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Review Article

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A Comprehensive Study on Counterfeit Medicine and its prevention in India through its Regulatory Approach

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Abstract

A counterfeit medication is one which is intentionally and false mislabeled with relevance identity or source. Counterfeiting applies to both brand and generic products which incorporate items with wrongs ingredients, without active ingredients, with inadequate active ingredients. Worldwide, each nation is that the survivor of substandard or spurious drugs, which end in life threatening issues, loss of consumer and manufacturer and loss in trust on health system. Internationally, the trade in counterfeit drug is of the quickest developing grey economies – after narcotics, terrorism, and arm trade.

In term of revenues, India Is world's leading in generic companies. India has the notoriety of being a significant producer of the world's counterfeit drugs. Counterfeit drugs structure 10% of the counterfeit drugs in line with the world Health Organization (WHO). As Per BASCAP-"Drug industry is that the premier falsified industry in India".

The point of this enumerative review was to clarify the effect of poor-quality drugs with their outcomes on public health and also the preventive measures taken by the Indian drug administrative framework by CDSCO. India should adopt the technologies present in other countries to combat counterfeit medicine.

Keywords: Counterfeit, CDSCO, WHO, BASCAP

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1. Introduction

The business of counterfeit drugs isn't new to the world although it persists throughout the ages. The problem of counterfeit drugs emerged within the 1980s when more and more member states of the world Health Organization (WHO) reported counterfeit medicines. In line with the Black law dictionary 'Counterfeit drug' is a drug made by someone apart from the real manufacturer, by copying or imitating an inventive product without authority or right, with a view to deceive or defraud. World Health Organization (WHO) has given a brand-new name to counterfeit medicines i.e., the substandard, spurious, falsely labeled, falsified and counterfeit (SSFFC) medicines. (1)

With a population of very 1,403,126,972, a right to wellbeing is additionally an important right in India and has been perceived inside the general public constitution and legal regulations yet as in worldwide laws. Nearly 2 billion individuals internationally haven't got any admittance to fundamental medications. This means fundamental prescriptions are inaccessible, exorbitant, difficult to succeed in, inadmissible or of inadequacy for each 1/4 of the populace worldwide. (2) The majority drugs are counterfeited, but the commonly counterfeited medicines in developed countries were new, expensive lifestyle medicines, like hormones, steroids, pills for male erectile dysfunction and antihistamines. However, in developing countries the foremost commonly counterfeited medicines are those which are accustomed treat life threatening conditions like malaria, cancer, tuberculosis, HIV/AIDS, various antibiotics, etc. (3) In India, in step with Drug and Cosmetic (D and C) act, 1940, under segment 17, 17A and 17B quality medication contains misbranded, false and defiled drugs, respectively. (4) With the 2008 amendment of D and C act, Indian administrative body that's Central Drugs Standard Control Organization (CDSCO) has arranged not of standard quality (NSQ) items in three classifications A, B and C that's useful in ordering the things during quality evaluation.

Class A incorporates spurious and adulterated drug products; which conceal the important identity of the merchandise or formulation and be just like some well-known brand. These products may or might not contain active ingredients and usually manufactured by unlicensed antisocial people or sometimes by licensed manufacturers. Products that contain adulterant/ substituted product or incorporate some filth materials are called adulterated drugs.

Class B incorporate terribly substandard drugs during which item bombs the breaking down or disintegration test and where active ingredient examine get beneath 70% and 5% of allowed limit for thermo labile and thermo stable item, individually for tablets or capsules.

Class C involved products with minor defects like emulsion cracking, change in formulation color, small variation in net content, sedimentation in clear liquid. (5) The Indian administrative framework has double liability a) protecting Indians from the menace of spurious and substandard drugs and b) preparing Indian companies to satisfy the very best standards of the world market. It's time the regulatory system works. it's when the present laws are reinforced uniformly and stringently, and if the guilty manufacturers, up to those involved in dispensing are caught and punished accordingly, this menace are often curbed to an outsized extent. The tip users of the drugs, namely, the doctors and also the patients should be educated and made conscious of the matter, and that they should also take responsibility in curbing the menace. (5)

Table 1. Incident associated with counterfeit drugs in India

Region	Report	Source
25-May-21 Haryana	Drug Controller Authority of Haryana have seal a Pharmaceutical Unit in Nalagarh for Allegedly manufacturing fake Remdesivir Injection	Hindustan Times
01-Oct-21 Mumbai	Woman Arrested for selling fake Cancer Medicine "Adcetris Inj" to Cancer Patience	India Today
23-Dec-21 Kanpur	Fake Ayurvedic Medicine Unit busted for an allegation of preparing medicine to increase potency and decrease Obesity.	Times of India

2. Objective

Our Objective is to look at the matter of Counterfeit Drugs & its Effect around in India, current scenario of Spurious and NSQ in drugs in India & also to review the assorted technological features embedded to beat the issues of spurious and NSQ drugs.

