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"Counterfeit Medicines - A challenging threat upon Public Health"

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Abstract
Counterfeiting of medicines is a challenging threat to the public health and to the global economy. In this review, we focus on the characteristics of the counterfeit medicines, their impacts on the public health and the prevailing strategies to combat the issue. The definitions of counterfeit medicines vary across distinct regulatory authorities and countries, and they are placed under different categories based on the sophistication of counterfeiting. Counterfeiting of medical products is a global issue and affects all type of populations. Since these products are manufactured in the unregulated facilities and illegally distributed, they pose substantial health risks to the consumers as well as economic strain on society and the state. Strategies to combat the threat of the counterfeit medicines include knowledge and awareness of the healthcare professionals and the public, intervention of the regulatory authorities and the use of modern technologies.

Keywords: Counterfeiting, Counterfeit Medicines, Health Impacts, Antimicrobial Resistance, Combat Counterfeits, Good Health, Well-Being

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1. Introduction

Counterfeit medicines are the fake or unauthorized versions of the authentic products and they pose a major risk to the public health and economy worldwide. Counterfeit medicines are products which are manufactured by someone other than genuine manufacturer, they copy or imitate an original product without the permission or rights from the original manufacturer (European Medicine Agency) [1]. World Health Organization uses the term 'Falsified Medical Products' to describe the products that deliberately or fraudulently misrepresent their identity, composition or source [2]. US FDA interprets a counterfeit drug as product or medicine which, or whose container or labeling, without proper authorization or rights, carries the trademark, trade name, or other identifying mark, imprint, or device, or any similar likeness of drug manufacturer, processor, packer, or distributor other than the individual who actually manufactured, processed, packed, or distributed the original drug [3].

Analysts estimate that the yearly value of the global counterfeit medicine market will be approximately from $200 billion (CHF180 billion) to $432 billion.According to the WHO around 10% drugs are falsified or substandard . Counterfeiting is one of the major serious issue that is affecting both developed and developing nations. Data from the Pharmaceutical Security Institute (PSI) reveals that incidents of illegal trafficking of pharmaceuticals increased by 38% rising from 3146 in 2016 to 4344 cases in 2020 across 137 countries,. The 2020 PSI data covered 2451 distinct medications with multiple therapeutic categories. North America accounted for the largest share of counterfeit seizure medications (32%) in 2020 . Other regions included in counterfeiting are Asia Pacific 23%, followed by Latin America, Eurasia, the Near East, Europe, and Africa with 3% each [4].In India under section 17B of the Drugs and Cosmetics Act, 1940 the counterfeit medicines are considered as spurious medicines [4]. As per this section a drug shall be considered to be spurious, if it is manufactured under a name that belongs to other drug; or if it imitates, or substitutes or resembles another drug in a manner likely to mislead or bears the name of another drug in their label or container unless it is clearly and conspicuously marked so as to disclose its true identity with such other drug; or if the label or container bears the name of an individual or company claimed to be the manufacturer of the drug when such individual or company is does not exist; or if it has been wholly or partially substituted by another drug or substance; or if it claimed to be the product of a manufacturer when it is not actually manufactured by them.

Based on the level of sophistication the counterfeit and falsified medicines are categorized into five groups as follows [5];

Category 1: Completely fraudulent products with unknown ingredients and therapeutic effects that differ from the original drug.

Category 2: These products look somewhat similar to the imitated drug, but whose composition is not known.

Category 3: Products that look very similar or identical to the genuine product but contain an entirely different drug, if any.

Category 4: Products that look very similar or identical to the original product but contain an alternative drug or

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synthetic analogue providing similar therapeutic effects, intended to create repeat business.

Category 5: Visually identical, highly sophisticated copies or synthetic analogues with some therapeutic effect that are difficult to detect using most field and laboratory methods.

Detection and regulation of the counterfeit medicines is a challenging task and in most of the cases it is practically difficult or sometimes impossible to distinguish the counterfeit medicines from the authentic products.

