



Review Article

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## A Survey to the Extent of Spurious Drugs in the Market of India

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### ABSTRACT

*The emergence of the spurious drug has created a consequential worldwide health crisis and economic burden in many countries. Marketing, availability, and consumption of spurious drugs can lead adverse side effects to consumers (Patients) and even death also. The prevalence of spurious drugs appears to be rising and has not been countered by close cooperation between pharmaceutical industry, government and international organization concerned with health, trade, customs, and excise. According to report published in media and also information from Drug Control Offices, the extent of availability of counterfeit drug is about 0.3%. The problem has been growing exponentially and solutions are immediately required. The WHO (World Health Organization) has taken all the possible initiatives to combat counterfeiting and laid various guidelines also. The continuous increase of spurious drugs in the marketplace of India is a serious problem for the health of people. Therefore, drug registration in India should be strengthened to ensure all the drugs are domestically produced as well those imported are assessed for the safety, efficacy, and quality before they are available to the consumers. In this regards all the organization should take active initiation to combat such problem, especially pharmacist can perform a significant role to identify the actual spurious drugs and to suggest the common people not to purchase such type of drug from the market. The present study provides insights into the extent of counterfeit drugs with their consequences on public health and to make awareness among the community, medical practitioner and pharmacist in India.*

**Keywords:** Spurious drug; Indian market; Drugs & cosmetics act 1940; Health hazards; Central drugs standard control organization

### INTRODUCTION

A drug is any chemical substance that mainly used to treat, prevent or cure diseases, relieve pain and to slow down the disease process [1]. Spurious defines those which is basically fake in nature or not genuine but claimed or presented to be genuine [2]. A spurious drug possesses an addictive danger to the patient [3]. The emergence of the spurious or substandard drug is becoming a global issue, which results in serious health hazard and an economic crisis to consumers along with manufacturers [4]. Currently, it has been predicted that the market for spurious or counterfeit drugs is approximately about the US \$200 billion. Unfortunately, in developing countries, the problem of spurious drugs has been growing day by day [5]. Globally 10% of the drugs are spurious in nature but in few countries, more than 50% of supplied drugs are spurious which make the condition even more inferior and it is still increasing with time [6]. Some developing countries are not only victimized by fake drugs but some of them also aid as a birthplace of the spurious drugs [7] Basically, India trades of generic medicine in many countries and it becomes a prominent supplier of low-cost generic medicine of economically poor countries like Africa [8]. Contrariwise, in developing countries, spurious drugs are manufactured especially for different life threatening diseases like cancer, malaria, tuberculosis, AIDS etc. by which the concern industrialist make huge money [9]. In

spite of different actions taken by Government to provide generic medicine for certain category of patient in free of cost, countries like India where many people live below poverty line, the situation are becoming worse because they still prefer to purchase substandard or spurious drugs over generic or branded medicine because of their inexpensive price and easy availability in market [10,11].

According to The World Health Organization (WHO), Spurious or counterfeit drugs are those where the identity and source of the manufacturer are intentionally and duplicitously mislabelled. These false drugs represented with an incorrect ingredient or correct ingredient with wrong proportion or without principle ingredient with fake packaging [12].

The discussion includes the possible causes for the spurious drug, to find out the various processes by which the spurious drugs can be minimized in the market, to know the number of spurious drugs within the Eastern zone as well as all of the country and its impact on economic and public health.

### Spurious Drug

According to WHO, spurious drugs are those which are intentionally and illegally mislabelled and manufactured to misinform and misrepresent the consumers (patients) by hiding their identity. The name manufacturer or its content is grounded on the reputation of fast-moving branded or generic medicines. Spurious drugs may or may not comprise the principle components in the manner mentioned on the label [13].

In India, there is no official definition of spurious drugs available. According to Section 17-B of the Drugs & Cosmetics Act, 1940, a drug can be considered to be spurious if it is manufactured with a name which belongs to another drug, if it has been replaced with another drug wholly or partly, or if it is a rationales to be from a fake manufacturer of whom it does not truly belong to, or if it is a mock of another drug, or if the label or container bears the name of a company purporting to be the manufacturer of the drug, which is actually fictitious or does not exist [14,15].

