

Public Health Measures to Fight Counterfeit Medicine Market

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DEAR EDITOR.

World Health Organization defines a counterfeit medicine as the one which is deliberately and fraudulently mislabeled with respect to identity and/ or source. It incorporates both branded and generic products and even includes products with correct/ wrong/insufficient/no active ingredients, or fake packaging.[1] However, the European Union has proposed falsified medicines as a more appropriate term than counterfeit medicines, which actually refers to those medicines that are not compliant with the intellectual-property rights or that infringe trademark law.[2] Counterfeiting in pharmaceutical products has resulted in serious health repercussions such as no relief/partial relief from complaints, development of adverse drug effects, multiple unintended drug interactions and economic burden on the health care delivery system. [3,4] Findings of a systematic review revealed that the prevalence of counterfeit drugs is high throughout Africa and Asia in lower income countries and lower middle-income countries.[5] Although, no single country is immune to the problem, the manner in which countries have been affected is variable ranging from production and trade of illegal medicines in developing countries and consumption of fake drugs by consumer in developed countries. [4,6,7] However, amidst globalization, no strict compartmentalization can be ascertained to differentiate the level and aspects of concerns in different countries. Internet pharmacies, non-regulated outlets and parallel import of drugs have been identified as the potential sources of counterfeit drugs.^[5,8,9] The exact burden of the problem is still unclear because of variable definitions for counterfeit medicines and inadequate surveillance mechanisms in majority of the resource-poor countries.^[4,7]

Multiple key factors such as lack of political will;[7] absent or weak national drug regulating authority; [8] inadequate legislations or loopholes in existing legislations; [6] poor cooperation among different stakeholders;[1,7] lucrative business due to continued high demand for medicines and low production costs;[1] lack of awareness about ill-effects of counterfeit medicines among the general community/health care professionals/ pharmacists; [1,9,10] poor socio-economic status; [6] health illiteracy; [6,10] globalization and free trade policies; [1,7] and availability of medicines outside conventional and government-regulated networks viz., internet pharmacies;[7] have been identified that have contributed to a great extent in making counterfeiting possible. Counterfeit medicines can result in a wide range of adverse consequences ranging from non-relief

symptoms, non-adherence, ineffective treatments as they may endanger patient safety, emergence of community-wide resistance, damage to the reputation of drug companies and even death, if they contain toxic substances.^[8,10,11]

Counterfeiting of medical products is flourishing in most of the countries because the health authorities alone are ill-equipped to adequately address the situation.^[7] To combat the menace of counterfeit medicines following steps can be implemented by the Governments based on the local settings namely

- First and foremost requirement is to have an exact estimate of the nature and extent of the counterfeit drugs problem in the country so that scarcely distributed resources can be utilized to the optimal extent^[7]
- The policy makers should formulate a comprehensive policy to address all the potential threats in the field of counterfeit medicine market^[7]
- Subsequently strategy should be to actively involve all stakeholders namely health authorities, drug regulatory authorities, wholesalers, retailers, police, customs, judiciary, pharmaceutical industry and patients. [3,7] Creating awareness among the population regarding generic drugs and the dangers of the illicit medicines with the help of appropriate mass media aids is of paramount importance [10]
- Designing appropriate laws with the help of legal department and facilitating their strict enforcement;^[6] providing legal assistance to the consumers; and employment of strict pharmacovigilance mechanisms^[7]
- Organizing training sessions for the benefit of pharmacists and health care professionals in different aspects of counterfeiting^[8,10]
- Building of a network to strengthen collaborative activities at local, district, regional, national and international levels;^[8] and ensuring continuous monitoring and evaluation of implemented measures^[8]
- Adoption of newer technologies like use of cost-effective electrophoresis devices/more sophisticated devices for warranting quality assurance of drugs.^[12]

To conclude, counterfeiting medicines is a widespread public health concern that has significant direct and indirect impact on health and quality of life. Thus, governments should not only create awareness among the community about the menace but also foster development of strategies to promote intersectoral coordination between different public and private stakeholders.

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