

Current Scenario of Spurious and Substandard Medicines in India: A Systematic Review

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Khan and Khar: Current Scenario of Spurious and Substandard Medicines in India

Globally, every country is the victim of substandard or spurious drugs, which result in life threatening issues, financial loss of consumer and manufacturer and loss in trust on health system. The aim of this enumerative review was to probe the extent on poor quality drugs with their consequences on public health and the preventive measures taken by the Indian pharmaceutical regulatory system. Government and non-government studies, literature and news were gathered from journals and authentic websites. All data from 2000 to 2013 were compiled and interpreted to reveal the real story of poor quality drugs in India. For minimizing spurious/falsely-labelled/falsified/counterfeit drugs or not of standard quality drugs, there is urgent requirement of more stringent regulation and legal action against the problem. However, India has taken some preventive steps in the country to fight against the poor quality drugs for protecting and promoting the public health.

Key words: SFFC, poor quality drugs, Central Drugs Standard Control Organization, whistle blower scheme

With a population of more than 1.24 billion^[1], right to health is a fundamental right in India and has been recognized in the national constitution and statutory laws as well as in international laws^[2]. Globally, about 2 billion people, one third of the global population lack access to essential medicines^[3]. As medicine are life saving entities and thus are more essential for the treatment, while they account for 20-60% of care cost and 50-90% of this cost is being paid by the patient, particularly in low and middle income countries^[4]. India is a developing country where more than 40% of the population survives on less than US \$1 a day^[5] and if a patient needs medicines he has to pay more than half of this. There are some schemes by Indian Government for distribution of free generic medicines for certain categories of patients^[6]. However, people accept, prefer and buy counterfeit or substandard products over genuine or branded products due their cheap price, easy accessibility and availability in the market^[7]. Consumer does not know about the manufacturer or the quality of the product and many time they are unaware of expired, degraded or substandard products which ultimately results in failure of the treatment and with antibiotics this lead

to antimicrobial resistance^[8,9]. Substandard product arises correspondingly due to lack of expertise, unfair manufacturing practices or insubstantial infrastructure; whereas counterfeit is the product of black marketer^[9]. The problem of poor quality is already very serious and steadily growing and is likely to cause much more damage in the near future^[10]. As such poor quality drug does not bear any universal definition as it may vary from country to country^[11]. In general poor quality drug are the spurious/falsely-labeled/falsified/counterfeit (SFFC) drugs that can cause treatment failure or even death^[12]. Accordingly, International medical products anticounterfeiting taskforce (IMPACT) of World Health Organization (WHO) defines SFFC medicines as “medicines which are deliberately and fraudulently mislabelled with respect to identity and/or source, and also which may include products with correct ingredients or with the wrong ingredients, without active ingredients, with insufficient or too much active ingredient, or with fake packaging”.

In India, as per Drug and Cosmetic (D and C) act, 1940, under section 17, 17A and 17B poor quality drug comprises of misbranded, spurious and adulterated drugs, respectively^[13]. With the 2008 amendment of D and C act, Indian drug

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regulatory authority that is Central Drugs Standard Control Organization (CDSCO) has categorised not of standard quality (NSQ) products in three categories A, B and C that is helpful in categorising the products during quality evaluation^[14]. Category A incorporates spurious and adulterated drug products; which conceal the real identity of the product or formulation and be similar to some well-known brand. These products may or may not contain active ingredients and generally manufactured by unlicensed antisocial people or sometimes by licensed manufacturers. Products that consist of adulterant/substituted product or incorporate some filth material are known as adulterated drugs. Category B include grossly substandard drugs in which product fails the disintegration or dissolution test and where active ingredient assay get below 70% and 5% of permitted limit for thermolabile and thermostable product, respectively for tablets or capsules. In case of parenteral preparation, failing sterility, pyrogen/endotoxin test or inappropriate toxicity, and fungus presence in any liquid preparation hold such products in this substandard category. Category C involved products with minor defects like emulsion cracking, change in formulation colour, small variation in net content, sedimentation in clear liquid preparation, failing of weight variation test, spot or discolouration on product, uneven coating, presence of foreign matter and labelling errors.

In this evaluative review, an attempt has been made to know the correct extent of the SFFC or NSQ drugs in India and to make awareness among the public, medical practitioners and pharmacists. Data was acquired from governmental and non-governmental studies, literature, news, journals and authentic web sites. All the data was compared and interpreted to reveal the real story of poor quality drugs in India.

