International Journal of Community Medicine and Public Health
Sivakumar A et al. Int J Community Med Public Health. 2023 Sep;10(9):3403-3405
http://www.ijcmph.com
pISSN 2394-6032 | eISSN 2394-6040
DOI: https://dx.doi.org/10.18203/2394-6040.ijcmph20232709

Letter to the Editor

An inconspicuous threat to our nation-it's time to end

Sir,

It is well known that counterfeit medical products cause harm to patients and fail to treat the diseases for which they were intended. They lead to loss of confidence in medicines, healthcare providers and health systems. They are becoming common in every region of the world. It is believed that up to 10% of all medicines sold worldwide are counterfeit, with higher prevalence in regions where drug regulatory and enforcement systems are weakest.[1] An estimated 1 in 10 medical products in low- and middle-income countries and it contributes to antimicrobial resistance and drug-resistant infections.[2]

Counterfeiting medical products, from their manufacture to their supply to patients, is a serious crime that puts human lives at risk and undermines the credibility of health systems.[3] Counterfeit medical products jeopardize progress achieved in public health and threaten the effectiveness of major initiatives aimed at priority diseases. Cases have involved widely-used medicines such as atorvastatin and paracetamol, limited-use medicines such as growth hormone, paclitaxel, and filgrastim, erectile dysfunction medicines, and medical devices such as contact lenses, condoms, surgical mesh, and diagnostic test strips used by diabetic patients to monitor their blood glucose concentrations.[4] Both expensive products and cheap ones, generic and branded products are being counterfeited with the result that they appear in community pharmacies and hospitals, as well as other less-regulated settings. In addition to direct harm to patients and therapeutic failure, the presence of counterfeit medical products weakens public confidence in the entire health system, affecting the reputation of manufacturers, wholesalers, pharmacists, doctors, private organizations and government institutions alike.[5,6]

The 1992 definition of WHO on counterfeit medicines is as follows "A counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with correct ingredients or with wrong ingredients, without active ingredients, with insufficient ingredient/with fake packaging." Substandard also called "out of specification", these are authorized medical products that fail to meet either their quality standards/ specifications/ both.[7] Unregistered/unlicensed medical products that have not undergone evaluation or approval by the national/ regional regulatory authority for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.

IDENTIFYING A SUBSTANDARD OR FALSIFIED MEDICAL PRODUCT

Some falsified medical products are almost visually identical to the genuine product and very difficult to detect. However, many can be identified by-Examining the packaging for condition, spelling mistakes or grammatical errors; Checking the manufacture and expiry dates and ensuring any details on the outer packaging match the dates shown on the inner packaging; Ensuring the medicine looks correct, is not discoloured, degraded or has an unusual smell; Discussing with your pharmacist, doctor or other healthcare professional as soon as possible if you suspect the product is not working properly or you have suffered an adverse reaction and reporting suspicious medical products to your national medicines regulatory authority.[8]

DANGERS OF COUNTERFEIT DRUGS

Failure to provide effective treatment: As patients think they are addressing their disease, insufficient active ingredients put children and the elderly at severe risk. Adulterants with toxic chemicals: Often leading to death or injury.

Drug resistance: When drugs contain too little of their active ingredients to kill all of the disease, it can lead to the emergence of drug resistant strains.

Loss of confidence in the pharmaceutical industry: Even a single case of a counterfeit drug undermines the entire credibility of the pharmaceutical supply chain.

Diversion of funds to organized crime.

This has enticed criminal organizations to become involved, some with links to the narcotics trade or other forms of organized crime.[9]

STRATEGIES TO PREVENT COUNTERFEIT DRUGS

A variety of interventions have been recommended to combat the problem of drug counterfeiting. These include: legal actions and regulations on illicit traders, countermeasures using technologies, consumer education and cooperation with enforcement agencies. The need to identify effective anticounterfeiting strategies has recently been raised as a main policy concern by policymakers from several low-income and middle-income countries including the Eastern Mediterranean region.[10]

Table 1: Definitions of various strategies to prevent counterfeit drugs.

Strategies	Definitions
Drug registration	A form of regulation to ensure access to effective and safe medicines. It involves assessments by relevant drug regulatory authorities of manufacturers of all components of drugs to ensure they are certified as meeting the international standards for GMP before authorising the drug for sale.
WHO pre-qualification of drugs	A service provided by the WHO to "facilitate access to medicines that meet unified standards of quality, safety and efficacy primarily for HIV/AIDS, malaria TB and reproductive health"
Licensing of drug outlet	This refers to the authorisation of pharmaceutical establishments by drug regulatory authorities with the aim of ensuring that the supply and sale of drugs are carried out by qualified personnel on premises that meet regulatory requirements.
Increasing public awareness	A public awareness campaign, mainly using TV and radio announcements, to promote public awareness of dangers of counterfeit medicine from illicit drug market. Campaign designed based on prev survey data collected to evaluate purchasing practices of consumers.
Local and international collaboration	An international cross-disciplinary model of interaction and collaboration between WHO officials, physicians, pharmacists and scientists, and the Interpol, to investigate the source of counterfeit drugs in South East Asia
Quality assurance system within the NDPP	The system encompassed three main features: development of regulations, for example, improvement of drug registration system and increased requirement for imported drugs, training of drug inspectors in good manufacturing and pharmacy practice and implementation of legal actions, for example, fines and product recall.[10]

MEASURES TO COMBAT COUNTERFEIT MEDICINES

WHO has proposed the establishment of international medical products anti-counterfeiting taskforce (IMPACT).[11] IMPACT aims to build co-ordinated networks across countries in order to halt the production, trading and selling of counterfeit medicines around the globe. IMPACT-partnership comprising of international organisations, enforcement agencies, pharmaceutical manufacturers association, drug regulatory authorities.