In a country wide survey conducted in India, the counterfeit medicines were detected by identifying the differences in the label and packaging like foil quality, text matter and font size in the label, manufacturer's symbol, colour and characteristics of the packaging material, etc [6,7] Figure 1.

Since these fake products are manufactured in the unregulated facilities, the quality of such products is not supposed to comply with the standards. Counterfeit medicines may contain wrong ingredients, high or low quantity of ingredients or no active ingredient at all, or contain other harmful ingredients [8]. Falsified products can prolong illness of the patients and the inconvenience, and cause wastage of precious time of doctors and other healthcare workers [9].

Online pharmacy counterfeiting has emerged as a major factor for the growth of counterfeit medicines . The rapid expansion of online pharmacies, fueled by increased internet access, consumer convenience, and cost lowering benefits, has provide various new opportunities to distribute counterfeit drug . The global online pharmacy market was valued at approximately USD 68 billion in 2021 and is expected to grow to USD 206 billion by 2028. However this growth along with the increased illicit online pharmacies that offer counterfeit, adulterated, and unapproved medicines without any valid prescriptions. These illegal platforms and regulatory frameworks pose significant risks to public health and patient safety [10]This review emphasizes a comprehensive and integrated perspective on counterfeit medicines by checking their characteristics, regulatory inconsistencies across the world, and classification based on the level of counterfeiting sophistication with combining public health and economic impacts. Furthermore, the article suggests multiple strategies to address the issue, bringing awareness among healthcare professionals and the public, strengthened regulatory actions, and the use of modern technological solutions, while highlighting that counterfeit medicines represent a worldwide threat impacting all populations.

~~3.~~2. Scope Of The Problem

Counterfeit medicines are a global issue and a menace to the public health, affecting all type of populations throughout the world. According to a research data from the World Health Organisation, an estimated quantity of 1 in every 10 medical products in low- and middle-income countries is either substandard or falsified [10]. In the year 2023 Novo Nordisk, a US based pharmaceutical manufacturer, has warned the consumers about the entry of several thousands of counterfeit units of their product Ozempic Injection (Semaglutide) in the supply chain of United States of America [11]. To figure out the exact magnitude of the spurious drugs in India a survey was conducted and funded by the Ministry of Health and Family Welfare, Government of India, was conducted and its report was published in the year 2009 by the Central Drugs Standard Control Organisation (CDSCO) [7]. Factors contributing to this widespread problem include weak regulatory frameworks, insufficient supply chain controls, and high demand for low-cost medication [12].

In 2003, US FDA recalled more than 18 million tablets of Lipitor (Atorvastatin 20mg tablets manufactured by Pfizer) from the US market, due to just one counterfeit case [6]. In a data analysis of the alerts issued during the period 1997-2014 in Peru, it was observed that out of 669 alerts 52.91% were concerned with the counterfeit medicines [13].

In India, as per the country wide survey report of 2009 the extent of spurious drugs detected was only 0.046% (11 out of 24,136 samples) during the survey period [7]. But in the year 2023 the drug alerts from the CDSCO shows that 14 (0.096%) out of 14,536 samples tested in the central laboratories were found spurious products [14]. This data does not show the data from the state regulatory authorities, so the exact extent of the availability of the spurious medicines will be more than this. In January 2024, the Drugs Control Administration of the Telengana State published the details of 9 products that are detected as counterfeit/spurious in December 2023 [15].

High risk products like vaccines are also subjected to counterfeiting. In the year 2017 one batch of Typhoid Vaccine and in 2022, Five batches of Covid Vaccines were declared as spurious by the CDSCO [16]. Evidence of falsification of Influenza Vaccine was detected in a study conducted in Brazil [17] .

Counterfeiting has expanded partially due to the high margins it provides to criminal groups, and the relatively low risk of detection and minimal penalties [18]. The internet has also helped counterfeiters, by increasing the opportunities to sell medicines by boosting the scope to market drugs anonymously. In addition, the illegal supply chain has evolved in to a well-structured system consisting of manufacturers, distributors and local vendors, whose primary objective is to "complicate" the legitimate chain, so the traffic of their counterfeit medicines remains unnoticed[19].