SFFC drugs: A pandemic threat:

Poor quality drug or substandard product encounters a major stringent issue for the global health system^[5] and it cannot be ignored. In most streamlined regions of the globe like Japan, Canada, Australia, New Zealand, the United States of America and most of the European Union, hardly 1% of the market value products are counterfeit, developing countries like Africa, Latin America and many parts of Asia may markedly be the seller and producer of SFFC medicines^[12]. Russia, China, India, Brazil, Mexico, Pakistan, Southeast Asian and Middle

Eastern countries are considered as the chief operators in distribution and manufacturing of counterfeit drugs^[15]. A decade ago, it was examined by WHO that 10% of the global medicines were counterfeit. However, contrary to its previous communicated data WHO-IMPACT pointed out that data was not much authentic^[16]. It means no absolute extent is reported. Now, it is questionable that what are the causes and influences of this problem. In turn, one reason is poverty and other is ignorance and these could contribute to the demand for counterfeit and substandard drugs^[5]. Moreover, ignorance of poor quality, unregistered medicines, lenient penalties, inadequate enforcement of laws are some of the significant causes which provoke the situation^[9].

Day by day, public trust in health system may deteriorate as the consumption of substandard drugs by patients increase due to availability and lack of detection of SFFC or NSQ medicine in the market. Consumption of SFFC medicines can be responsible for failure of treatment or even death^[12,17]. Unbelievably, 0.20 to 0.30 million people die every year in China just because of counterfeit and substandard drug product^[17]. No such data is available in India, yet many patients are dying every year. According to a report revealed by International Policy Network, globally 0.70 million deaths were reported for malaria and tuberculosis because of counterfeit drugs^[18]. This data reveals the loop holes in the regulatory system and the cautions for avoiding the poor quality medicines.

SFFC or NSQ drugs in India:

India is the largest manufacturer of generic drugs and probably 12-25% of the medicines supplied globally are contaminated, substandard and counterfeit^[18]. Being the world's largest manufacturers of active pharmaceutical ingredients and finished products, it is likely that India along with China could be the major contributors to spurious medications as per Patrick Lukulay, vice president of US Pharmacopoeial Convention's global health programs^[19]. In a report, it has been declared by the European Commission that 75% of the global cases of SFFC medicines originate from India^[20]. Indian Government officials initiated an investigation to scrutinize the drugs product which are supplying by India to Nigeria when India was accused along with other 29 Asian countries as the main originator of counterfeit drugs^[21]. On one side, India extensively interacts with the African countries in

providing quality medicine at affordable prices, while on other side predictive blames were imposed on India and China for exporting the fake or substandard quality of antimalarial, antibiotics and contraceptives drug product to Uganda and Tanzania. In turn, India and China is denying for such blames^[22]. At present, Indian drug regulatory authority has taken various steps against the causes and they have put all their efforts to improve the drug regulation in the country.

India is considered as the main originator and distributor of SFFC drugs. However, no authentic evidences exist against the country according the data provided by the government and non government agencies of India. Many researchers have investigated only individual drugs or narrow range of drug preparations and formulations. Currently, no large randomized studies of drugs quality have been done in India^[23].

In the year 2000, it has been stated that around 35.0, 23.1 and 13.3% global sales of counterfeit medicines come from India, Nigeria and Pakistan, respectively and counterfeiting includes all therapeutic classes of drug and mainly antibiotics^[24]. A decade ago, Indian government officials estimated that 9% of the drug products were of substandard quality^[25]. Although according to Indian press media, 30-40% of the total marketed drugs are considered as spurious, but this data is without any scientific confirmation^[26]. Under laboratory analysis in a survey accomplished in 2007 by South East Asia Region Pharmaceutical (SEARPharm) Forum, a group of Pharmaceutical Associations of International Pharmaceutical Federation (FIP) and WHO, 10 743 samples were collected from 234 retail outlets. About 3.1% were estimated as spurious and 0.3% were out of pharmacopoeial standard^[26]. In 2007, 294 fixed drug combinations (FDCs) products were unlawfully available in the market since these were not approved by the Drugs Controller General of India (DCGI)^[27]. In 2008, out of 1 83 020 chemist shops, 8418 chemist licenses were suspended or cancelled by the State Drugs Control Organizations on behalf of their trade with spurious drugs^[28]. According to CDSCO, estimation of the data during 2003-2008 indicates 6.3-7.5% of the samples were of substandard quality and 0.16-0.35% were encountered as spurious^[26]. In 2009, CDSCO reported that in 1995-96, 10.64 and 0.30% tested samples out of 32 770 were substandard and spurious, respectively, while in 2007-2008,

6.42 and 0.16% tested sample out of 42 354 were substandard and spurious, respectively^[29]. It was good achievement by the drug authority.

