

Counterfeit drugs: problem of developing and developed countries

Sankalp Yadav^{1*}, Gautam Rawal²

¹General Duty Medical Officer-II, Chest Clinic Moti Nagar,
North Delhi Municipal Corporation, New Delhi, India,

²Attending Consultant, Critical Care, Rockland Hospital,
Qutab Institutional Area, New Delhi, India,

***Corresponding Author:**

E-mail: drsankalpyadav@gmail.com

ABSTRACT

The world is facing the problem of substandard or spurious drugs. These substandard drugs have resulted in life threatening issues, financial loss of consumer and manufacturer and loss in trust on health system. The problem is graver in developing countries where these drugs are easily available to the people. There is an urgent need to address this issue and take measures to control the widespread availability and usage. Although, India has taken some preventive measures to fight against the problem of substandard/spurious drugs for protecting and promoting the public health but, still a lot needs to be done.

Key Words: Counterfeit drugs, Developing countries, Generic medicines.

INTRODUCTION

Around the world, one third of the population lacks access to essential medicines¹. In developing countries like India, where more than 40% of the population earns less than USD 1 per day, it is very difficult to buy the costly medications by the general public². In such conditions the criminals involved in spurious drugs trade has infiltrated the supply chain easily and thus the market of cheap and easily available counterfeit drugs is mushrooming. The phenomenon of drug counterfeiting was first identified as an emerging problem by the WHO in 1985³. But, since then this problem has grown to a much larger extent with more than 10% of drugs globally are counterfeit, and in some countries the situation is even worse with more than 50% of the drug supply is counterfeit³. The problem of spurious drugs in India is a very common problem⁴. The developing countries are not merely the victims of the problem, but also serve as the sources of fake drugs with India and China being the biggest culprit's globally⁵. One statistic by the European Commission described India as the source of 75% of fake drugs and according to one report; most of the fake drugs in Nigerian markets originate from India⁶. A counterfeit drug is a pharmaceutical product which is produced and sold with the intent to deceptively represent its origin, authenticity or effectiveness³. It may contain inappropriate

quantities of active ingredients, may be improperly processed within the body or may contain ingredients that are not on the label, and is often sold with inaccurate, incorrect, or fake packaging and labeling³. Almost all drugs are counterfeited, but the commonly counterfeited medicines in developed countries were new, expensive lifestyle medicines, such as hormones, steroids, pills for erectile dysfunction and antihistamines^{3,7,8}. However, in developing countries the most commonly counterfeited medicines are those which are used to treat life threatening conditions such as malaria, cancer, tuberculosis, HIV/AIDS, various antibiotics, etc.³

Although, the Government of India has taken measures to provide free generic medicines for certain categories of patients⁹. But still, people accept, prefer and buy counterfeit or substandard products over genuine or branded products due to their cheap price, easy accessibility and availability in the market¹⁰. These innocent buyers are unaware of the whereabouts of the manufacturer or the quality of the product, and many times they are not even aware of the expired, degraded or substandard products which ultimately results in failure of the treatment and with antibiotics this lead to escalation of antimicrobial resistance^{11,12}. The problem of drug counterfeit was once confined to exotic and costly pills like Viagra, but now it has proliferated to cough syrups, vitamin

supplements and painkillers¹³. The major source countries of counterfeits seized by European customs organizations include China, the United Arab Emirates and India^{14,15}. India, being the world's largest supplier of generic drugs, has become an epicenter for counterfeit and fake drugs. In India, Most cases of fake and spurious drugs in the local market were found in Bihar, West Bengal, Uttar Pradesh and Gujarat¹³. As is the case with some pockets of parasite resistance, due to Artemisinin-based medicines that have been attributed to the sub-therapeutic doses derived from falsified and substandard medicines¹⁶. Various studies have reported the widespread circulation of poor quality medicines in some parts of Asia and Africa⁸. Most of them have been shown to contain sub-therapeutic amounts of the active pharmaceutical ingredient's (API) or no API at all or even toxic compounds¹⁷⁻²⁰.