The occurrence of counterfeit and falsified medicines is different across countries and regions, mainly because of variations in regulatory strengths, enforcement effectiveness, and healthcare infrastructure. The table below provides a comparative overview of these regional differences.

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Table: Prevalence of Counterfeit Medicines Across Countries and Regions

Country/Region	Estimated Prevalence	Reference
United States	Below 1% in the regulated supply chain; risk involved through illegal online platforms/ pharmacies	U.S. Food and Drug Administration (2023)
European Union	Under 1% in legal supply chains as a result of strong regulatory controls	European Commission (2021)
Canada	Below 1 %	Health Canada (2022)
India	Variable ; counterfeit medicines remain a concern despite regulatory improvements	Central Drugs Standard Control Organisation (2025)
China	Variable; counterfeit medicines remain a concern despite regulatory improvements	World Health Organization (2017)
Sub-Saharan Africa	10–30% in some medicine categories, especially antimalarials and antibiotics	World Health Organization (2017); United Nations Office on Drugs and Crime (2020)
Southeast Asia	10–20% in certain studies and therapeutic categories	World Health Organization (2017)
Latin America	5–10% in some markets	Pan American Health Organization (2021)
Middle East and North Africa	5–15% in selected studies	World Health Organization (2017)

4.3. Impacts On Public Health

The public health implications of counterfeit medicines are severe and multifaceted. They range from direct health effects, such as treatment failures, adverse reactions and antimicrobial resistance, to broader socio-economic impacts like loss of confidence in the healthcare system and economic burden.

The public health effect of the counterfeit medicines is clear. Less quality medications may cause harm by neglecting because patients consume these drugs that lack active ingredients. In some cases, the counterfeit medicines can be deadly, if they contain toxic substances and impurities resulting from low quality ingredients, unhygienic manufacturing , or lack of rigorous cleaning between different production batches [18].

Some of the critical implications of the counterfeit medicines on the public health are following;

3.1 Therapeutic Failure and Toxicity

Therapeutic failure and toxicity are the direct adverse effects to the patients who are exposed to the counterfeit medicines. The falsified products may cause mortality and morbidity to the patients because the medicines they take contain no active ingredient or at sub-therapeutic concentrations [20]. For example the World Health Organization (2017; 2022) has reported recurring cases in which coun terfeit antimalarial and antibiotic drugs reduced therapeutic effect and prolonged the disease spread in low- and middle-income countries[21]. Any product containing a dangerous contaminant (including dangerously high levels of the expected active ingredients) will pose an immediate hazard to the individual taking it. Patients may also die, or suffer a longer bout of disease, if their condition goes untreated because the “medicine” they take contains no active ingredient, or the active ingredient is at subtherapeutic concentrations [22].

3.2 Mortality data

According to the World Health Organization counterfeit medicines are associated with large number of deaths each year including malaria, pneumonia, and tuberculosis . Studies reported that counterfeit antimalarial drugs associated with hundreds and thousands of deaths annually mainly in Sub-Saharan Africa, due to treatment failure and the development of drug resistance [22]. In addition, these medicines also indirectly increase mortality by antimicrobial resistance .

3.3 Anti-microbial Resistance (AMR)

Antimicrobial resistance is a major concern , with forecasts estimating that drug-resistant infections could account for up to 10 million deaths annually by 2050. If the anti-microbial medicines are counterfeited, their consumption would contribute more serious threat on public health. Consumption of poor quality anti-microbial medicines contributes to the emergence and spread of AMR [23]. Evidences show that exposure to sub-therapeutic level of anti-microbial medicines can promote development of resistant bacterial strains and increased virulence [24]. Counterfeit antibiotics contributed to the development of resistance in various pathogens such as Mycobacterium tuberculosis, Escherichia coli, and Klebsiella pneumoniae. When infectious diseases are not prevented because the