3. Types of counterfeit

1. Products with the right ingredients or the incorrect ingredients.

2. Products with insufficient or no active ingredients.

3. Products with fake packaging.

4. Medicines with active ingredients different from what's stated on the package.

5. Expired medicines relabelled with the aim to increase the shelf-life.

6. Products without the name and address of the manufacturer. (7)

3.1. India-Capital of Counterfeit Drug

India is quick becoming capital of counterfeit medications, representing 33% of the fake medications created around the world. it's assessed that 40% of the pharma market in our nation, as an example Rs 8000 crore is under the grasp of spurious and dark advertised drugs. The pharma business, including those manufacturing spurious drugs, is developing at the pace of 20% per annum, which suggests that consistently the chances purchasing a medicine which is ready to cause more damage than great is additionally rising proportionately. Notwithstanding the employment of a hologram by enormous drug store organizations to safeguard their items, fake medications business keeps on thriving in Punjab, Haryana, Himachal Pradesh , Delhi, Uttar Pradesh ,Gujarat, Maharashtra, and Karnataka.

Manufacturers of spurious drugs are taking advantage of selling their spurious drugs in significant medication mandis like Patna, Agra, Kanpur, Satna, Coimbatore, Bangalore, Mumbai, Kolkata and Delhi. Almost 60% of absolutely the false medications and dark showcasing within the state are sold under the particular nose of the Central Government - at Bhagirathi Place in Delhi. (8)

3.2 Factors Facilitating Counterfeiting of medication

A) Absence of regulation with relevance: the rule of the drug dispersion framework. The clearest escape clause in an exceedingly nation is when practically zero regulation exists.

B) Frail or missing drug administrative body: A comprehensive drug regulation mechanism must be in situ, not just for coping with manufacturers but also for tracking offending importers and distributors country wise.

C) Absence of a legal mandate for licensing of manufacture/import of medicine. Without strict licensing of drug makers and importers, counterfeit drugs can easily slip onto the market.

D) Lack of enforcement of existing regulations: Existing measures and regulations are often unevenly enforced. Several factors are chargeable for this, including the extent of corruption in a very country and its poverty rate.

E) Request surpassing stock: Disappointment of a nation's production network to satisfy the requirement for meds, as within the occurrence of plagues, urges

forgers to flood the market with misleading medications Exorbitant costs. (9)

F) Online Pharmacy: In general terms Online pharmacy is an association that permits Consumers to shop for drugs, including prescription-only medication, by means of an online based requesting and mail conveyance system. Legitimate Online pharmacy's will demand registration and card payment information as well as requesting that prescription be sent , typically by post, before the order be delivered. Without a legitimate prescription, endorsed by a doctor, the provision of those prescriptions is illicit. All the more regularly alluded to because the Dark net, The Onion Router (TOR) network is an encoded region of the online considering unknown interchanges with none hint of site history or physical location. (10)

3.3 Impacts of Counterfeit medications

Counterfeit medications have various unfriendly consequences for both wellbeing and financial parts of a populace. There are different situations where fake medications can unfavorably affect wellbeing.

Situation 1: The counterfeit drug contains no active ingredient and no harmful ingredients: during this case the patient doesn't get harmed directly by the counterfeit drug but indirectly through prolongation of sickness due to delayed treatment. Also antibiotic resistance is also wrongly diagnosed as a result of the ineffectiveness of the counterfeit drug.

Situation 2: The counterfeit drug has no active ingredient but has harmful ingredients: Here, the patient may develop unexpected adverse drug reactions and cause harm to the patient by causing death or morbidity.

Situation 3: The counterfeit drug has the incorrect active ingredient: This scenario would be equivalent to the patient taking another drug rather than the prescribed without knowing it.

Situation 4: The counterfeit drug has all necessary active ingredients and other ingredients but within the wrong quantities: this could cause increased morbidity of the patient additionally as an increased chance of antimicrobial resistance.

3.4 Monetary impacts of Counterfeit medications

Counterfeit medications thusly cause financial weight by causing a resulting expansion in morbidity, adverse drug reactions and drug resistance. Notwithstanding expanded morbidity there's an increment mortality, which might likewise prompt loss of monetary potential. Sale of counterfeit drugs will harm sale of genuine drugs, thus, influencing organizations that have put resources into quality, research and development of medicine. This might likewise discourage organizations from putting resources into research and development work furthermore as deter foreign investments. There's also a major loss of taxation to the govt. Additionally to the present large amounts must be spent to guard the availability chain of medication and creation of systems that may detect counterfeit drugs. Fake medications can prompt the boycott of Indian companies in numerous nations as depicted above alongside an additional expense for fines. (11)