Nevertheless, in 2009, 24 136 samples of 62 brands of drugs product were collected in a nationwide survey to find those products which are covertly manufactured and thus to explore the extent of spurious drug in India. Samples were drawn from over 100 pharmacy outlets from various regions of India, which were belong to nine therapeutic categories of 30 manufacturers. Survey affirmed that only 11 products (0.046%) were spurious. Supplementary information revealed by the State Drugs Control Departments declared 1146 (4.75%) products were of substandard quality^[30]. Hereby, it can be observed from the government data that spurious drugs are at same level while there is a great decline in the number of substandard drugs from 10.64% in 1995-96 to 5.75% in 2008-09 as shown in fig. 1^[29,31]. These kinds of inspections and surveys by the government officials are some driving steps for the public safety. However, stringent actions are yet to be taken for the betterment of public health. Overlaying the effects of inferior manufacturing standards, deterioration with inactive or toxic fillers, relabeling of time expired drugs and degradation during storage are closely associated with drug quality^[32], which must be checked regularly by fast and efficient techniques.

Manufacturing of spurious and substandard quality drug products is a fraudulent activity and their availability in the market is the life threatening issue for the public health. In 2008, a pilot study performed in two major cities of India, Delhi and Chennai to explore the extent of substandard and counterfeit drugs available in market, under which it was estimated

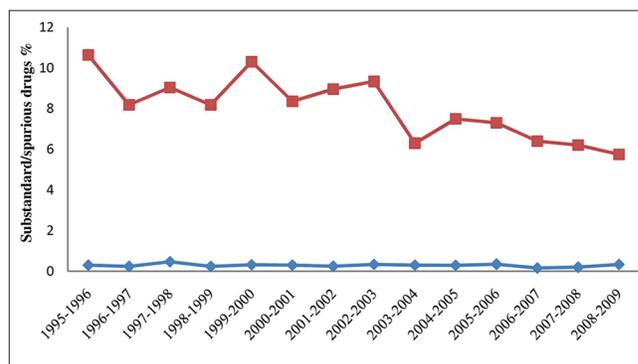


Fig. 1: Decline in substandard and spurious drugs cases from 1995 to 2009. Substandard drugs (—■—) and spurious drugs (—◆—).

that 12 and 5% samples from Delhi and Chennai, respectively, were of substandard quality^[33]. In 2007-08 maximum instances were from Maharashtra and in 2008-09 Kerala was the leading manufacturer of the spurious and substandard drugs^[31]. In 2007 four deaths were reported in Maharashtra related to spurious drugs^[34]. While more serious results came in news when it was reported that 300 infant died in 2012 in Kashmir because of ceftriaxone substandard quality product which was used to treat pneumonia^[35].

No absolute and entire data is reported for substandard and spurious drugs after 2010 by CDSCO, non government organizations or any individual research. For last 3 years, Government has noticed several cases of spurious and substandard drugs importation. In 2009, at Chennai sea port, CDSCO officials caught 3 cases of unregistered bulk drugs originating from China^[36]. Cases related to the substandard quality drug product importation in India showed 35, 35, 34 cases for 3 consecutive years 2009-2010, 2010-2011 and 2011-2012, respectively^[37]. On a surprise inspection by the CDSCO officials, 85 sales outlets out of 130 were trafficking with the banned drugs in Delhi and Bhiwandi city^[38]. News from the country reveals numerous incidences as shown in Table 1^[39]. It is highly recommended to investigate individually every drug product that is available in the domestic market.

Considering the expansion of the pharmaceutical industry and the degree of potentially mortal diseases, any amount of substandard or spurious medicines is unacceptable because it rises the morbidity and mortality^[40,41]. Only few published data admit the extent of the problem and its influence on the public health^[40-42]. Thus, there is requirement of immediate attention and research by the regulatory authority towards this public safety issue.

Generic medicine promoting strategies:

Indian pharmaceutical industry exists at third rank in volume and thirteenth in terms of value of worth US \$20 billion. Focusing on the accessibility and affordability of the drug products in the country, India excels as the 'pharmacy of the developing world'^[43]. Indian Government instructed to all Central Government hospitals and Central Government Health Scheme (CGHS) dispensaries to prescribe generic medicines in large extent as possible. Physicians are also instructed by State Government to prescribe generic medicines^[44].

Department of Pharmaceutical, ministry of chemical and fertilizers, in collaboration with the State Government commenced nationwide "*Jan Aushadhi Campaign*" (Medicines for Public Campaign) by way of launching '*Jan Aushdhi*' generic drug stores in the Government hospitals and supply of generic medicine through Central Pharma Public Sector Undertaking. Till mid of 2012, Government has already opened 122 *Jan Aushdhi* stores, where about 231 generic medicines are being marketed^[6].