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medicines are substandard or falsified, or when infections are not properly cured or controlled, disease rate is likely to rise. Antimicrobial resistance can develop when the pathogens are exposed to low doses of substandard and falsified treatments. In the case of substandard and falsified medicines the levels of the active ingredients are so low or non-existent so that the treatment will be ineffective [22]. According to WHO, antimicrobial resistance is one of the top global public health threats and effect the countries at all income levels [25]. It is estimated that about 4.95 million deaths worldwide in 2019 and also estimated to impose cumulative economic burden up to US$100 trillion by 2050 were associated with the bacterial AMR [26].

3.4 Loss of Confidence in Healthcare System

Patients and their family would lose their confidence in the healthcare system due to failure to cure or prevent the disease, toxicity of medicines and increased mortality and morbidity. Loss of confidence in the treatments, health care professionals and health care institutions is an extremely relevant impact of counterfeit medicines on public health [19]. Substandard or falsified medical products can reduce the trust the health care system. As a result, some patients may avoid treatment completely or seek alternative treatment from unregulated shops or unqualified providers. Several stakeholders, including academics to policy-makers, have highlighted the important consequences of counterfeit products in health care systems [22]. This loss of confidence may discourage patients from seeking medical care, following prescriptions, or utilizing healthcare facilities, leading them to take unregulated sources of medicines. In addition to compromising patient health, counterfeit medicines can damage trust in healthcare professionals, government regulators, and public health interventions.

3.5 Economic Impact

Economic loss for patients, their families, health systems, authentic manufacturers, supply chain actors and governments are a major socio-economic impact of the counterfeit medicines. The most direct cost of substandard and falsified medical products to patients and their families is the money they spend on medical products that cause harm, or that do not work. Products that are toxic, or that fail to cure or prevent further disease, will certainly represent a wasted financial outlay. Toxicity, treatment failure, or infection resulting from failed prophylaxis may also lead to extra spending on health services and new medical products. An annual economic impact upto USD 44.7 million was estimated due to substandard and falsified antimalarials in sub-Saharan Africa in a study conducted between 2001 and 2016 [22].

Counterfeiting has an important commercial impact as it undermines the margins of legitimate drug companies, reducing the profits available for reinvestment in new drugs and for low-cost, high quality generics [18].

Two measures of the direct cost of substandard and falsified medical products are important. The first is the amount of money spent on such products by individuals and health systems. The other is the amount of money forfeited by manufacturers (and other actors in the supply chain) because patients or suppliers have bought products that are not quality-assured. Although the measures are similar, they are not the inverse of one another [22].

Antimicrobial resistance which may be caused by counterfeit products also, considered as a threat to the global economic future. World Bank estimates an annual shortfall of about 1 trillion USD in the global gross domestic product after 2023 due to a scenario of low impact AMR [27].

3.6 Clinical evidences

Several clinical studies reported the serious impact of counterfeit medicines on patient health. The U.S. Food and Drug Administration (2008) also revealed severe adverse reactions and deaths of heparin contamination. The World Health Organization documented various cases of counterfeit anti cancer medications, including bevacizumab without any active ingredients, leading to treatment failure and prolonged illness. In addition, clinical evidence reported that counterfeit antimalarials (artemisin), insulin, antibiotics, and chemotherapy drugs have resulted in reduce4d therapeutic effectiveness, disease worsening, hospitaladmission, and increased mortality due to absent or substandard active ingredients [28].

5.4. Strategies To Combat The Issue

Infiltration of the counterfeit medicines to the hands of the consumers are to be controlled effectively in order to combat its threat on the public health and economy. To tackle the issue of substandard and falsified products, WHO summarises the need of actions to (i) prevent the manufacture, sale and consumption of substandard and falsified medical products, (ii) implement systems to detect any substandard or falsified products that are already in the supply chain and (iii) respond quickly and proportionately to any incidents that are detected, in ways that safeguard patients and the supply chain, take appropriate action against those responsible, whilst not causing unnecessary shortages [2]. Hence all stakeholders from the manufacturers to the consumers including regulatory authorities have significant roles in addressing the issue of counterfeit medicines.

