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A Systematic Review of the Current Situation of Fraudulent and Substandard Medicines in India

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ABSTRACT:

Every nation on the planet suffers from subpar or fake medications, which can be fatal, cause manufacturers to lose money, and cause consumers to lose faith in the medical system. This enumerative review's objective was to examine the amount of subpar medications, their effects on the general public's health, and the preventative steps the Indian pharmaceutical regulatory system had made. Studies, books, and news from both the public and private sectors were gathered from reputable publications and websites. All information from 2000 to 2013 was gathered, analysed, and synthesised to tell the true tale of India's subpar medicine supply. More stricter regulation and judicial action against the issue are urgently needed to reduce spurious/falsely labelled/falsified/counterfeit/drugs, or pharmaceuticals of substandard quality. To protect and advance the general public's health, India has still implemented some preventative measures throughout the nation.

Keywords*:* SFFC, poor quality drugs, Central Drugs Standard Control Organization, whistle blower scheme

INTRODUCTION:

In India, which has a population of more than 1.24 billion [1], the right to health is recognised as a basic right in the national constitution and statutory laws both in domestic and foreign laws [2]. A third of the world's population, or 2 billion people, lack access to basic medications [3]. Since medicine can save lives, it is more important for treatment even if it accounts for 20–60% of care costs and 50–90% of these costs are covered by the patient, especially in low- and middle-income countries [4]. In India, a developing nation, more than 40% of people live on less than $1 USD a day[5], and patients must pay more than half of this amount for medications. The Indian government has programmes in place to provide specific patient groups with free generic medications [6].

However, due to their low cost, simple accessibility, and availability on the market, individuals accept, prefer, and purchase counterfeit or subpar products over authentic or branded products [7]. Consumers frequently are ignorant of items that are out-of-date, defective, or of low quality, which results in treatment failure and, in the case of antibiotics,

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can lead to the development of antimicrobial resistance [8,9]. In contrast to counterfeit goods, substandard goods result from black marketeers, unethical manufacturing practises, or a lack of adequate infrastructure [9].

Poor quality is already a very serious issue that is continuing to spread and is expected to do much more harm in the near future[10]. As a result, there is no single definition of a poor quality medicine because it can differ from nation to nation[11]. Spurious/falsely-labeled/falsified/counterfeit (SFFC) medications are typically of low quality and can result in treatment failure or even death[12]. In accordance with this, the World Health Organization's (WHO) International Medical Products Anticounterfeiting Taskforce (IMPACT) defines SFFC medications as medicines which are deliberately and fraudulently mislabelled with respect to identity and/or source, and which also 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 order to educate the public and determine the true prevalence of SFFC or NSQ medications in India, an evaluation review was conducted both physicians and pharmacists. Information was gathered from research, books, news articles, journals, and reliable websites that were both government and non-government sponsored. The data were compared and analysed to uncover the true nature of India's subpar medicine supply.

Drugs with SFFCs: A pandemic risk - For the global health system, low-quality drugs and inferior products present a serious problem that cannot be ignored [5]. Fewer than 1% of the market value products in the world's most developed nations, including Japan, Canada, Australia, New Zealand, the United States of America, and the majority of the European Union, are fakes. However, developing nations like Africa, Latin America, and many regions of Asia may be notably the seller and producer of SFFC medicines [12]. Russia, China, India, Brazil, Mexico, Pakistan, Southeast Asian, and Middle Eastern nations are thought to be the main producers and distributors of fake medications [15]. WHO research from ten years ago found that 10% of medicines sold worldwide were fake.

WHO-IMPACT, however, noted that the data was not very authentic[16], in contrast to what it had previously communicated. It indicates that no precise extent is reported. What led to this issue and what factors contributed to it are currently under debate. The desire for fake and inferior medications may be influenced by a number of factors, including poverty and ignorance [5]. Additionally, ignorance of subpar, unregistered drugs, liberal fines, and insufficient law enforcement are among of the important factors contributing to the problem[9].

Due to the availability and lack of detection of SFFC or NSQ medicines in the market, patient consumption of substandard drugs may worsen day by day, eroding public confidence in the health system. Consumption of SFFC medications may result in treatment failure or even death[12,17]. Unbelievably, counterfeit and subpar medication products alone cause 0.20 to 0.30 million deaths annually in China[17]. In spite of the lack of such information, many

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patients pass away in India each year. In the world, counterfeit pharmaceuticals have been blamed for 0.70 million deaths from tuberculosis and malaria, according to a research released by the International Policy Network [18]. This information highlights regulatory system flaws and warnings to stay away from subpar medications.

