitors (PDE5i), come next in line. Regretfully, research on Pfizer's popular PDE5i drug, Viagra, by the company's global security department revealed that 77% of the pills purchased online were fake.[30] With 11.6% of the market in authentic supply chains, cardiovascular medications rank as the next most counterfeit medications.[31].

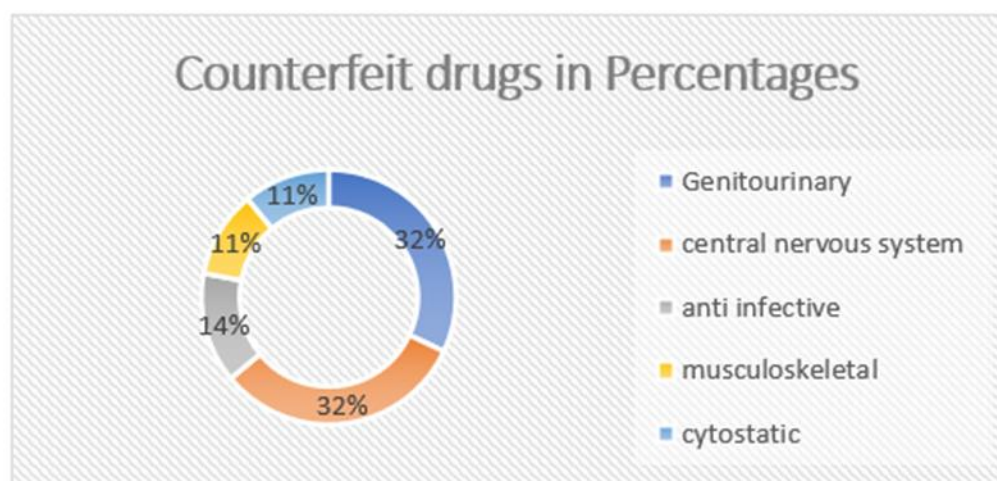


Fig. 2: The Data represent drugs that are being counterfeited.

Nearly one out of every six samples did not meet the requirements, including a high incidence of substandard cardiovascular medications, according to data from the SEVEN study, which was carried out in ten sub-Saharan countries.[32] An estimate of the number of counterfeit medications seized in 2021 has been supplied by the Pharmaceutical Security Institute.

3.6 SFFC OR NSQ DRUGS IN INDIA[33]:

Low-quality medications not of Standard Quality (NSQ) or spurious/false-labeled/falsified/counterfeit (SFFC) medications have the potential to kill patients or result in treatment failure. India is a major producer of generic medications, and between 12 and 25 percent of the medications it distributes are tainted, inferior, and fake. Along with China, India, the largest generic manufacturer in the world, may be a significant source of the fake medications. The Drug and Cosmetic Act classified pharmaceuticals into different categories, including adulterated,

spurious, and mislabeled. The Central Drugs Standard Control Organization (CDSCO), the Indian drug regulatory body, has divided non-standard quality (NSQ) items into three groups, A, B, and C, in accordance with the 2008 revision of the D and C Act. This helps classify the products during quality assessment. A number of samples had previously undergone testing and been categorized. These samples demonstrate the division of the category of counterfeit drugs and the quantity of samples evaluated.

3.7 FACTORS CONTRIBUTING TO COUNTERFEITS [34]:

In the past, fake or poor-quality drugs made up a small part of the medicines sold in India. But now, estimates show that this number has gone up to almost 15%. Several factors have led to this problem. The factors are described as:

i. Consumer Preferences:

- Many people choose medicines over higher-quality ones, often buying discounted items without knowing the risks.
- This has led to more fake medicines being sold because they are much less expensive. These fake products may not be safe or effective.

ii. Weak Regulatory Framework:

- The rules that control how medicines are made, sold, and moved around are not strong enough.
- The Drugs and Cosmetics Act was meant to keep medicines safe, but it doesn't punish those who break the rules enough.
- Even though there have been some changes, the punishment for selling fake medicines is only up to three years in jail. Often, people who break the law are released on bail very quickly.

iii. Post-GST environment:

- When the Goods and Services Tax (GST) was introduced in 2017, it made it easier to move medicines between states.
- Due to the ease of movement, counterfeit medicines are now spreading more rapidly.
- The uniform tax system has also reduced the focus on checking the quality and proper storage of medicines, which puts public health at risk.

For example, due to the lack of particular medications, the COVID-19 epidemic has caused a global issue that has increased the trade in counterfeit medicines by creating more and more fake alternatives. Antimalarials, antivirals, vitamin C, antibiotics, painkillers, herbal remedies, and medical supplies like face masks, ventilators, gloves, disinfectants, gels, and wipes were among the most counterfeit medications associated with COVID-19. Cleaning, Soap, and the marketing of fake vaccines, which have been documented in some nations.[35-37]

The study of reviewing counterfeiting drugs detection and prevention, which mainly focused on examining the efficiency, reliability, and economic outcomes of the barriers, interventions, and facilitators to their implementation.

3.8 VARIOUS THREATS AND RISKS THAT ARE CAUSED BY COUNTERFEIT MEDICINES:[38]

1. Treatment failure: Using fake medications may result in treatment failure and death.
2. End organ damage: The liver, kidneys, heart, and central nervous system can all sustain harm as a result of consuming fake medications.



3. Toxicity: These drugs carry a significant risk of toxicity, side effects, and therapeutic failures, which could result in fatalities.

4. False vital signs: Taking a fake medication might cause vital signs to read unrealistically.

5. Death: Using fake pharmaceuticals can result in the loss of innocent life.

6. Loss of confidence: Adverse or therapeutic occurrences cause people to lose faith in the health system, as well as in the drug control and enforcement system.

7. Economic loss: Since their drugs are being copied and resold at lower prices, many pharmaceutical businesses suffer significant financial losses.

IMPACT OF COUNTERFEIT DRUGS[39]:

WHO determines the public health and socio-economic impact of counterfeit drugs.

socio-economic impact

- Lost productivity
- Lost income
- Lack of social morbidity
- Increased poverty

Economic Impact

- Economic loss
- Wasted resources
- Increased out-of-pocket spending

Health factors

- Loss of confidence

- Increased death rate

- Higher disease prevalence, anti-microbial resistance.