### History of Spurious Drugs

Globally, the spurious drugs have become a great problem, which seeks attention among the researchers, managers, and policymakers. In the 1980s, WHO first identified this growing problem of spurious drugs [6]. 'Black Law Dictionary' says, a drug which is manufactured by someone other than original manufacturer by replicating or reproducing the genuine product without taking prior permission with a view to defraud [8]. A spurious drug may compose of an inappropriate amount of principle component or may contain an unlevelled ingredient or may be marketed with duplicate leveling or wrapping [16,17]. The emergence of spurious drugs is most frequent in countries with a poor economic situation where various types of infectious diseases are very prominent. But developed nations where the drug used for the treatment of chronic disease like anticancer, anti-allergic, lipid-lowering drugs are also being counterfeit [18].

The continuous spreading of spurious drugs in particularly developing nations are becoming a serious clinical and health issue. The problem includes under or over-concentration of active ingredients, contamination, poor quality of ingredients, poor stability [12]. To recover the therapeutic efficacy and bioavailability, drugs can be formulated in different types of modified dosage forms like nanocapsules, nanoemulsion [19]. Valid pharmaceutical methods also should be applied for the enhancement of drug stability [20-22]. Although natural products having ethnomedicinal properties have been used to cure or treat various diseases [23-29], one can expedite design and development of rational drugs or plant-derived biologically active molecules after being coupled between synthetic chemistry and QSAR to combat different deadly diseases like cancer, diabetes etc. [30-32]. In spite of these tremendous efforts and development also, empirical observation showed that there may be more spurious or fake drugs than generic drugs in worldwide circulation. Drugs which are mainly forbidden by controllers or manufacturer may be vended in marketplaces are considered spurious fake [33].

The extent of the problem regarding spurious drugs or fake medicines is varying widely between countries, ranging from less than 1% in more developed countries to 50% in some poor countries. According to WHO recent estimate, about 10% of drugs circulating worldwide and 25% in less developed countries are fake [34]. Between in the year of 1984 and 1999, there was around 771 information of fake drugs with approximately 78% of coming from the developing countries [35]. In 1998, 89 persons and 30 infants died in Haiti India respectively due to consumption of paracetamol cough syrup which was manufactured by diethylene glycol (a toxic chemical used in antifreeze) [36]. According to WHO, only in the year 2003, the annual incomes from spurious or counterfeit or substandard drugs exceeded the US \$32 billion [6]. The figure has been put at 12% and 40% in Russia and Ukraine respectively [37].

In India, according to Drug and Cosmetics Act 1940, under section 17, 17A and 17B, indigent quality drugs are mainly comprised spurious, substandard, fake, misbranded etc. [4]. In India, approximately 12-25% of marketed

drugs are thought to be counterfeit [8]. Alongside developing countries, the rise of spurious drugs is also increasing in the developed countries as well [38].

### Sources of Spurious Drugs

The spurious drugs are not only manufactured by unlicensed antisocial persons but licensed manufacturers also involved in this fraud business [39]. The business of spurious drugs is a duplicitous movement and their obtainability in the market is the life-threatening issue [4]. Recently due to the large volume of sales of pharmaceuticals, an illegal production of spurious drugs has also started on an alarming large scale [40]. The global trade in the spurious or counterfeit drug is estimated to be around the US \$20 billion and is recklessly growing in grey economics. The network of the illegal trade is protected by some of the politicians have vested interest and corrupt officer [41]. Sophisticated equipment is used to produce spurious or counterfeit drug and even the experts cannot distinguish these from the genuine packing [42]. The Spurious drugs are often manufactured and marketed with the intent to disingenuously represent their source, genuineness or efficiency [43]. The nature of these fake drugs ranges from those containing no active ingredient (e.g., when a bag of powdered lactose claimed to be cocaine), with inadequate principle component or with some diluents (e.g., Baking soda or lactose) or sometimes with a wrong active ingredient (e.g., when methamphetamine is sold as cocaine) or with a fake packaging [44].