3.5 SFFC OR NSQ

India is that the biggest producer of generic drugs and presumably 12-25% of the drugs provided universally are contaminated, substandard and counterfeit. Being the world's biggest manufacturers of active pharmaceutical ingredients and finished products , almost certainly, India alongside China can be the many contributors of spurious medications per Patrick Lukulay, VP of US Pharmacopoeial Convention's worldwide health programs. In a report, it's been pronounced by the European Commission that 75% of the worldwide instances of SFFC medicines originate from India. (12) Spurious drugs are cause for concern for all those that are working in health sector such as doctors, pharmacists, nurses and health regulators. (5)

(Note: Spurious, Substandard, Counterfeit and fake medications have been utilized reciprocally notwithstanding having contrasts in definition, as the emphasis is on the risks to the consume)

Table 2. Recent Data of Number of Sample Tested, Found, Substandard/Spurious from February-2022 to October-2021

Year	Total No. of Sample Tested	Standard Quality	Not of Standard Quality	Spurious	Misbranded
February-2022	1221	1181	39	0	01
January-2022	1227	1200	27	0	0
December-2021	1385	1350	33	0	02
November-2021	1102	1080	22	0	0
October-2021	1061	1025	36	0	0

4. Anti-counterfeit technology for preventing counterfeit medicine-

Counterfeit drugs can lead to drug recalls and liability suits. Furthermore, brand loyalty is compromised as consumers perceive extra dangers while utilizing a company's items. A effective anti–counterfeit strategy avoid this and guarantees patient wellbeing. The way to combating counterfeit include: lawful activities on illegal dealers, countermeasures utilizing technologies, consumer education and information, and collaboration with implementation offices. The government authorities, by employing these technologies, may ensure that drugs in the supply chain are legitimate.

Holograms for Anti-counterfeiting

Holograms can join three layered security includes and become a most remarkable weapon against counterfeiting. In such solutions, holograms can provide overt first line authentication while covert features such as scrambled images, micro text, UV-sensitive or other

specialized inks provide second line authentication for trained examiners and appropriate decoding equipment. Serialization of holograms is another trend that combines authentication with traceability. Some of these developed technologies are binary encrypted holograms, light diffraction hologram elements in a product label, or a combination of a hologram, 2D data matrix, and thermal monitoring. (13)

Quick Response Codes: Quick reaction (QR) codes are likewise being tried. These printed squares are a high level adaptation of the 2D standardized barcode tags. Anybody with a camera-empowered telephone and web access can check the code and be taken more time to the pharma organization site to validate the medication.

Serialization: This involves assigning a unique identity to each stock unit during manufacture, which then remains with it through the supply chain until its consumption. This identity will normally include details of the product name, strength, lot number and expiry date - although in principle it may simply take the form of a unique pack coding which enables access to the same information held on a secure database

The Unique Identification Number should comprise of Country Code, Company Code, Manufacturing, Plant Code, Product Code, Batch Number, Package Code, Expiry Date and Number of packs

Whenever every one of the codes is consolidated a unique code will be created which will be a 23-character code for a specific pack of drug item. After assigning UIN to the drug product it will pass through a supply chain and verified immediately. (14)

5. Writing Selection Criteria

The pursuit terms are picked in light of the normal name, the substance, the planned use, and the pointers. The accompanying models were utilized to decide if an article was appropriate for consideration or avoidance Screening.

a. Once the inquiry terms are finished, they are utilized to look through the writing.

b. Each search term's outcomes will be separated depending on the situation, and further it be done to screen will.

c. Titles and abstracts are turned upward on the web to get overview on literature.. The article is assessed for its pertinence to item execution and security.

d. Literatures that are judged to be relevant are then downloaded for further consideration.

6. Consideration Criteria

a. The most careful and current information available.

b. The writing incorporates information for a comparable hardware tending to its conventional name/brand name; c. The writing picked is level headed and legitimized the essential information, including both positive and negative information.

d. Preferably, the writing ought to start from notable, insightful, peer-looked into diaries in the field.

e. Literature gives data about the item's risk, wellbeing, and viability.

f. Independent survey articles depicting comparable item execution/specialized or non-clinical outcomes.

g. The writing plainly characterizes and investigations the utilization of a practically identical gadget, either through contextual analyses, clinical exploration, or by framing the foundation of the gadget's method of activity, wellbeing, and unfriendly occasions.

7. Conclusion

Counterfeit medicines address a huge public health challenge. It represents a public health risk on the grounds that their content can be perilous or they can lack active ingredients. The current Indian regulations had Reward Scheme for Whistle blowers in the fight against the menace of spurious or counterfeit drugs .The Indian government has now made it compulsory for all drug manufacturers to put QR codes on Active Pharmaceutical ingredients being utilized in their medicines and these to be scheduled from January 1,2023 To drive the impression and worldwide view of India as a profoundly trustworthy provider of medications, the Indian drug industry should go to lengths to battle the scourge of counterfeit medicines and start to lead in guaranteeing the safety of its supply chain.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

Abbreviation

NSQ: Non Standard Quality

SFFC: Squirous/Falsely labeled/falsified/counterfeit

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