3.10 IMPACT OF COVID-19 ON COUNTERFEIT DRUGS[40, 41]:

The recent COVID-19 pandemic that wreaked devastation around the world has benefited the illegal market for counterfeit medications, which is already a significant global concern. This was brought on by a startling increase in 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 develop a vaccine to combat the harmful effects of COVID-19, the WHO issued a warning about the dangers 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 multiple reports of people 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, vaccines, and drugs valued at \$3.5 million. Another estimate predicted that the illegal drug market would have expanded by over 400% by the end of 2021.

The constantly growing demand for vaccinations 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. 42 COVID-19 pushed healthcare systems to their limits, even in developed countries. Most countries, including the USA, had very few medications like hydroxychloroquine (HCQ), which were believed to be effective against COVID-19. Due to a shortage, India initially banned the export of HCQ; however, this ban was later lifted after the country sent 50 million HCQ tablets to the US. People who frequently used HCQ for lupus and arthritis were having problems locating a supply because of the acute shortage. In several cases in India, Remdesivir was sold under pretenses, with saline or even liquid paracetamol used in place of the drug's empty vials. Additionally, it was found that Remdesivir was being sold in India in fake batches. During COVID-19, Indian regulatory authorities 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 report. 44 COVID-19 also played a major role in the increase in counterfeit drugs because 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 majority of raw materials and active pharmaceutical components. During the outbreak, counterfeiters were able to greatly expand their market share in the countries that depended on these items because of shortages in those countries.

3.11 IMPACT OF COUNTERFEIT MEDICINES ON THE GOVERNMENT[42, 43]:

False medications can lead to the waste of health resources for national government programs, NGOs, and international humanitarian

organizations in addition to individual patients (OECD, 2016). By taking funds away from legitimate care, counterfeiters deplete already meager health budgets. However, counterfeits can result in higher regulatory and enforcement costs for supply chain security, losses in corporate taxes and VAT, and higher medical expenses to cure the negative effects of phony medications. According to EUIPO (2016), the tax costs incurred by EU governments as a result of lost revenue from counterfeit medications were around EUR 1.7 billion. Since they are included in the overall budgets of the agencies involved, the total costs of regulatory and enforcement actions in the pharmaceutical sector are typically not disclosed (OECD, 2016). Although there are tools for identifying counterfeits, they can be expensive. The nature of the fake goods determines a lot. They fall into the following categories (IOM, 2013):

Category 1: Totally fake goods with unclear ingredients and therapeutic effects that differ greatly from those of the real thing.

Category 2: They resemble the substance being mimicked in appearance, but their content is unknown.

Category 3: Contains a completely new substance, if any, yet looks very similar to or identical to the real thing.

Category 4: Identical or very similar in appearance to the real product, but containing a synthetic counterpart or substitute medication that has therapeutic value comparable to the real product and is meant to encourage repeat business.

Category 5: Synthetic analogues or visually identical, highly advanced duplicates that have some therapeutic efficacy but are undetectable with the majority of field and lab techniques.

3.12 FRAMEWORK FOR ASSESSING THE ATTRACTIVENESS OF COUNTERFEITING PHARMACEUTICALS[44]:

Assesses the situation for pharmaceuticals, based on a general framework and analysis presented in OECD (2008). As shown, the pharmaceutical market can be highly attractive for counterfeiters.

Driving Factor	Conditions favouring counterfeiting pharmaceuticals	Situation for Pharmaceuticals
Market Characteristics		
Profitability	High unit profitability and/or large volume	Can be very large, especially if cheap ingredients are used
Market size	Large potential market	The pharma market is large (more than USD 1 million)
Brand power	High level of brand recognition	Strong brand power
Production, technology, and distribution		
Investment required	Simple, low-cost equipment	The cost of making crude fakes can be modest; a pill press may suffice
Technology required	Not sophisticated; easy to acquire	Production technology, packaging, and labelling challenges vary; they can be easy or a significant challenge
Logistics	Simple and cheap	Shipping costs are low; free trade zones have facilitated trade in fakes
Marketing and sales of products	Easy to establish/infiltrate distribution channels	Difficult to infiltrate principal supply chains; easier if second-tier wholesalers targeted; the internet has facilitated trade in fakes
Ability to conceal operations	Easy to hide illicit operations	It can be easy if operations are on a small scale
Ability to deceive consumers	Easy to deceive consumers	Easy to deceive visually; anti-counterfeiting technology can complicate it significantly
Institutional characteristics		
Legal and regulatory framework	Weak laws	The complicated situation in many countries makes it difficult to prosecute
Enforcement	Weak enforcement	Enforcement levels vary across countries; clever counterfeiters often succeed in avoiding enforcement efforts
Penalties	Weak sanctions	Criminal sanctions provided for in many countries; fines are generally a manageable cost of business in many countries

3.13 ROLE OF VARIOUS STAKEHOLDERS IN PROTECTING AGAINST COUNTERFEITING OF DRUGS:

3.12.1 ROLE OF THE CONSUMERS AND PHARMACISTS[45, 46]:

End users and pharmacists are key participants in the fight against drug counterfeiting. The people who have direct contact with the drug suppliers. Therefore, it becomes crucial to make sure that patients and pharmacists understand the issue of counterfeiting and how to distinguish real medications from fake ones. Since reports indicate that the majority of counterfeit products are supplied via unreliable internet pharmacies, patients should purchase their medications from reputable sources and refrain from utilizing dubious online pharmacies. If the patient observes any differences in the appearance, taste, or action of the drug they have taken, they must inform the pharmacist or the doctor right away. Pharmacists need to make sure that the companies they get their medications from are reliable and have been authorized by the relevant drug regulatory bodies. It is recommended that pharmacists maintain product records in order to determine the traceability of the medication or medical equipment. For the sake of patient safety, this becomes essential. Notifying the appropriate authorities of any suspected or confirmed drug counterfeiting case is another crucial responsibility of the pharmacist.