4.1 Knowledge and Awareness

Knowledge and awareness of the healthcare professionals and the public on the counterfeit medicines plays an important role in detecting the counterfeit medicines.

In a study in Sudan, Alfadl AA, et al concluded that lack of knowledge have a significant role in increasing vulnerability to counterfeit medicines [28]. Requirement of improvement of knowledge and skill of community Pharmacists for effective contributions to reduce the counterfeit medicines has been identified in a survey conducted in Egypt by Bashir A et al. [29]. In another study to examine the knowledge of California pharmacist knowledge on counterfeit medications, Pharmacists agreed that lack of knowledge (46.8%) and resources (82.5%) were barriers to detect the counterfeit products [30].

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During a survey conducted in India to figure out the exact magnitude of spurious medicines in India, the following label characteristics like foil quality, text matter in the label, font size in the label, manufacturer's symbol and colour of the strip were considered for distinguishing the spurious medicines [7]. In that survey report, the photographs of the spurious medicines were published along with the distinguishing remarks. An example is given in Figure 2 and the remarks for that sample were a) Foil is of poor quality, b) Kangaroo symbol is not matching, c) Font size of 'NISE' on PVC side is not matching and d) Font size of text matter on foil not matching.

By publishing the picture and the distinguishing remarks of the spurious medicines the authorities are effectively transferred the information to the healthcare providers and to the consumers regarding the characteristics of a counterfeit medicine. Availability of such information to the public will be useful for the easy detection of the counterfeit medicines.

According to a statement of Novo Nordisk, they were became aware that the Ozempic Injections are counterfeited by visual inspection of the cartons and needles and for the public awareness they published the relevant images as shown in the Figure 3 [11];

Awareness and knowledge of the general public also have significant role in detection of the counterfeit medicines. A cross-sectional survey conducted in different geographic areas of Asia, Europe, America, Africa and Middle East concluded the need to raise awareness among general population through different awareness and educational campaigns to help identifying counterfeit drug products [31].

4.2 Regulatory Interventions

Detection of the substandard medicines, publication of its details and taking subsequent legal proceedings are the duties performed by the regulatory authorities. As the counterfeiting of authentic products is a surreptitious activity and carried out in the unregulated facilities, it is a tough task to find out the source of the counterfeit medicines. Regulatory interventions to curb counterfeit medicines have made significant strides around the world particularly in developed countries. However, counterfeit medicines continue to thrive in many regions especially in low-income countries where regulatory framework is weak.

One of the important legislation enacted in the USA to address the issue of the counterfeit drugs is the Drug Supply Chain Securities Act (DSCSA). The DSCSA mandates that all prescription drug packages shall carry a standardized graphic that includes the product's standardized numerical identifier, lot number, and expiration date, in both human- and machine-readable formats [32]. The incidence of entry of several thousands of units of counterfeit versions of the product Ozempic Injection from outside into the authorised supply chain was determined in December 2023 by the product manufacturer [11].

In India, amendments along with a new schedule (Schedule H2) came into force with effect from 01/08/2023 in the Drugs Rules, 1945 to ensure the authenticity of the drugs. As per the amended rules, the manufacturers of drug formulation products as specified in Schedule H2 shall print or affix Bar Code or Quick Response Code on its label that store data or information legible with software application to facilitate authentication [33]. This requirement is limited to 300 brands of the drug products listed in the Schedule H2. Those 300 brands comprising only 0.5% of the 60,000 generic brand products available in India [34]. Even after commencement of this regulation some of the listed (in Schedule H2) products were reported as spurious. In the List of the Spurious Drugs for the months of September 2024 and October 2024 published by the CDSCO, three products were the brands included in the Schedule H2 list viz. SHELCAL 500 (Manufactured in 08/2023), PAN-D (Manufactured in 09/2023) and PAN-D (Manufactured in 12/2023) [35], [36].