Lack of expertise, unfair manufacturing practices or insubstantial infrastructure leads to substandard drugs; whereas counterfeit is the product of black marketer¹². The definition of poor quality drug are the spurious/falsely-labeled/falsified/counterfeit (SFFC) drugs varies from country to country and in general the use of such drugs may lead to treatment failure or even death^{21,22}. The International medical products anti-counterfeiting taskforce (IMPACT) of the World Health Organization (WHO) defines SFFC medicines as "medicines which are deliberately and fraudulently mislabeled with respect to identity and/or source, and also which may include the products with correct ingredients or with the wrong ingredients, without active ingredients, with insufficient or too much active ingredient, or with fake packaging"³. In India, as per the Drug and Cosmetic (D and C) act, 1940, under section 17, 17A and 17B poor quality drug comprises of misbranded, spurious and adulterated drugs, respectively²³. With the 2008 amendment of D and C act, Indian drug regulatory authority that is Central Drugs Standard Control Organization (CDSCO) has categorized not of standard quality (NSQ) products in three categories A, B and C that is very important and helpful in categorizing the products during quality evaluation^{3,24}.

Counterfeits of antimalarial drugs are widespread in developing countries, particularly Southeast Asia and Africa^{25,26}. Even fake antiretroviral drugs have been reported in Africa²⁷. A drug Nimulid (Nimesulide) manufactured by Panacea Biotech had more than 35 counterfeits in the market at one time⁴. A report had found about 8% drugs brought to the Philippines, as fake²⁴. In 2006, in the UK the drug Lipitor was found to have been lacking the sufficient quantities of API. A countrywide survey in Cambodia in 1999 showed that 60% of the antimalarial Mefloquine, tablets contained the ineffective but much cheaper sulphadoxine-pyrimethamine, obtained from stocks that should have been destroyed, or fakes that contained no drug at all^{28,29}. Xenical, a drug for obesity has sold in the United States via internet sites operated outside USA with no API in 2007. A survey found 38% of tablets sold in five countries in mainland South East Asia as the antimalarial Artesunate were fake²³. In 2008, Viagra and Cialis for erectile dysfunction were smuggled into Thailand from an unknown source. Examples of use of aspirin, in the manufacture of fake Chloroquine in Africa are also available in the literature³⁰. There are also examples from China where in the year 2009, an antidiabetic traditional medicine used for lowering the blood sugar, with six times the normal dose of Glibenclamide leads to the death of 2 people and the hospitalization of 9. There were 771 reports of counterfeit drugs with 78% of those coming from developing countries between 1984-1999^{3,31}. The consumption of Paracetamol cough syrup made up of diethylene glycol (a toxic chemical used in antifreeze) led to 89 deaths in Haiti in 1995 and 30 infant deaths in India in 1998³². From January 1999 to October 2000, 46 reports of counterfeit drugs were received from 20 countries; 60% from developing countries and 40% from developed nations^{3,33}. The number of cases of counterfeit drugs being investigated by the US Food and Drug Administration (FDA) has quadrupled from an average of five per year in the 1990's to about 20 per year in 2001 and 2002³⁴. The International Federation of Pharmaceutical Manufacturers Associations (IFPMA) has estimated that 7% of all drugs sold around the world are counterfeits³. Furthermore; they have suggested that the

value of this trade is more than USD 30 billion. In Russia, the figure has been put at 12%, while in the Ukraine it may be as high as 40%^{3,34}. In late January 2006, the United States Food and Drug Administration (FDA) issued an alert about fraudulent flu remedies, including counterfeit prescription Oseltamivir (Tamiflu) medication^{3,33}. Many more cases are appearing, not only in the developing world but, increasingly, in developed countries³⁵⁻³⁷.

What can be done?