3.13.2 ROLE OF THE PHARMACEUTICAL COMPANIES[47, 48]:

According to data that are now accessible, medicine counterfeiting costs pharmaceutical businesses around \$200 billion a year. Pharmaceutical companies invest large sums of money and years of time in the research and development of both innovative and generic

medications. Rigid safety precautions are taken thanks to randomized controlled studies. Therefore, one of the effects of drug counterfeiting is the loss of revenue for pharmaceutical businesses. Companies, including wholesalers, distributors, the pharmacy community, and regulatory bodies, must stop counterfeiting at its source in order to stop the same thing. In 116 countries, Pfizer alone is selling 103 counterfeit medications. The most commonly counterfeited medication is their popular erectile dysfunction medication, ViagraTM. Another Pfizer medication that is often counterfeited is Lipitor (atorvastatin). It is the collective responsibility of medicine production businesses, packagers, regulatory agencies, and primary and end users to prevent drug falsification. There are certain actions that could be taken to combat the threat of drug counterfeiting. First and foremost, businesses should concentrate on increasing awareness among physicians, pharmacists, and final consumers. To identify, stop, and discourage top manufacturers and distributors of their medication imitations, Pfizer has started a counterfeit awareness campaign. The integrity of the medicinal supply chain should be a priority for businesses. It is important for businesses to make sure that counterfeiters cannot influence their supply chain. To safeguard the products at manufacturing facilities, warehouses, during shipping, and at the end-user level, a dedicated team within the organization must be established to oversee the integrity of the supply chain. To guarantee supply chain security, this procedure needs to be thoroughly audited. Additionally, the businesses might use intelligent packaging that has quick-response (QR) codes embedded with artificial intelligence (AI). Additionally, a medicine can be uniquely identified by common digital tags like near-field communication (NFC) and radiofrequency identification (RFID). In addition to carrying product information, these



identities provide a track-and-trace feature that helps pharmaceutical businesses increase product visibility across the supply chain.

3.13.3 ROLE OF THE REGULATORS^[49]:

Regulators in many nations are in charge of making sure that their citizens are getting authentic medications. In order to stop the spread of fake medications, the WHO formed the International Medical Products Anti-Counterfeiting Taskforce in 2006 with the goal of bringing together relevant stakeholders, including national governments, the pharmaceutical industry, non-governmental organizations (NGOs), and law enforcement agencies like Interpol. To combat the proliferation of drug counterfeiting, the European Parliament and European Council published the Falsified Medical Directive (FMD). Manufacturers and holders of marketing authorizations are required under the FMD 2011/62/EU to implement a system that keeps counterfeit medications out of the legitimate supply chain. Additionally, it seeks to enhance patient safety. To stop the spread of fake drugs, the US Food and Drug Administration (US FDA) has implemented the Drug Supply Chain Security Act (DSCSA). In order to identify and monitor individual prescriptions as they are supplied in the United States, the legislation outlines how to install electronic tracing that is compatible at the packaging level. This enhances the FDA's ability to help prevent consumers from being exposed to drugs that could be counterfeit, stolen, contaminated, or otherwise dangerous. Additionally, every imported shipment of a product governed by FDA regulation is evaluated electronically by the FDA. Imported pharmaceuticals must meet FDA standards for efficacy, safety, and quality. BeSafeRx and Know Your Source are two more FDA programs aimed at preventing counterfeiters from infiltrating the supply chain. The majority of drug counterfeiting

incidents occur in India. A task force was established by the Indian government to address the problem of drug counterfeiting. The task force concluded that for track and trace to be successful, two systems needed to be implemented simultaneously: a 2-D bar coding system that includes all product information for fast data retrieval at every supply chain stage, and a unique identification number for each primary pack that enables consumers to identify the medication. India has already adopted the idea of adding a bar code and a unique identifying number to each medication package in accordance with the task force's suggestions. Another way to confirm the authenticity is to send an SMS to the Drug Technical Advisory Board's (DTAB) number using the special code found on the bottle or packaging. The maker of the medication should send an authentication message in response to the DTAB. Despite all of these laws from various nations, drug counterfeiting is still becoming a bigger problem in emerging nations, especially in Africa. Therefore, it is imperative that international regulatory bodies collaborate to develop a plan to stop medicine counterfeiting globally.

3.14 RECOMMENDATIONS TO REDUCE HARMS FROM COUNTERFEIT PILLS^[50]:

The spread of illegal synthetic drugs in fake pills is an important factor to take into account, since their distribution, consumption, and overdose are increasing in many nations across the world. The following tactics are suggested in order to mitigate the negative effects of accidental exposure to illegal synthetic substances.

BROAD EDUCATION ABOUT COUNTERFEIT PILL RISK:

Compared to other medications, primary prevention may be more important when it comes



to counterfeit tablets because customers who are ignorant of their inauthentic status pose a significant risk. By promptly alerting prospective customers about the risks of new counterfeit goods, including synthetic pharmaceuticals, public health organizations could prevent injury. Schools, colleges, and universities could be useful sites for interventions because of the unique danger of overdosing involving counterfeit medications among adolescents and young people in North America.

PILL TESTING SERVICES:

By using point-of-care technologies to describe the contents of drug samples, drug checking services enable customers to move demand away from more harmful or counterfeit drugs, making them a valuable form of secondary prevention. These programs range from mail-in services, where customers anonymously submit samples and the findings are shown online, to community-facing systems that give customers real-time results. In order to achieve the greatest impact, we recommend that client-facing services be widely implemented in locations that drug users and those who may be at risk of overdosing frequent, such as music venues, club scenes, harm reduction centers, and syringe exchanges, to offer comprehensive drug testing results in addition to individualized counseling. Advances in portable drug testing technology, which are getting more affordable and capable of producing comprehensive qualitative and quantitative data, are helping to assist these initiatives. Additionally, drug checking technology can help public health and medical professionals identify new medications that need regular testing. Customers who live in poverty or who are more likely to be criminalized by the police, however, frequently have less access to these services. As a result, testing services need to be provided in a way that specifically targets

populations that are more vulnerable to overdose. Additionally, if a customer has opioid dependence and there are no safer alternatives available, testing services may not reduce their risk of overdosing. Nonetheless, drug monitoring enables people to prioritize safer options for drug users who can change or adjust their need.

INCREASE PUBLIC HEALTH MONITORING OF COUNTERFEIT PILL CONTENTS:

It is uncertain if public health monitoring will be able to keep up with the illicit drug supply's rapid evolution, which is characterized by the continuous development and sale of novel drugs and combinations. To identify novel chemicals, sources, and polysubstance formulations in use, as well as usage trends, supply-side monitoring initiatives require renewed funding. Communication networks that inform consumers about new hazards must be connected to these monitoring initiatives. The European Union Drugs Agency's Early Warning System for Novel Psychoactive and the Organization of American States' Early Alert System for the Americas are two examples of ongoing initiatives to support public health monitoring of synthetic drug crises and establish early warning alert networks. These systems should ideally use and integrate a wide range of supply-side indicators to best monitor for new threats. These include data from law enforcement drug seizures, (which people and researchers need to have quick access to), community-engaged drug checking services, routinely collected clinical indicators from pre-hospital and emergency department encounters involving fatal and non-fatal overdose events, and rapid toxicology from overdose autopsy investigations using panels of tests for novel synthetic substances.