In the last three years ie, from 2023 to 2025 , the CDSCO has been declared 63 batches of drug products as spurious under section 17B(e) of the Drugs and Cosmetics Act, 1940 ie the concerned manufacturers as given in the label has not accepted the impugned batch of products as their genuine product [14]. In many of those instances, the manufacturers communicated to the regulatory bodies that the impugned batches of the products had not been manufactured by them solely subsequent to the announcement that the products were declared as not of standard quality through the tests and analysis conducted by the regulatory laboratories. In most of the cases, the products were declared as spurious after one year of manufacturing the product.

4.3 Technological Solutions

Detection of substandard and falsified medical products is difficult because advanced laboratory equipment is very expensive and difficult to maintain and requires personnel to operate. Current methods used for detecting counterfeit or falsified medicines include vibrational spectroscopy, x-ray diffraction, gas chromatography, liquid chromatography, and mass spectrometry. These techniques require expensive and bulky instrumentation, and are usually carried out in laboratory by skilled operators [37]. Several field detection technologies are also available, but each has its own advantages and limitations and they are not always used by the skilled or properly trained individuals [38]. In order to overcome this problem WHO worked with partners to develop a smartphone-based application health care worker. They could take photographs of a suspicious medical product and send them to the regulator in less than 90 seconds. Regulators are expected to the report within 48 hours. That system has been tested in the United Republic of Tanzania and is planned for pilot testing in south-east Asia [2].

Scientists at the US FDA scientists have also developed reliable prototypes of two different models called Counterfeit Detector Version 5 – CD. They demonstrated that the device is useful for multiple applications including detection of counterfeit products and packaging [37]. It is an updated version of the counterfeit detectors.

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4.4 Impact on the Pharmaceutical Industry

The circulation of falsified medicines leads to significant financial losses for genuine pharmaceutical companies by diverting sales and damaging brand reputation. It may also reduce incentives for research and development, thereby negatively influencing pharmaceutical innovation. Furthermore, counterfeit drugs interfere with supply chain operations and lead to higher operational costs as a result of enhanced stricter authentication, monitoring, and regulatory compliance

Comparative Economic Impact of Counterfeit Medicines

Impact Area	Estimated Economic Burden
Global counterfeit pharmaceutical market	Hundreds of billions of USD annually
Losses to pharmaceutical industry	Tens of billions of USD each year
AMR-related cumulative global cost (by 2050)	Up to USD 100 trillion
Annual global GDP loss due to AMR	Around USD 1 trillion or more
Healthcare system treatment costs	Multi-billion USD burden annually
Productivity losses due to illness and mortality	Substantial global economic impact
Regulatory and enforcement expenditure	Significant national-level cost

6.5. Conclusion

Counterfeit medicines present multitude of threats to the global public health from individuals to society and to the economy of the countries. The difficulties in distinguishing the counterfeit medicines from the authentic ones, necessitating a multi-faceted approach to combat this issue effectively. Despite the existence of challenges in addressing the counterfeiting, knowledge and awareness of the healthcare professionals and the public, prompt interventions by the regulatory authorities in a timely manner, and modern technological solutions are significant in the mitigation of this issue. Formulation of more robust strategies to identify the counterfeit medicines and to prevent the infiltration of them into the supply chain, its efficient implementation and the prompt detection of counterfeit medicines through modern technological advancements, are imperative for safeguarding public health.

Addressing the issues of counterfeit medicines requires comprehensive and collaborative global approach. The use of AI-assisted surveillance systems can help in the detection of suspicious activities within pharmaceutical supply chains, online pharmacies, and safety monitoring databases. This allows the substandard medications to be identified more efficiently. Global regulatory harmonization promotes consistent standards and policies, lowering the gaps that counterfeiters can exploit regulatory differences. Collaboration through public-private partnerships enables governments, healthcare providers, pharmaceutical manufacturers, and law enforcement agencies to work together in prevention, detection and enforcing counterfeit drug distribution. Furthermore, stronger pharmacovigilance systems improve the monitoring of medicine safety and effectiveness by identifying the presence of falsified or substandard products through the reports of adverse effects and treatment outcomes.Additionally effective international data sharing also supports to exchange information on substandard medicine cases, trafficking networks, and emerging threats, facilitating rapid and coordinated action. Together, these measures contribute to a safer pharmaceutical environment, safeguard patients, and strengthen global efforts against counterfeit medicines.