Counterfeit drugs are a major cause of morbidity, mortality, and loss of public confidence in medicines and health structures⁴. A number of examples from all over the world are available. About 50% of the drugs utilized by patients are purchased from the private places (Pharmacies, patent medicine stores and street vendors; where control is difficult, hence they are expected to be more easily invaded by drug counterfeiters compared to the public health sector³⁸. Despite close cooperation between drug companies, governments, or international organizations concerned with trade, health, customs and excise, and counterfeiting, the prevalence of counterfeit drugs appears to be rising^{1,4}. The World Health Organization gave guidelines for the development of measures to combat counterfeit drugs³⁹. The remedy to this global problem lies in appropriate regulatory processes and rules and strict implementation of these, along with coordination between the players at every level from the policy maker to the regulator to the consumer⁴. The problem is very big and requires radical steps to be taken. The law enforcement is very important and anybody involved in such corrupt practices should be arrested and along with the punishment they should be penalized. This way fear will be there in the minds of those who are involved in this practice and more people will refrain from indulging in such practices. Also, the Government should increase the posts of the regulatory officers. The Mashelkar Committee (1993) recommended strict vigilance, with regular surprise checks at pharmacies and for the cause checks (suspicious checks)^{4,40}. The more will be the number of controlling officers higher will be the supervision and lesser chances of manufacture and

marketing of spurious drugs. The drugs should have sophisticated techniques, which will be unique and general public should be encouraged to check drugs before buying, but usually these are expensive^{41,42}. Besides, the newer techniques like near-infrared spectroscopy, Raman spectroscopy, isotopic characterization, tensiography, chromatographic and mass spectrometric radio-frequency identification (RFID), electronic pedigree (E-Pedigree) system, or handheld refractometer can be used to identify the spurious drugs^{4,43}. The developments of complex labels, which are difficult to imitate as well as use of SMS text message to check the authenticity of a particular pharmaceutical product are examples of recent progress in this regard. This SMS technology, developed in the USA in Dia and Ghana is increasingly being adopted by other countries in Asia and Africa^{8,44}. The pharmacy shops should be vigilant about the products that they are selling as these products are often sold out of any controlled distribution channel⁴⁵. The generic medicines should be made available to all and campaigns aimed at the widespread use of such medicines should be encouraged. The role of community leaders, politicians, drug controllers, doctors, etc. is very important for the control of spurious drugs market. Regular surveillance of the drugs is very important and essential. The Government's should publish information about standard quality/spurious/adulterated/misbranded drugs. This will help the over the counter buyers. Laboratories equipped with fast and cheap if not, a free checking facility for the quality of drugs should be opened at least one in every district. Imported drugs should be checked before they enter in the Indian market. These are some of the provisions which will help a lot in the controlling the spurious drugs market.

CONCLUSIONS

The problem of poor quality of drugs is already very serious and steadily growing and is likely to cause much more damage in the near future. The substandard drugs affect the general health of the citizens. The problem of spurious or counterfeit drugs has evolved a lot and has roots throughout the country. Tackling corruption at various levels of the pharmaceutical systems is

indispensable for the success of the crusade against fake drugs⁸. The maintenance of the drug quality is an essential component of medical care²². The masses should be informed about this problem. The role of health information and health education is very important for this. There is a need for mass scale public awareness campaigns to create awareness. The generic drugs should be extensively publicized and marketed. The role of supervision and drug inspectors are very important in this regard. For minimizing spurious / falsely-labelled / falsified / counterfeit drugs or not of standard quality drugs, there is the urgent

requirement of more stringent regulation and legal action against the problem thus the role of Governments and policy makers is very important. However, drug counterfeiting is a worldwide concern and requires worldwide actions to be taken to combat this problem [46].

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CONFLICT OF INTEREST:

The authors declare they have no conflict of interest

REFERENCES:

1. WHO. WHO medicines strategy: countries at the core, 2004–2007. World Health Organization. 2008. Available from URL: <http://www.apps.who.int/medicinedocs/pdf/s5571e/s5571e.pdf> [Last accessed on 2015 April 5].
2. Bate R, Zhe Jin G, Mathur A. Does price reveal poor-quality drugs? Evidence from 17 countries. *J Health Econ*. 2011; 30:1150-63.
3. Gupta P, Singhal K, Pandey A. Counterfeit (Fake) Drugs & New Technologies to Identify it in India. *Int J Pharm Sci Res*. 3(11); 4057- 4064.
4. Swaminath. Faking it - II: Countering and preventing counterfeiting of drugs. *Indian J Psychiatry*. 2009 Jan-Mar; 51(1): 9-11.
5. Bate R, Boateng K. Bad medicine in the market. *Am. Enterprise Inst. Public Policy Res*. 2007; 43:13-21.
6. Raufu A. India agrees to help Nigeria tackle the import of fake drugs. *Br. Med. J*. 2003; 326: 1234.
7. WHO. Counterfeit medicines. Fact Sheet Revised. November 14, 2006. Available from URL: http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/index.html [Last accessed on 2015 April 5].
8. Chika A, Bello SO, Jimoh AO, Umar MT. The Menace of Fake Drugs: Consequences, Causes and Possible Solutions. *Research Journal of Medical Sciences*. 2011; 5(5):57-261.
9. PIB. Generic Medicines. Press Information Bureau of India. 2012. Available from URL: <http://www.pib.nic.in/newsite/erelease.aspx?relid=89323> [Last accessed on 2015 April 5].
10. Gentry JW, Putrevu S, Shultz C, Commuri S. How now Ralph Lauren? The separation of brand and product in a counterfeit culture. *Lincoln, Nebraska*. 2001. p. 258-65. Available from URL: <http://www.acrwebsite.org/search/view-conference-proceedings.aspx?Id=8485> [Last accessed on 2015 April 5].
11. Taylor RB, Shakoor O, Behrens RH. Drug quality, a contributor to drug resistance? *Lancet* 1995; 346:122.
12. Newton PN, Green MD, Fernandez FM. Impact of poor-quality medicines in the “developing” world. *Trends Pharmacol Sci*. 2010; 31:99-101.
13. The alternative (2011). Pharma secure: Fighting fake drugs in India. Available from URL: <http://thealternative.in/social-business/pharma-secure-fightingfake-drugs-in-india/> [Last accessed on 2015 April 5].
14. Reynolds L, McKee M. Organised crime and the efforts to combat it: a concern for public health. *Global Health*. 2010; 6:21.
15. Verma S, Kumar R, Philip PJ. The Business of Counterfeit Drugs in India: A Critical Evaluation. *International Journal of Management and International Business Studies*. 2014; 4(2):141-148.
16. Dondorp AM, Yeung S, White L, Nguon C, Day NPJ, Socheat D, et al. Artemisinin resistance: current status and scenarios for containment. *Nat Rev Microbiol*. 2010; 8:272-80.
17. Newton PN, White NJ, Rozendaal JA, Green MD. Murder by fake medicines. *BMJ*. 2002; 324:800-1.
18. Nayyar GML, Breman JG, Newton PN, Herrington J. Poor-quality antimalarial, medicines in southeast Asia and sub-Saharan Africa. *Lancet Infect Dis*. 2012; 12:488-96.
19. Maponga C, Ondari C. The quality of antimalarials; a study in selected African countries. *World Health Organization (WHO) Department of Essential Medicines and Medicines*. WHO/EDM/PAR/2003. 4; 2003. Available from URL: <http://apps.who.int/medicinedocs/pdf/s4901e/s4901e.pdf> [Last accessed on 2015 April 5].
20. Chikowe I, Osei-Safo D, Harrison J, Konadu DY, Addae-Mensah I. Post-marketing surveillance of anti-malarial medicines used in Malawi. *Malar J*. 2015; 14:127.