Spurious or counterfeit drugs are mainly present in the industrialized and developing countries. The market share of fake drugs is below 1% of the total medicines market value for rationalized parts of the country like Canada, United States of America, Japan, most regions of the European Union, New Zealand, and Australia [45]. Developing countries like Latin America, Africa and many regions of Asia may prominently be the merchant and manufacturer of spurious, counterfeit or fake medicines [46]. Other countries like India, Mexico, China, Brazil, Pakistan, Russia, Southeast Asian and Middle Eastern countries are considered as the principal operators in spreading and manufacturing of spurious or counterfeit drug [47].

In developing countries, the most frequently fake medicines are those which are used to treat different life-threatening diseases such as malaria, cancer, tuberculosis, HIV/AIDS etc. [9]. Anti-malarial, anticancer or antibiotics are not only the drugs that are get victimized by drug counterfeiting, other other antiprotozoal drugs like miltefosine (for treatment of leishmaniasis) and other life-saving vaccines against tetanus, influenza and rabies have been also targeted [48]. European customs are seizing every day who are trying to bring these counterfeit drugs from China, the United Arabian Emirates, and India while entering in their countries [49].

The commerce of drug fabricating is thriving due to innumerable reasons like poor pharmaceutical regulation, high drug expenses, value added tax, prescription of drugs without registration, an absence of public consciousness, Weak implementation of legislation and flexibility in the existing authorized agenda [50].

### Indian Scenario of Spurious Drugs

With the manufacturing of huge generic medicines, India has also become a large marketplace for spurious and counterfeit drugs. The local market of Uttar Pradesh, Bihar, Gujarat, and West Bengal are the most prone areas of spurious drugs availability. According to European Commission, India is a hub of approximately 75% of the worldwide cases of fake medicines [51]. A report from WHO also confirms that nearly 35% of spurious drugs are marketed from India. But, in this connection, the Indian government argue this surveillances and according to the studies piloted by Central Drugs Standard Control Organization (CDSCO) along with the health, ministry guesstimates that only 5% of drugs in India are counterfeit, while of 0.3% is spurious [52].

Government officials of India declare that approximately 9% of the marketed drug products were of substandard quality [53]. According to Indian press media, about 30-40% of the total marketed drugs are spurious in nature, but this announcement has no valid scientific endorsement [4]. Without any legal approval from Drugs Controller General of India (DCGI), 294 fixed drug combinations (FDCs) products were illegally accessible on the market in the year of 2007 [4]. In the year 2008, State Drugs Control Organizations have canceled 8418 chemist licenses out of 183020 chemist shops, because of their trade with spurious drugs [4]. According to an aviator study conducted in two major cities of India (Delhi and Chennai) in 2008, it was found that approximately 12% samples from Delhi and 5% samples from Chennai were of inferior superiority [54]. In the academic year of 2007-08 and 2008-09, leading manufacturer from Maharashtra and Kerala were involved in the production of spurious and substandard drugs [4]. Due to the adverse effect after consumption of spurious drugs, 4 persons died in Maharashtra in the year of 2007 [4]. In 2012, 300 infants were died in Kashmir due to ceftriaxone substandard quality product, a drug used to treat pneumonia [55].

A recent survey on the number of spurious drugs in India was carried out by SEARPharm Forum in Association with SEARO (South-East Asia Regional Office), WHO and according to their report, the spread of imitation suspects was to the tune of 3.1% [56]. To minimize the production and availability of spurious drugs and to maintain

the quality of marketed drugs in the country, state drug controllers need to keep vigil and draw drug samples for the analysis of their genuineness. The state-wise data reveals that more suspects were found in Bihar followed by Gujarat, Uttar Pradesh, West Bengal, Rajasthan, and Maharashtra [57] (Table 1).