Avoid crackdowns on diverted (authentic) pharmaceutical products until safe replacement options are widely available:

Reducing access to prescription drugs, including the illegal use of diverted prescriptions, requires careful consideration of where demand for these items may be moved, according to data from North America and other countries. The shift in demand toward fake medications is a potentially dangerous consequence. The best-case scenario is that demand shifts to safe, medically controlled medicines and services, like methadone and buprenorphine. Additionally, there is a growing body of research that supports the use of a wider range of medically controlled substitution therapy choices, including as morphine, hydromorphone, and diacetylmorphine. However, most patients around the world still have few options due to legal and regulatory constraints, and in many nations, like the USA, these options are almost nonexistent. In Canada, community-based safer supply pilot programs and trials are still in progress. These programs offer access to opioid maintenance through a variety of collaborations between health

care providers and community and harm reduction organizations, some of which have demonstrated encouraging drops in overdose deaths. With varying degrees of success and repercussions, governments have attempted to curtail the availability of synthetic pharmaceuticals and their precursors through a variety of strategies. Because established demand will frequently move to higher risk options during crackdowns unless safer solutions are made easily available, we recommend decision makers to carefully consider the costs of these strategies. It's also important to remember that fentanyl and its analogues are critical drugs that can be used safely for a variety of medical conditions, so efforts to restrict access should only target illegal opioids.

1. DETECTION STRATEGIES:

In the world, throughout laboratory analysis, analyzed and detected lots of counterfeit samples/preparations. Various simple, visual, spectrometric, and chromatographic approaches have the potential to analyze and characterise counterfeit drugs and others.

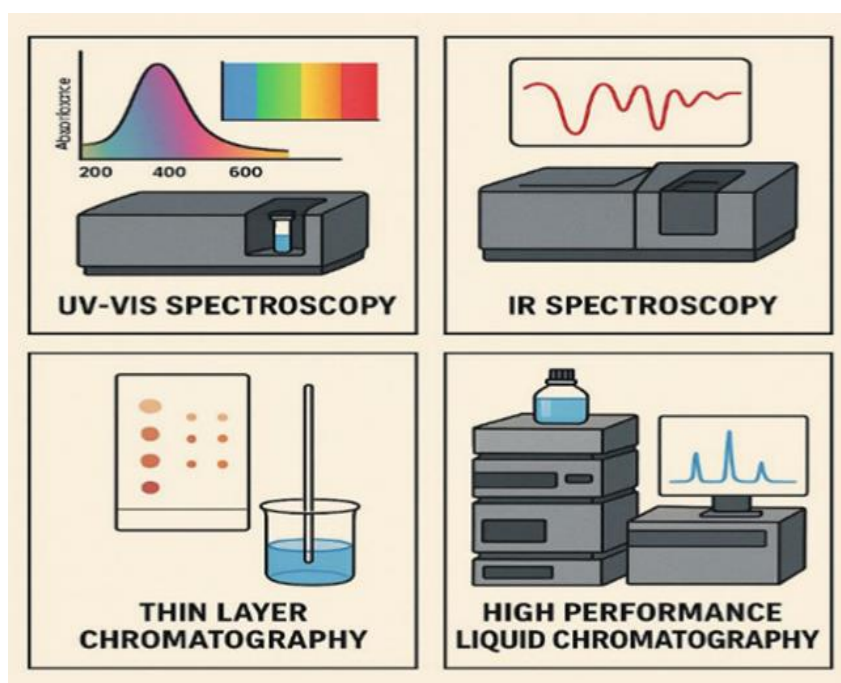


Fig.3: spectroscopy and chromatography approaches for the detection of counterfeit drugs

4.1 VISUAL INVESTIGATION^[51]:

Visual inspection of the product, along with its packaging and labelling, is the initial step in spotting any counterfeit medications, regardless of the analytical technique employed. It is usually preferable to compare a product to the actual medicine. Disparities in the dosage form's physical characteristics, such as its shape, color, and packaging, as well as its labeling, suggest a possible counterfeit. A visual examination may reveal evidence of tampering, non-uniform coloration of the drug product under inquiry, etc., even if the physical properties of the genuine medicines are unknown. Once more, these observations raise the prospect of a counterfeit. In order to benefit themselves, legal medication producers should be encouraged to work with the WHO and national DRAs by supplying materials and information about the physical characteristics of their goods.

4.2 SIMPLE CHEMICAL APPROACHES:

Colorimetry is used for evaluating the drug quality, which is a cheap, sensitive, and specific technique. Through colorimetry possible to visually assess the intensity of a color reaction/color intensity can be measured by applying a portable filter photometer.^[52]

Counterfeit drugs may have a sufficient amount of API but fail the disintegration test. By using tablet disintegration behaviour during the analysis for mefloquine, a yellow color is generated, indicating the presence of artesunate. This is a colorimetric analysis described by Green et al. to determine the quality of antimalarial drug artesunate in South Asia.^[53, 54]

4.3 SPECTROMETRIC APPROACHES:

To detect counterfeit drugs, various spectroscopy techniques are widely available, from simple ultraviolet spectroscopy to more sophisticated Raman spectroscopy techniques.

4.3.1 UV-VISIBLE SPECTROSCOPY:

The field of research that examines the relationship between electromagnetic radiation and matter is called spectroscopy. One of the most regularly used methods in pharmaceutical examination is UV-VIS spectrophotometry, and several UV-VIS tests have been developed to examine fake drugs. Since the majority of prescription medications include chromophores, they may be identified in the UV spectrum without the need for a derivatization step. It entails calculating how much visible or ultraviolet light a material in solution absorbs. Ultraviolet-Visible spectrophotometers are devices that measure the ratio, or function of ratio, of the intensity of two light beams in the UV-VIS area. Quantitative spectrophotometric analysis is used to determine the number of molecular species absorbing the radiation, whereas qualitative analysis uses a spectrophotometer to identify organic molecules. Small amounts of chemicals can be detected using the straightforward, quick, and reasonably selective spectrophotometric method. The Beer-Lambert law is the fundamental law governing quantitative spectrometric analysis. The number of absorbing molecules causes an exponential drop in the intensity of a parallel monochromatic radiation beam. In other words, Beer's law states that absorbance is proportional to concentration. Lambert's law states that when a beam of parallel monochromatic radiation travels through a material of uniform thickness, its intensity drops exponentially. Beer-Lambert's law is the result of combining these two laws. By making a solution in a clear solvent and measuring its absorbance at an appropriate wavelength, one may use a

spectrophotometer to quantify therapeutic compounds. The wavelength of maximum absorption should be changed to produce an absorbance of around 0.9, which is the range at which the measurement's accuracy and precision are at their best.^[55]