21. Nayyar GML, Breman JG, Newton PN, Herrington J. Poor-quality antimalarial drugs in southeast Asia and sub-Saharan Africa. *Lancet Infect Dis* 2012; 12:488-96. Available from URL: <http://www.ncbi.nlm.nih.gov/pubmed/22632187> [Last accessed on 2015 April 5].
22. WHO. Medicines: Spurious/false-labeled/falsified/counterfeit (SFFC) medicines. Geneva: World Health Organization; 2012. Available from URL: <http://www.who.int/mediacentre/factsheets/fs275/en/index.html> [Last accessed on 2015 April 5].
23. Government of India. The Drugs and Cosmetics Act and Rules (Amendment) 2005. Ministry of Health and Family Welfare. Available from URL: <http://www.cdsc.nic.in/forms/contentpage1.aspx?lid=1888> [Last accessed on 2015 April 5].
24. Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under The Drug and Cosmetic (Amendment) Act, 2008. New Delhi: CDSCO report; 2008 p. 1-13. Available from URL: [http://www.cdsc.nic.in/writereaddata/Guidelines under new penal provisions9.pdf](http://www.cdsc.nic.in/writereaddata/Guidelines%20under%20new%20penal%20provisions9.pdf) [Last accessed on 2015 April 5].
25. Dondorp, AM, Newton PN, Mayxay M, van Damme W, Smithuis FM, et al. Fake antimalarials in Southeast Asia are a major impediment to malaria control: Multinational cross-sectional survey on the prevalence of fake antimalarials. *Trop. Med. Int. Health*, 2004; 9:1241-1246.
26. Atemnkeng MA, De Cock K, Plaizier-Vercammen J. Quality control of active ingredients in artemisinin - derivative antimalarials within Kenya and DR Congo. *Trop. Med. Int. Health*. 2007; 12:68-74.
27. Ahmad K. Antidepressants are sold as antiretrovirals in DR Congo. *Lancet*. 2004; 363:713-713.
28. Rozendaal JA. Fake antimalaria drugs in Cambodia. *Lancet*. 2001; 357:890.
29. Rozendaal J. Fake antimalarials circulating in Cambodia. *Bull Mekong Malaria Forum*. 2000; 7:62-68.
30. Sesay MM. Fake drugs—a new threat of health care delivery. *Africa Health*. 1988; Jun/Jul:13-15.
31. Medicines: counterfeit medicines. WHO. Available from URL: <http://www.who.int/mediacentre/factsheets/fs275/en/print.html> [Last accessed on 2015 April 5].
32. Clark C. Pharmaceutical counterfeiting. *Pharm J*. 2003; 271:453.
33. Hileman B. News. *Chem Eng* 2003; 85(45):36.
34. Sekhar S, Mary CA, George RM, Sasidharan S. *IJPSR*. 2011; 2(7):1645-1650.
35. Behrens RH, Awad AI, Tsaylor RB. Substandard and counterfeit drugs in developing countries. *Tropical Doctor*. 2002; 32:1-2.
36. Rudolf PM, Bernstein IB. Counterfeit drugs. *New England Journal of Medicine*. 2004; 350:1384-1386.
37. Sreedhar D, Subramanian G, Udupa N. Counterfeit drugs: problem of developing and developed countries. *Current Science*. 2006; 90(8) 25:1054-1055.
38. Cars O, Nordberg P. Antibiotic resistance: The faceless threat. *Int. J. Risk Safety Med*. 2005; 103-110.
39. World Health Organisation. Counterfeit drugs—guidelines for the development of measures to combat counterfeit drugs. Geneva: WHO; 1999.
40. Mashelkar Committee Report. Ministry of Health and Family Welfare, Government of India. August 2003.
41. Reconnaissance International. *Authentication News*. 2001; Jul:7.
42. Newton PN, White NJ, Rozendaal JA, Green MD. Murder by fake medicines. *BMJ*. 2002; 324:800-1.
43. Sukhlecha A. Counterfeit and substandard drugs: The need for an effective and stringent regulatory control in India and other developing countries. *Indian J Pharmacol*. 2007; 39:255.
44. Harris J, Stevens P, Morris J. Keeping it real: Combating the spread of fake drugs in poor countries. *Int. Policy Network*. 2009.
45. Juillet Y, Vlasto AP. Counterfeiting of medicinal drugs: issues and threats. *Fundam Clin Pharmacol*. 2005 Dec; 19(6):621-4.
46. Wertheimer AI, Chaney NM, Santella T. Counterfeit pharmaceuticals: current status and future projections. *J Am Pharm Assoc*. 2003. Nov-Dec; 43(6):710-7; quiz 717-8.