Table 1: Number of samples tested and enforcement actions taken by state drugs controller during 2009-10 \*\* [57]

Sl. No	State or Union Territory	No. of Drug Sample Tested	No. of Test Samples Declared not of Standard Quality	No. of Drug Sample Declared Spurious	No. of Prosecution Launched	No. of Persons Arrested	Approx. Value of Drug Seized (in lakh)
1	Andaman & Nicobar Island	Nil	Nil	Nil	Nil	Nil	Nil
2	Andhra Pradesh	4647	97	1	1	Nil	573.47
3	Arunachal Pradesh	Nil	Nil	Nil	Nil	Nil	Nil
4	Assam	549	22	Nil	Nil	Nil	Nil
5	Bihar	2955	48	27	41	26	Nil
6	Chandigarh	113	3	Nil	Nil	Nil	Nil
7	Chhattisgarh	26	11	Nil	Nil	Nil	Nil
8	Dadra & Nagar Haveli	10	Nil	1	1	Nil	55
9	Daman & Diu	51	Nil	Nil	Nil	Nil	Nil
10	Delhi	539	22	6	2	5	2.45
11	Goa	656	19	Nil	Nil	Nil	Nil
12	Gujarat	373	56	2	Nil	Nil	Nil
13	Haryana	1517	36	8	10	1	0.3
14	Himachal Pradesh	953	16	Nil	Nil	Nil	Nil
15	Jammu & Kashmir	1245	36	1	5	Nil	Nil
16	Jharkhand	186	36	2	1	Nil	0.19
17	Karnataka	3100	156	Nil	Nil	Nil	Nil
18	Kerala	4506	169	Nil	27	Nil	1.98
19	Lakshadweep	Nil	Nil	Nil	Nil	Nil	Nil
20	Madhya Pradesh	477	22	Nil	Nil	Nil	Nil
21	Maharashtra	5877	378	9	9	9	132.6
22	Manipur	Nil	Nil	Nil	Nil	Nil	Nil
23	Meghalaya	1	1	Nil	Nil	Nil	Nil
23	Mizoram	75	2	Nil	Nil	Nil	Nil
25	Nagaland	4	Nil	Nil	Nil	Nil	Nil
26	Orissa	1657	25	1	Nil	Nil	Nil
27	Punjab	1968	112	1	Nil	Nil	Nil
28	Pondicherry	Nil	Nil	Nil	Nil	Nil	Nil
29	Rajasthan	1194	87	17	Nil	7	2.57
30	Sikkim	4	Nil	Nil	Nil	Nil	Nil
31	Tamil Nadu	3770	419	3	2	8	1.5
32	Tripura	352	20	Nil	Nil	Nil	Nil
33	Uttar Pradesh	1403	88	27	57	109	162.46
34	Uttaranchal	Nil	Nil	Nil	Nil	Nil	Nil
35	West Bengal	1040	61	11	9	8	75
	<b>Total</b>	<b>39248</b>	<b>1942</b>	<b>117</b>	<b>165</b>	<b>173</b>	<b>1007.52</b>

\*\*The above-mentioned data was provided by CDSCO/State Drug Control Authority

### Effects of Spurious Drugs on Human Being

Progressively, civic liability in healthcare scheme may depreciate as the intake of spurious or fake drugs by patients upsurge because of obtainability and absence of recognition of such kind of medicines in the marketplace [4,35]. Regular consumption of spurious or fake drugs can be responsible for treatment failure or even death [47]. Desperately, every year 0.20 to 0.30 million people die in China just due to spurious or fake medicines [58]. According to International Policy Network (IPN), globally 0.70 million deaths were documented for fake tuberculosis and malaria drugs [59]. So the negative effects of spurious or fake drugs on the society is more than that of either narcotic agent or combined effects of tuberculosis, malaria, HIV/AIDS [60]. Few of these unfortunate effects are mentioned below.

- **Treatment failure:**

Consumption of spurious or fake drug can lead to treatment failure or even death. Detection of the genuineness of a drug is important in medicine because of the related health jeopardies. Fake drugs with inadequate or no active ingredient can lead to therapeutic failure [61].

- **Toxicity:**

Consumption of spurious drugs can make patients in a high risk of toxicity that would become calamitous and absolutely clinical disastrous and mortality rates will also be increased. Some spurious drugs comprise constituents that, if consumed or injected can lead serious health problems [61].