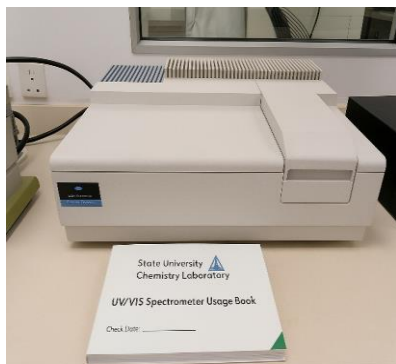


Figure 4 : UV-VIS Spectrophotometric

4.3.2 RAMAN SPECTROSCOPY:

Chemometrics and Raman spectroscopy have been utilized to detect and profile the chemical composition of counterfeit drugs. This is a two-step method that has been implemented. The first step outlines how to recognize medicinal tablets and capsules, as well as how to spot counterfeit products. API peaks in the suspect product are identified, a correlation with the database is calculated, and a non-linear classification method called support vector machines (SVM) is applied. The second step allows for the chemical profiling of a counterfeit alongside other counterfeits for forensic intelligence purposes, should one be detected. This stage involves categorizing the counterfeits' 23 Raman spectra utilizing PCA (Principal Component Analysis) and correlation distance measurement.^[56]

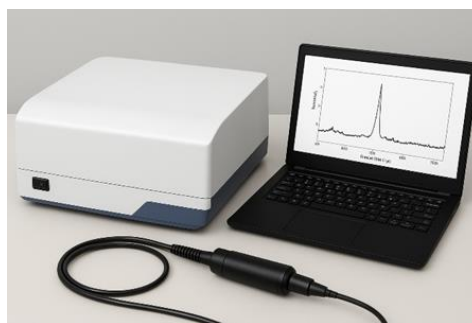


Figure 5: Raman Spectroscopy

4.3.3 NUCLEAR MAGNETIC RESONANCE:

In a reasonable amount of time, quantitative NMR was employed with excellent reproducibility to identify several drugs.^[57] NMR can provide beneficial data for resolving the structures of associated compounds in cases where many techniques fail. The characterization of vardenafil, an analogue, was performed via NMR analysis.^[58] A poly-nuclear magnetic resonance may be more complex and require complex statistical analysis, but it may prove very important in determining the identity of counterfeit drugs with different origins. Wawer et al. Presented a polynuclear NMR involving ^{13}C , ^1H , and ^{15}N for the detection of sildenafil base and citrate in a pharmaceutical dosage form.^[59]



Figure 6: NMR spectroscopy

4.3.4 XRD (X-ray Diffraction):

XRPD (X-ray Powder Diffraction) is an analytical method that is effective in identifying counterfeit pharmaceuticals. Ultra-fast X-ray detectors and

other latest advancements are making this a powerful tool for quality control uses. XRD and Radio frequency can be applied separately with Raman and IR spectroscopy to assess counterfeit medications. XRPD is a quick, flexible, and sensitive approach that offers comprehensive details about the chemical constitution and crystallographic structure of natural and synthetic materials. With low detection limits and control over the final dose form, it enables both qualitative and quantitative phase evaluation of the numerous elements of entire solid drugs, including API and fillers. Recently, XRD was applied to determine sibutramine, rimonabant polymorphs, and related compounds that were present in counterfeit goods purchased via the web.^[60] A novel technique for DNA fingerprinting becomes available for the authenticity of counterfeit drugs. The document of authenticity techniques is a fingerprinting technology that makes use of random 3-dimensional scattering structures that are distinct for each medicinal ingredient.^[61]

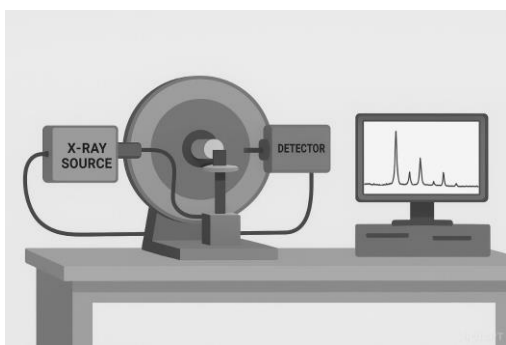


Figure 7: XRD Instrument

4.4 Chromatographic approaches:

4.4.1. Thin Layer Chromatography:

TLC was widely employed to determine Phentermine (Ionamin) alteration in conjunction with UV detection and microcrystal testing. The determination confirmed that the only substances in the counterfeit capsules were phenylpropanolamine and caffeine.^[62] A quick

chemical detection approach comprising two TLC systems and two chemical color reactions was recently proposed by Hu et al.^[63] For the assessment of counterfeit macrolide antibiotic formulations. Based on the color reactions, this method can differentiate between macrolides with 14 & 16 members. The relevant macrolide is identified using the TLC systems. Another use of TLC for detecting sildenafil alteration in dietary supplements was reported by Moriyasu et al.^[64] Wu et al.^[65] Presented an example of how to identify *Curculigo orchioide*, a counterfeit herbal remedy, in addition to the traditional morphological test; TLC and UV spectrometry were used to achieve this goal.

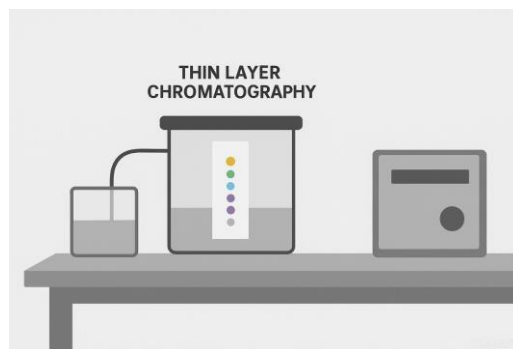


Figure 8.: Thin Layer Chromatography

4.4.2 LIQUID CHROMATOGRAPHY:

A common method for identifying and characterizing counterfeit pharmaceuticals is LC. In this field, LC is used in conjunction with various detectors for multiple purposes. The first is a technique for quantification and target analysis (for the detection of one or more known compounds). When it comes to structural clarification and the screening of counterfeit samples, LC and MS are frequently used together. Chromatographic fingerprints are frequently used to distinguish genuine plants from those sold as counterfeits and to ensure the quality of herbal products. To characterize illicit pharmaceutical formulations, LC with UV or DAD is a crucial approach. Numerous techniques are covered in the

literature for analysing impurities and unregistered analogues, as well as active components in counterfeit formulations.^[66]