References

1. https://www.ema.europa.eu/en/glossary/counterfeit-medicine. European Medical Agency.
2. WHO Global Surveillance and Monitoring System for substandard and falsified medical products [Internet]. 2017. Available from: http://apps.who.int/bookorders.
3. US FDA. Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act Guidance for Industry [Internet]. 2023. Available from: https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htmand/or
4. The Drugs and Cosmetics Act, 1940 (Act 23 of 1940). Available from: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTIyNw==
5. Institute of Medicine. Countering the problem of falsified and substandard drugs. Countering the Problem of Falsified and Substandard Drugs. National Academies Press; 2013. 1–351 p.
6. Case Study: Lipitor US Recall. [cited 2024 Jul 30]; Available from: https://cdn.pfizer.com/pfizercom/products/LipitorUSRecall.pdf
7. Central Drugs Standard Control Organisation (CDSCO). Report on countrywide survey for Spurious Drugs [Internet]. 2009 [cited 2025 Jan 26]. Available from: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzI1Nw==
8. U.S Food and Drug Administration. Counterfeit Medicine: Counterfeit Medicine May Be Harmful [Internet]. [cited 2024 Jul 7]. Available from: https://www.fda.gov/drugs/buying-using-medicine-safely/counterfeit-medicine

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9. WHO Global Surveillance and Monitoring System for substandard and falsified medical products [Internet]. 2017. Available from: http://apps.who.int/bookorders.
10. 1 in 10 medical products in developing countries is substandard or falsified. World Health Organisation [Internet]. 2017 [cited 2024 Jul 6]; Available from: https://www.who.int/news/item/28-11-2017-1-in-10-medical-products-in-developing-countries-is-substandard-or-falsified
11. Novo Nordisk Warns Consumers about Counterfeit Ozempic® (semaglutide) injection 1 mg in the U.S. [Internet]. Available from: https://www.novonordisk-us.com/media/latest-news/company-statement-consumer-counterfeit-warning.html
12. Kaur H, Clarke S, Lalani M, Phanouvong S, Guérin P, McLoughlin A, et al. Fake anti-malarials: Start with the facts. In: Malaria Journal. BioMed Central Ltd.; 2016.
13. Medina E, Bel E, Suñé JM. Counterfeit medicines in Peru: A retrospective review (1997-2014). Vol. 6, BMJ Open. BMJ Publishing Group; 2016.
14. Central Drugs Standard Control Organisation (CDSCO). Monthly Drug Alerts [Internet]. [cited 2026 May 10]. Available from: https://cdsco.gov.in/opencms/opencms/en/Notifications/Alerts/
15. Drugs Control Administration Telengana. Batch Details of the Spurious/Counterfeit Drugs [Internet]. [cited 2024 May 5]. Available from: https://dca.telangana.gov.in/files/Spurious%20Drugs_Jan_2024.pdf
16. CDSCO. Details of Samples declared as NSQ by CDLs. [cited 2024 Oct 11]; Available from: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTE5NTU=
17. da Costa JAC, de Lourdes Aguiar-Oliveira M, Brown D, Bermudez JAZ, Netto EJR, de Lima Leitão O, et al. Ensuring vaccine safety: Case studies of falsified influenza vaccines detected in Brazil. Vaccine X. 2023 Aug 1;14.
18. Andrew Jack. Counterfeit medicines. Bitter pills. Br Med J. 2007;335.
19. Lima MBA, Yonamine M. Counterfeit medicines: relevance, consequences and strategies to combat the global crisis. Brazilian Journal of Pharmaceutical Sciences. 2023;59.
20. A study on the public health and socioeconomic impact of substandard and falsified medical products [Internet]. 2017 [cited 2024 Jul 7]. Available from: https://www.who.int/publications/i/item/9789241513432