- **End organ damage:**

Ingestion of spurious drugs can consequence in impairment to the liver, kidneys, heart and the central nervous system. The liver is in charge of the metabolism of drugs while the kidneys eradicate them from the body. When these poisons are entered into the body they can injure the vital organs [61].

- **Deaths:**

Many people die each and every year after consuming of spurious or fake drugs. These spurious or counterfeit drugs exert a prolonged adverse effect on the body which ultimately results in death. More than 500 children around the world died from counterfeit cough syrup that was tainted with ethylene glycol [61,62].

- **Economic loss:**

Due to drug counterfeiting, economic loss is enormous. Many pharmaceutical companies undergo huge economic loss because their drugs are being fake and marketed at inexpensive rates. Selling of these counterfeit drugs will damage the market for those companies who have invested in quality, research, and development of genuine drugs [61, 62].

- **Loss of confidence:**

There is a loss of confidence in the health system and drug control and enforcement system because of therapeutic and adverse effects of spurious drugs. Industries who have invested a huge amount of money for the development of novel and safe drugs are finally suffering and the name of the generic medicine is also damaged [61].

- **False vital signs:**

Value values of vital signs can result due to the use of counterfeit drugs [61].

- **Antibiotic resistance:**

The emergence of antibiotic resistance is one of the foremost problems in human health and global economy [63]. The relationship between spurious or counterfeit drug and antibiotic resistance is twofold. Although drug counterfeiting is one of the important causes of antibiotic resistance in developing countries. Spurious antibiotics with low doses of active ingredients are potentially more dangerous than that containing no active ingredient at all in terms of the negative effect of drug resistance that may affect the entire community [64].

- **Unintended effects:**

Few counterfeits replace one drug for another. For instance, insulin has been replaced for a more costly injectable drug and there was information that counterfeiters emptied bottles of Zyprexa (a drug practiced for the treatment of schizophrenia and acute bipolar mania) and substituted them with white tablets embossed with the word "Aspirin" [65]. To attain the objective of safe and sound health for all, the threat of spurious or counterfeit drugs must require being controlled. Spurious or counterfeit drugs possess a harmful threat to public health [61]. More developed techniques should be introduced to investigate spurious drug manufacturing and their trafficking [64].

### **Minimize the Ability of Spurious Drugs**

In order to minimize the availability of spurious drugs in India, the drug control mechanism should be stringent with modern infrastructure and technology. The penalty imposed shall not only be in currency but there should be the provision of rigorous imprisonment which may be to the extent of a death sentence.

### **Mashelkar Committee**

To curb the availability of fake medicines in the Indian market, the Indian Government had established an expert committee under the chairmanship of Dr. R.A. Mashelkar, the DG (CSIR) was recommended different measures in February 2003 for establishing the drug monitoring system in the country as well as undertaking the problem of spurious drugs [56,57].

In November 2003, the Commission has submitted its report mentioning numerous variations in the penal provisions of the Drugs & Cosmetics Act. The key endorsements of the Committee are as follows:

- Enrichment of penalty, aimed at production and marketing of spurious drugs that cause serious hurt or death, from life sentence to death.
- Production and marketing of spurious drugs, which are improbable to cause penalties as specified in (i) above, be made perceptible and non-bailable.
- One major drawback is that, during their purchase time they are unable to produce the supportive documents.

- There should be a facility for tackling minor crimes so that these should be persuaded of expeditiously while the inquiry is able to concentrate on serious cases in the appropriate courts.
- The file is approved by the police for file hearing.
- Law of special courts for trial of a felony according to the Drugs & Cosmetics Act so that judicial records can be furthered.
- Augmentation of custodial terms and penalties for different offenses, including the perception of reimbursements.

According to the commendations specified by the Mashelkar Committee, a bill was approved in both the houses of Parliament and the bill has been reported as The Drugs and Cosmetics (Amendment) Act No.26 of 2008 dated 5th December 08 [56,57].

#### **Guidelines for Taking Action on Drugs Declared Spurious according to the Drugs and Cosmetics (Amendment) Act, 2008 [60-67]**

The following recommendations should be implemented as model guidelines by the State Drug Control Organizations for uniform execution of the establishment of the Drugs and Cosmetics Act and rules made thereunder.