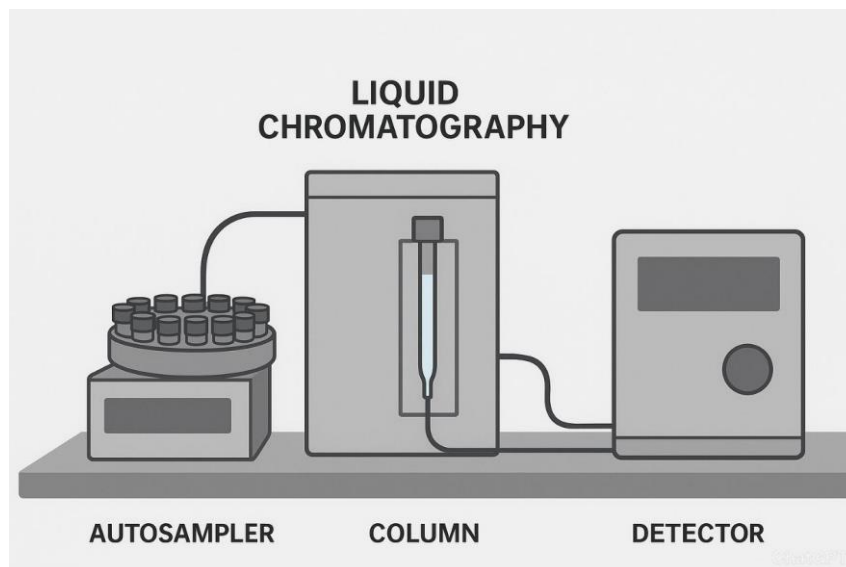


Figure 9: Liquid Chromatography

4.4.3. LC-MS:

The preferred technique for handling counterfeit pharmaceutical preparations is LC-MS. Target analysis and screening for the presence of drugs in an unidentified preparation are both made possible by this technique. Numerous unregistered analogues and contaminants have been found in the PDE inhibitor class. IR and NMR methods in conjunction with LC-MS have been used to detect the majority of the cases.^[66]

An LC-MS-MS technique was presented by Bogusz et al.^[67] To screen herbal medications for

the presence of artificial adulterants. Adulterants of several clinical classes, such as analgesics, antidiabetics, antibiotics, aphrodisiacs, antiepileptic medications, anabolic and hormonal drugs, psychiatric pharmaceuticals, and weight loss substances, could be screened for using the method provided. To check for the presence of lipid-lowering and pressure agents, anti-diabetic medications, sedatives, aphrodisiacs, and weight-reducing substances, Chen et al.^[68] Created an LC-linear ion trap (QTRAP)-MS. In their description of an additional use, Hall et al.^[69] Used LC-MS to characterize artesunate tablets that were imported from Asian nations.

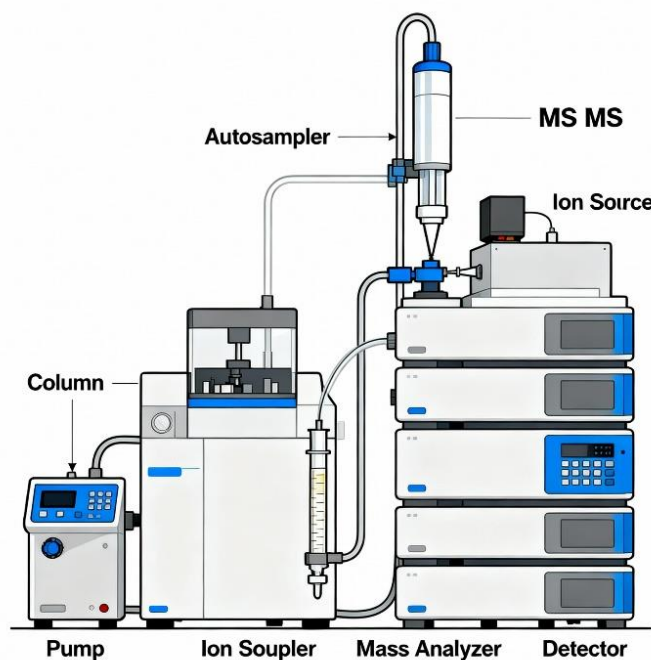


Figure 10: LC-MS/MS in Research Labs

4.4.4. HPLC-UV/DAD

The HPLC-UV/DAD method has been frequently utilized to identify counterfeit, contaminated, and imitation products that contain PDE-5 inhibitors. Once the presence of PDE-5 inhibitors was verified by LC-MS, Gratz et al. created an HPLC-UV method for their quantification and detection.^[66] Using HPLC-UV, Park and Ahn

examined 105 samples of counterfeit drugs that were confiscated in Korea to check for the presence of sildenafil and tadalafil.^[70] The quality control of antimalarial pills bought from the Goma market was done by Gaudiano et al.^[71] Using HPLC-DAD. A benzodiazepine screening approach using HPLC-UV was presented by Mikami et al.^[72]



Figure 11: HPLC-UV/DAD instrument

2. PREVENTION STRATEGIES:

The market offers numerous methods to stop the drug from being counterfeit. However, as

medicine counterfeiting has been growing daily, two methods that can be applied in the pharmaceutical industry have been suggested. These methods have the potential to significantly

alter the way that medication counterfeiting is prevented. This approach should be implemented by the Indian healthcare system as well.^[73]