21. Dondorp AM, Newton PN, Mayxay M, Van Damme W, Smithuis FM, Yeung S, et al. Fake antimalarials in Southeast Asia are a major impediment to malaria control: Multinational cross-sectional survey on the prevalence of fake antimalarials. Vol. 9, Tropical Medicine and International Health. Blackwell Publishing Ltd; 2004. p. 1241–6.
22. World Health Organization. A study on the public health and socioeconomic impact of substandard and falsified medical products [Internet]. 2017. Available from: http://apps.who.int/bookorders.
23. The United States Pharmacopeial Convention. How medicine quality affects antimicrobial resistance and the medicines supply chain. 2022 [cited 2024 Jul 14]; Available from: https://qualitymatters.usp.org/how-medicine-quality-affects-antimicrobial-resistance-and-medicines-supply-chain
24. Nwokike J, Clark A, Nguyen PP. Medicines quality assurance to fight antimicrobial resistance. Vol. 96, Bulletin of the World Health Organization. 2018.
25. WHO. Antimicrobial Resistance [Internet]. 2023 [cited 2024 Oct 13]. Available from: https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance
26. Murray CJ, Ikuta KS, Sharara F, Swetschinski L, Robles Aguilar G, Gray A, et al. Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis. The Lancet. 2022 Feb 12;399(10325):629–55.
27. World Bank. Drug-Resistant Infections: A Threat to Our Economic Future [Internet]. 2017. Available from: www.worldbank.org
28. Alfadl AA, Hassali MA, Ibrahim MIM. Counterfeit drug demand: Perceptions of policy makers and community pharmacists in Sudan. Research in Social and Administrative Pharmacy. 2013;9(3).
29. Bashir A, Galal S, Ramadan A, Wahdan A, El-Khordagui L. Community pharmacists' perceptions, awareness and practices regarding counterfeit medicines: A cross-sectional survey in Alexandria, Egypt. Eastern Mediterranean Health Journal. 2020;26(5):556–64.
30. Law E, Youmans SL. Combating counterfeit medications: The California pharmacist perspective. J Pharm Pract. 2011;24(1).
31. El-Dahiyat F, Fahelelbom KMS, Jairoun AA, Al-Hemyari SS. Combatting Substandard and Falsified Medicines: Public Awareness and Identification of Counterfeit Medications. Front Public Health. 2021 Oct 26;9.
32. Product Identifiers Under the Drug Supply Chain Security Act Questions and Answers Guidance for Industry [Internet]. 2021. Available from: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htmand/orhttp://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htmhttps://www.fda.gov/
33. Ministry of Health and Family Welfare. Extraordinary Gazette No. 734 Notification G.S.R 823(E). 2022 Nov.
34. Ministry of Chemicals & Fertilizers. Department of Pharmaceuticals - Annual Report 2023-24. 2024.

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35. CDSCO. List of Drugs, Medical Devices, Vaccine and Cosmetics declared as Spurious for the Month of September – 2024 [Internet]. [cited 2024 Oct 29]. Available from: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTIwODI=
36. CDSCO. List of Drugs, Medical Devices, Vaccine and Cosmetics declared as Spurious for the Month of October – 2024 [Internet]. [cited 2024 Dec 9]. Available from: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTIyMDM=
37. US FDA. A Hand Held Portable Device Based on LEDS for Use in The Detection of Counterfeit Pharmaceutical Drugs and Packaging [Internet]. [cited 2024 Dec 9]. Available from: https://www.fda.gov/science-research/licensing-and-collaboration-opportunities/hand-held-portable-device-based-leds-use-detection-counterfeit-pharmaceutical-drugs-and-packaging
38. Dr. Elizabeth Pisani. Antimicrobial resistance: What does medicine quality have to do with it? 2015.

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