At the national level CDSCO (Central drug standards control organisation) is the central drug authority to function against counterfeits. Control over import of drugs, carrying out inspections and rides over medical supply chain and quality control of medications. Zonal offices carry out joint inspections and coordinate with the State drugs controllers under their jurisdiction. Quality control of drugs imported is exercised by the port offices.[12] In India government had set up the first expert committee under chairmanship of Dr. Mashelkar in Feb 2003 to tackle problem of counterfeit drugs.

THE MAIN RECOMMENDATIONS OF THE COMMITTEE ARE AS FOLLOWS

Enhancement of penalty and prison terms for sale and manufacturing of counterfeit drugs that cause grievous hurt or death, from life imprisonment to death. Sale and manufacture of counterfeit drugs, which are not likely to cause consequences as mentioned above, be made cognizable and non-bailable. There should be a penalty for those who are unable to produce documents in support of their purchase. Constitution of special courts for trial of offence under the drugs and cosmetics act so that judicial proceedings can be expedited. Authorization of the police to file prosecution. Severe vigilance must be obtained with regular surprise checks and creation of competent national drug laboratories with high quality of testing facilities for checking counterfeit drugs.[13]

Pharmacist should implement the WHO's national and good pharmacy practices guidelines. Should purchase medicinal products only from reputable sources paying regard to the storage conditions should be alert to differences in quality of packaging, labelling or leaflets and in physical appearance of medicinal products.[14] Should isolate and with-hold the supply of the drug if it is suspected to be counterfeit and should co-operate in investigation to detect the source. They should play a major role to convince the government to use maximum efforts to enforce all appropriate measures to prevent manufacturing and distribution of the counterfeit medicines.

Drug counterfeiting is an important problem addressed by several countries. This requires multiple measures to protect supply chain. Implementation of anti-counterfeit technologies is an important strategy taken up by several drug manufacturers and regulatory authorities. The track and trace system and serialization are given importance and are widely used among all anti-counterfeit technologies in different countries. Recent notification from Indian government mandated the use of barcodes on all drug products manufactured and imported.

Abinav Sivakumar[1]*, Anugraha John[2]

[1]Department of Community Medicine, Chettinad Hospital and Research Institute, Kelambakkam, Tamil Nadu, India
[2]Faculty of Medicine, Sri Lalithambigai Medical College and Hospital, Dr. M.G.R. Educational and Research Institute, Tamil Nadu, India

***Correspondence to**
Dr. Abinav Sivakumar,
E-mail: abinav.thedoc3@gmail.com

REFERENCES

1. El-Jardali F, Akl EA, Fadlallah R, Oliver S, Saleh N, El-Bawab L et al. Interventions to combat or prevent drug counterfeiting: a systematic review. BMJ Open. 2015;5(3):e006290.
2. Dondorp AM, Limmathurotsakul D, Ashley EA. What's wrong in the control of antimicrobial resistance in critically ill patients from low- and middle-income countries? Intensive Care Med. 2018;44(1):79-82.
3. Enyinda CI, Tolliver D. Taking Counterfeits out of the Pharmaceutical Supply Chain in Nigeria: Leveraging Multilayer Mitigation Approach. J Afr Bus. 2009;10(2):218-34.
4. Boxtel CJ van, Santoso B, Edwards IR. Drug Benefits and Risks: International Textbook of Clinical Pharmacology - Revised 2nd Edition. IOS Press. 2008;846.
5. Wertheimer AI, Norris J. Safeguarding against substandard/counterfeit drugs: Mitigating a macroeconomic pandemic. Res Soc Adm Pharm. 2009;5(1):4-16.
6. Mackey TK, Liang BA, York P, Kubic T. Counterfeit Drug Penetration into Global Legitimate Medicine Supply Chains: A Global Assessment. Am J Trop Med Hyg. 2015;92(6):59-67.
7. A63_23-en.pdf. Available at: https://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_23-en.pdf. Accessed on 25 May 2023.
8. Blackstone EA, Fuhr JP, Pociask S. The Health and Economic Effects of Counterfeit Drugs. Am Health Drug Benefits. 2014;7(4):216-24.
9. Cockburn R, Newton PN, Agyarko EK, Akunyili D, White NJ. The Global Threat of Counterfeit Drugs: Why Industry and Governments Must Communicate the Dangers. PLOS Med. 2005;2(4):e100.
10. Fadlallah R, El-Jardali F, Annan F, Azzam H, Akl EA. Strategies and Systems-Level Interventions to Combat or Prevent Drug Counterfeiting: A Systematic Review of Evidence Beyond Effectiveness. Pharm Med. 2016;30(5):263-76.
11. WHO-led anti-counterfeiting coalition examines technologies to prevent fake drugs. Available at: https://www.who.int/news/item/13-03-2007-who-led-anti-counterfeiting-coalition-examines-technologies-to-prevent-fake-drugs. Accessed on 25 May 2023.
12. Bonthagarala B, Evangeline L, Mounica N, Reddy V, Ngabhushanam M, Redd D. Regulatory process and ethics for clinical trials in India (CDSCO). Pharma Innov J. 2017;6:165-9.
13. Final_Report_mashelkar.pdf. Available at: https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadCommitteeFiles/Final_Report_mashelkar.pdf. Accessed on 18 April 2023.
14. trs961-annex8-fipwhoguidelinesgoodpharmacy practice.pdf. Available at: https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/distribution/trs961-annex8-fipwho guidelinesgoodpharmacypractice.pdf. Accessed on 25 May 2023.

Cite this article as: Sivakumar A, John A. An inconspicuous threat to our nation-it's time to end. Int J Community Med Public Health 2023;10:3403-5.