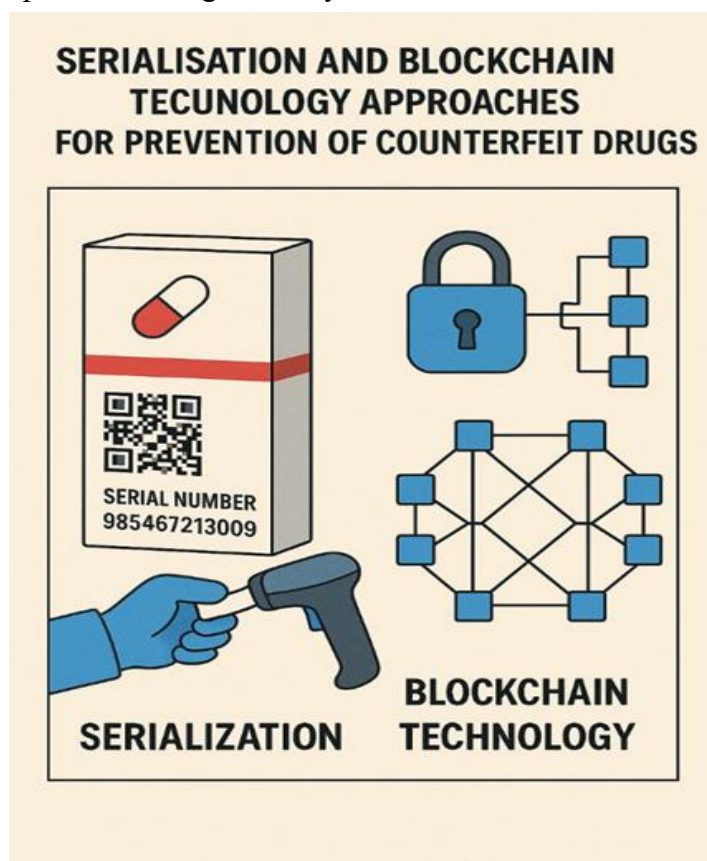


Figure 12: Prevention strategies for counterfeit drugs

5.1 SERIALIZATION^[74, 75]:

One special method of preventing counterfeiting is serialization. As implied by the name, each drug product will be assigned a unique code that will be kept on file throughout the drug supply until it is consumed. Thus, it will be simple to recognize the product and have quick access to all of the data kept in a safe database. The sequence is unpredictable if a random serial number or non-sequential numbering is used, although track and trace may not be immune to duplication or falsification. A distinctive identifying number is prominently displayed on a package and is easily verifiable by clients via phone and an online database. A unique 23-character code for a certain

pack of a medication product will be created when all the codes are merged. Once the drug product has been assigned a UIN, it will proceed through a supply chain and be promptly checked if there are any doubts about it at any point during the supply chain.

5.1.1 BENEFITS OF SERIALIZATION^[75] :

- Combating the use of counterfeit medications.
- Easier recalls and refunds.
- Confirmation and verification of product.
- To enhance the management of shelf-life.

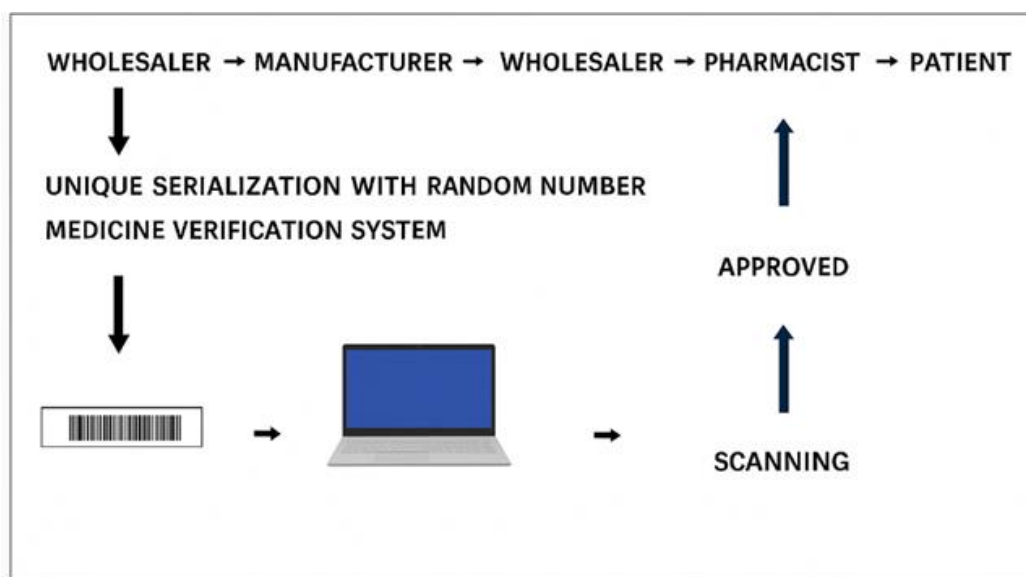


Figure 13 : Serialization Process

5.2 BLOCKCHAIN TECHNOLOGY:

The development of a permanent record system in the supply chain that provides information on a drug's location, contents, quality, and cost, as well as interfaces to clinical trials, medical records, and healthcare data, is known as blockchain technology.^[76]

The blockchain process steps in during the drug delivery method's production, distribution, supply, and consumption phases. It keeps track of decentralized drug information on the medication, physician, pharmacy, and prescription. Information sharing within a regulatory network is made possible by an advanced database mechanism.^[77]

It is composed of several blocks, each of which has many transactions. To monitor the medicine at different stages of the supply chain, convey drug information to regulatory bodies, and offer information about the drug product authentication, blockchain starts with a unique identifier that is applied to the drug. Every block inside the network is securely connected and secured by crypto and transaction codes.^[77, 78] Improving the detection

and verification of counterfeit medications is the alleged benefit of the blockchain investigative approach. Blockchain technology lowers transaction costs and improves the ability to identify and react to counterfeit medications more accurately. While there are many different kinds of blockchain, Hyperledger is a fabric-based system that focuses on enhancing the safety of Pharmaceutical Products by guaranteeing data storage, sharing, transparency, and traceability throughout the supply chain.^[79] AI and other counterfeit reduction strategies can be combined with blockchain technology. In this regard, artificial intelligence is being used more and more to detect counterfeit medications because of its capacity to analyse vast volumes of data and spot trends that can point to fraud. Through real-time blockchain data analysis, AI can combat counterfeit medications by facilitating quicker and more precise drug shipment monitoring and verification. Every drug-related transaction in the supply chain can be recorded by blockchain and AI, and blockchain can scan drug data quickly to identify irregularities, flag suspect activity, and confirm the legitimacy of products. In this regard, artificial intelligence systems can track the trans it of drugs from manufacturing to delivery, detecting

illegal variations or counterfeit products.^[80] AI is used in pharmaceutical research in a variety of ways, such as chatbots, natural language processing (NLP), and machine learning-enabled systems and pattern recognition. To start, blockchain systems and machine learning combine to reduce and eradicate counterfeit pharmaceuticals by utilizing healthcare systems and drug supply chain algorithms.^[78] To detect counterfeit pharmaceuticals in real-time, machine learning can use active data inputs to find characteristics and behaviours that are suspicious or fraudulent in the records about counterfeit drugs. Natural language processing (NLP) is an AI-based method for analysing and recognizing images at the text level of paperwork, packaging, and medicine labels. This refers to spotting textual variations that are often suggestive of counterfeit products, such as grammatical errors and disparities in product details.