The primary source of SFFC medications' invention and distribution is thought to be India. However, according to the data, there are no verifiable allegations against the nation offered by Indian government and non-government organisations. Numerous studies have only looked into specific medications or a small number of medicinal preparations and formulations. There have been no significant randomised trials evaluating the quality of medications conducted in India to date [23].

In 2000, it was reported that India, Nigeria, and Pakistan accounted for around 35, 23, and 13.3 percent, respectively, of all global sales of counterfeit medications, which primarily contain antibiotics[24]. Officials from the Indian government assessed that 9% of the pharmaceutical items were of subpar quality ten years ago[25].

Although 30–40% of all marketed medications are reportedly regarded to be fake, this information is unsupported by any scientific research [16]. 10 743 samples from 234 retail locations were collected for laboratory analysis as part of a survey carried out in 2007 by the South East Asia Region Pharmaceutical (SEARPharm) Forum, a coalition of pharmaceutical associations affiliated with the WHO and the International Pharmaceutical Federation (FIP). 0.3% were deemed to be outside of pharmacopoeial standards, while 3.1% were considered to be spurious[16]. Due to the fact that 294 fixed drug combinations (FDCs) items were not approved by the Drugs Controller General of India (DCGI) in 2007, they were illegally sold on the market [17].

The State Drugs Control Organizations suspended or revoked 8418 pharmacist licences in 2008 out of 1 83 020 chemical shops for dealing in fake drugs[28]. In accordance with CDSCO's evaluation of the data from 2003 to 2008, 6.3 to 7.5% of the samples were of subpar quality, and 0.16 to 0.35 percent of these were found to be spurious[26]. According to a 2009 CDSCO report, in 1995–1996 10.64 and 0.30 percent of tested samples out of 32 770 were substandard or spurious, while in 2007–2008, 6.42 and 0.16 percent of tested samples out of 42 354 were substandard or spurious[19]. The drug authority had achieved something worthwhile.

After 2010, neither CDSCO nor any non-governmental organisations nor any other entity has provided an absolute or comprehensive report on substandard and counterfeit medications individual investigation The government has been aware of numerous instances of fake and subpar pharmaceuticals being imported during the past three years. Officials from CDSCO discovered three cases of unlicensed bulk pharmaceuticals coming from China in 2009 at the seaport in Chennai[36]. Cases involving the importation of low-quality pharmaceutical products into India revealed 35, 35, and 34 incidents for the three consecutive years 2009–2010, 2010–2011, and 2011–2012, respectively [27].

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In Delhi and Bhiwandi city, 85 out of 130 sales shops were found to be dealing in illegal substances during a surprise inspection by CDSCO officials [18]. Numerous incidents are reported in local news, as seen in Table 1[39]. It is strongly advised to thoroughly research each drug product that is offered on the home market.

Any quantity of defective or fraudulent medications is undesirable since it increases morbidity and mortality [20,21] given the growth of the pharmaceutical industry and the magnitude of potentially fatal diseases. The size of the issue and its impact on public health are only partially acknowledged by published data[20–22]. Therefore, the regulatory authority must focus their immediate attention and investigation on this public safety issue.

Strategies for marketing generic medications:The $20 billion Indian pharmaceutical business ranks third in terms of volume and thirteenth in terms of value. India excels as the "pharmacy of the developing world," focusing on the accessibility and affordability of the pharmaceutical items in the nation [23]. All Central Government hospitals and Central Government Health Scheme (CGHS) dispensaries in India have been ordered to prescribe generic medications as frequently as feasible. The state government also gives doctors instructions on how to administer generic medications [24].

The Department of Pharmaceutical, Ministry of Chemical and Fertilizers, launched the Jan Aushadhi Campaign (Medicines for Public Campaign) nationwide in collaboration with the State Government by opening Jan Aushdhi generic drug stores in government hospitals and supplying generic medications through Central Pharma Public Sector Undertaking.

The government has already established 122 Jan Aushdhi outlets, where about 231 generic medications are being sold as of mid-2012 [25].More rigorous and stringent laws, policies, and regulations are urgently needed to reduce the use of SFFC or NSQ medications at the federal or state level actions to address the issue.

CONCLUSION:

Public health is impacted by pharmaceuticals of poor quality.Every category of generic and branded products contains fake or counterfeit medications. which is spreading its roots all across the planet, becoming a threat as a result. Standard quality requirements are influenced by a variety of elements, including as drug costs, sponsor competition, employment, and market openness. Transnational regulatory dimensions have been developed in response to the public health crisis caused by fake or subpar medications. Due to a decrease in the number of SFFC or NSQ drug cases, several significant initiatives and preventive measures taken nationwide, as well as harsh penalties to combat subpar drugs for the protection and promotion of public health, India is progressing and achieving its goals in the drug regulation process. To protect the interests of the patient population as a whole, the time has come to investigate this issue more thoroughly in the future.

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