Preventive measures for SFFC or NSQ drugs:

To scrutinize the complications of the SFFC or NSQ drug in India, Government has acquired numerous steps which are^[30,45-50], 1. Amendment of Drug and Cosmetic act, 1940 in 2008 for making penal provisions and reset certain offences as perceptible and non bailable. When adulterated or spurious drug cause death then imprisonment imposed for not less than ten years or for lifetime with penalty of not less than one million Indian Rupees (INR) or three times the value of the drugs confiscated whichever is more; in order to make restraint for illegal practices. 2. Since 2008, on various levels 216 additional posts generated to strengthen the regulatory mechanism. In 2008, there were 111 sanctioned posts and 64 officers in position

TABLE 1: REPORTS ON SUBSTANDARD AND SPURIOUS DRUGS DEFRAUDS IN INDIA FROM 2002-2004

Year	Region	Report
2002	New Delhi	Two arrested for running fake medicines racket: 1662 kg of the spurious/fake drugs, Avil, Betnesol, Diclowin, Erythrocin, Voveran and Zintec, forgery labelled as the product of Cipla, Ranbaxy, Cadila, Glaxo and Smithkline Beechem, were seized in New Delhi
2003	Jaipur	Spurious drugs recovered at Sriganganagar, Rajasthan: Drug Control Department, Rajasthan, seized several products
2003	New Delhi	Delhi police seized 100 kg of spurious version of nimesulide, ranitidine, and betadine drugs made in Agra, Meerut and Ghaziabad
2003	Mumbai	Maharashtra FDA raided spurious manufacturer in Palghar, and seized spurious and substandard drug amoxicillin, ampicilline and Solutone (used in multivitamins) worth around US \$60,000 (INR 30 lakh) worth of spurious drugs
2004	Faridabad	Spurious omstal Tablets recovered at Faridabad: Health Department of Haryana from a licensed drug trader seized 10,000 tablets of spurious Domstal product

FDA: Food and drug administration

while in 2012 there were 310 posts and 121 officers in position, which included 65 drug inspectors. 3. For trial of offences related to adulterated and spurious drugs product, Drug and Cosmetic (Amendment) Act, 2008 accredited establishment of special designated courts, and nationally 14 states/Union territories already introduced such courts. 4. For effective regulatory surveillance throughout the country, Hyderabad and Ahmadabad have upgraded from sub zone to full zone while Bangalore, Chandigarh and Jammu have established as new sub zones under the direction of CDSCO. 5. CDSCO publishes monthly a list of drugs, medical devices and cosmetics that are evaluated and declared as not of standard quality/spurious/adulterated/misbranded. 6. Enhancement of Central Drug Laboratories with new sophisticated testing equipment set up and creation of a new testing laboratory at Hyderabad. 7. To ensure proper traceability of those manufacturing units, which are situated abroad, from where drugs product are imported in India, new scheme for regular overseas inspection has been introduced. For instance, two such inspections have formerly done in China. 8. To encourage attentive public participation in exploring the detection of spurious drug product, a 'Whistle Blower' scheme is initiated. Under this scheme, if accurate information on the movement of spurious drugs product provided to the regulatory authorities, informers is suitably rewarded and 9. At state level, Tamil Nadu and Kerala Government undertake drug quality evaluation services by Tamil Nadu Medical Service Corporation Limited and Kerala Medical Service Corporation Limited, respectively; and regularly report the NSQ products, which they fetched from government hospitals.

For minimizing SFFC or NSQ drugs at national or states level, still there is an urgent requirement of more rigid and stringent regulations, policies and legal actions against the problem.

CONCLUSIONS

Poor quality drugs affect the health of the public. Spurious or counterfeit drugs are involved in both generic and branded products of every category throughout the world, which is growing and expanding its roots and thus emerging as menace. Standard quality obligations are related to a number of factors, including drug pricing, competition between sponsors, employment and market transparency. Responding to the

spreading public health crisis of spurious or substandard drugs has led to the creation of transnational regulatory dimension. India is improving and achieving its mission in drug regulation process on account of decline in number of SFFC or NSQ drugs cases and by taking several important initiatives and preventive steps in the country and stringent penalties as well to fight against the poor quality drugs for protecting and promoting the public health. It is now the time to explore this matter more vigorously in the times to come in order to safeguard the interests of the patient at large.

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Accepted 26 December 2014

Revised 14 October 2014

Received 28 January 2014

Indian J Pharm Sci 2015;77(1):2-7