Additionally, it may spot subtle differences or anomalies in images of prescription labels, packaging, and even some medications that could indicate counterfeiting. AI-powered chatbots, which allow users to report suspicious medications, increase public participation in the detection of counterfeit drugs. These systems can help users recognize counterfeit medications by using visual indicators such as appearance, labelling, and packaging. Faster reactions are

made possible by the system's ability to submit reports to the appropriate authorities or producers promptly. This facilitates more customer involvement, which aids in the more efficient detection and removal of counterfeit medications from the market. One type of AI that examines patterns in data related to sales, distribution, and customer feedback is called pattern recognition. This can help to detect unusual/abnormal buying patterns or abrupt changes in sales volumes that could point to the release of counterfeit medications and pharmaceuticals.^[80]

5.2.1 Advantages of Blockchain technology:

- Everybody takes part in the supply chain for pharmaceuticals.
- Blockchain is irreversible and time-stamped.
- Every product can be authenticated by registering on the blockchain.
- It cannot be a scam committed by a drug dealer.
- All information will be visible and safe.
- In India, blockchain technology is expanding in the medical field.
- The entire drug supply process is simple.

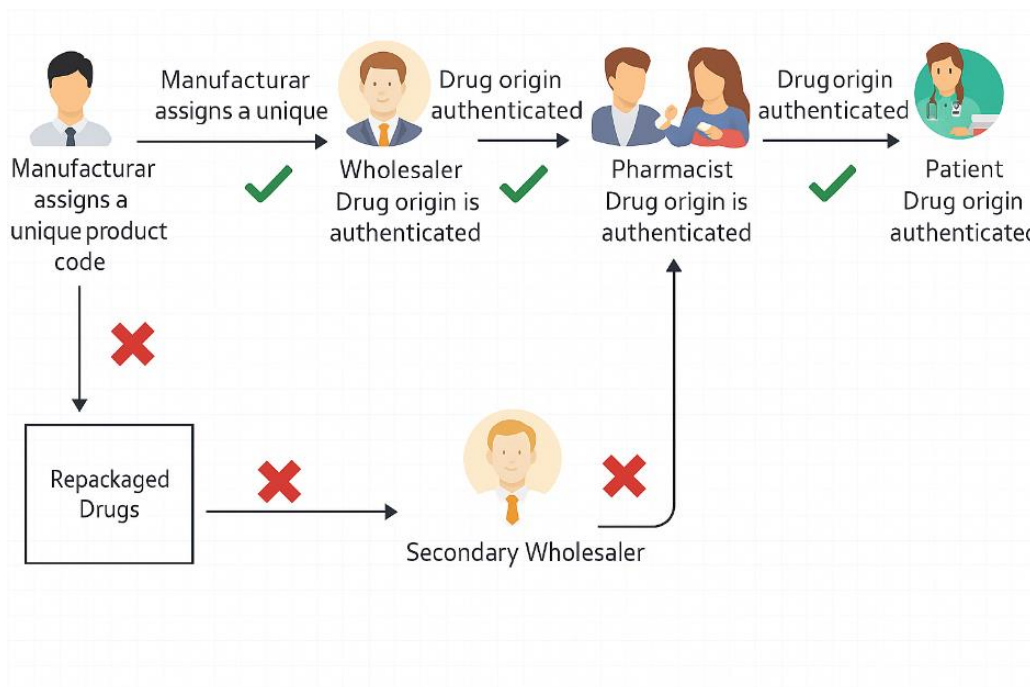


Figure 14: Blockchain technology

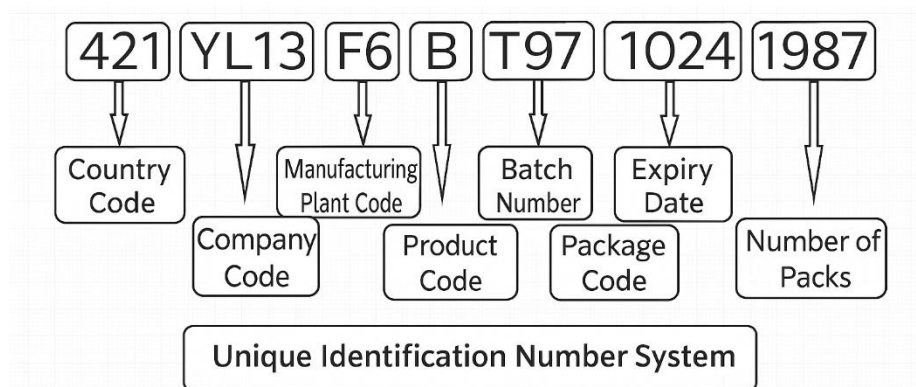


Figure 15: UIN System

5.3 OTHER CURRENT AND MODERN TECHNOLOGIES TO PREVENT DRUG COUNTERFEITING:

Now, a variety of technologies, including overt, covert, and track-and-trace technologies, are being used to combat drug counterfeiting. Without the need for specific knowledge or expensive equipment, packaging can be checked through visual representations using overt technology. In addition to the aforementioned ones, companies are concentrating on employing hidden technologies, such as RFID labels on packages and

unique UV links that are invisible to the naked eye but visible when exposed to UV light. To prevent drug counterfeiting, a mix of different overt and covert methods can be a useful deterrent to stop drug counterfeiting.^[81]



Figure 16: Current and Modern track-trace technology to prevent counterfeit Drugs

3. CONCLUSION:

Counterfeit pharmaceuticals remain a persistent and evolving challenge that demands a coordinated, multi-pronged response. The widespread availability of falsified medicines—driven by economic incentives, weak regulatory frameworks, and complex global supply chains—undermines therapeutic outcomes, fosters drug resistance, and erodes trust in healthcare systems. Advanced analytical techniques now enable rapid and reliable detection, but prevention requires equally robust measures, including product serialization, blockchain-enabled traceability, and integrated AI-driven monitoring systems. In India, the world's largest producer of generic medicines, urgent strengthening of regulatory enforcement, harsher penalties, and industry–government partnerships is vital to curbing counterfeit circulation. International collaboration, public awareness, and adoption of both overt and covert anti-counterfeiting technologies can collectively reduce the prevalence of falsified medicines. Sustained commitment from policymakers, healthcare providers, manufacturers, and consumers is Essential to protect patient safety, maintain pharmaceutical integrity, and uphold the credibility of the global healthcare ecosystem.

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