- In the case any drug deemed to be spurious under Section 17-B or which when used by any person for or in the diagnosis, treatment or prevention of any disease or disorder is likely to cause death or harm on his body as would amount to "Grievous Hurt" within the meaning of Section 320 of the Indian Penal Code (45 of 1860), the concerned drug is suspected to be spurious and the person will get punishment of imprisonment which is not less than ten years and can be extended to a term of life and with fine which shall not be less than ten lakh rupees.
- According to section 17-B if any drug is suspected to be spurious, but not being a drug referred to in clause shall be a punishable crime with imprisonment for a period which shall not be less than seven years but which may prolong to life and with a penalty which shall not be less than one lakh rupees.
- According to segment 36 AC of the act, detection of production or marketing of counterfeit drugs by the unlicensed industrialists or sellers should be inspected on the top importance and these crimes are considered cognizable and non-bailable.
- In case a registered manufacturer is found guilty of production and selling of counterfeit drugs, that criminal will get the same punishment as like an unlicensed manufacturer.
- In case any valid licensed manufacturer has been found that manufactured drugs are extremely sub-standard, and any criminal intention or negligence of anyone has been revealed after the investigation from the company's end, the person should be exposed to prosecution if there is a failure of justice from the manufacturer's end.
- In case any valid licensed manufacturer has been found that manufactured drugs are extremely sub-standard, and any criminal intention or negligence of anyone has not been revealed after taking various governmental procedures like suspension or termination of registration or compounding of corruptions, then a weapon of prosecution should be used judiciously.
- In case of not of standard quality information due to slight flaws rising out of differences from the recommended standards or infringements of other provisions of Chapter IV of the Act, governmental procedures like suspension or termination of offenses may be engaged.
- To expedite the arrest of any anti-social elements associated with the production of counterfeit or contaminated drugs, Section 36 AC comes into existence where this type of offense has become cognizable and non-bailable.
- Screening committees including of at least three senior officers, not below the level of Assistant Drugs Controllers or equivalent can be constituted by State Drug Control Departments to inspect the inquiry reports of the cases where examinations are anticipated to be propelled. The committee may submit a judgment on the analysis reports in written concerning their feasibility of taking lawful action.
- On the basis of written permissions of the controlling consultant all the prosecutions shall be propelled by the Inspectors, and the expert, in turn, shall consider all the commendations of the screening committee while taking a final decision on the matter.
- All the Patent and Proprietary preparations should be verified by the Government analysts as mentioned in the regulation 46 of the Drugs and Cosmetics acts.
- In the year of 1993, the comprehensive guidelines are sanctioned by the DCC (Drugs Consultative Committee) for taking action in particular cases on information of substandard and spurious drugs.

- For taking an appropriate decision in cases of defilement of the necessities of the Drugs and Cosmetics acts, harmonization between controlling authorities is mandatory.
- A quick vigilant scheme shall be generated by State Drug Control Organizations so that any important information about counterfeit/adulterated medicine handover to the suitable authorities rapidly for taking additional action in the matter.
- For battling the hazard of counterfeit/contaminated drugs a strong arrangement is important to gadget the requirements of the Drugs and Cosmetics Act.

### SUMMARY AND CONCLUSION

The issue of spurious drugs is a burning topic, which is effective not only in India but also throughout the world. The effort of not only Regulatory Authority but also efforts by NGOs and Social Organisation are required to work hand in hand to combat this problem. All the organizations should take the active initiation to circulate the different matters related to spurious drugs among the common people of the society. In this case, only the law and order are unable to remove the problem of spurious drugs within the country. Unless and until peoples are not aware of the spurious drugs.

In this regard pharmacist can play very vital role to identify the actual spurious drugs and should be alert to differences in quality of packaging, labelling or leaflets or physical appearance of medicinal products, also convince the Government to use maximum efforts to enforce all appropriate measures to prevent or minimize the manufacturing and distribution of fake medicines and to suggest the common peoples not to purchase such type of drug from the market. If they observed or suspect such category of drugs, immediately they should inform the corresponding Drug Control Department. So then the Department can take the proper measure of this matter.

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