EDITORIAL

SUBSTANDARD AND COUNTERFEIT DRUGS; A THREAT TO HEALTH

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Globally the ever-present issues of substandard medicines remain a challenge. World Health Organization (WHO) defines substandard medicines as genuine medicines provided by the manufacturer which do not meet quality specifications set for them by national standards. Substandard medicines include products with poor physical characteristics (for example friable tablets), inadequate quantity of the active ingredients, poor dissolution or bioavailability profiles and those that are poorly packaged and/or labeled. Counterfeit medicines on the other hand can be described as medicines that are deliberately and fraudulently mislabeled with respect to identity or source. They may contain the wrong active ingredient or no active ingredient and are of lesser value than the genuine product. Substandard medicines are often produced by licensed manufacturers but counterfeits can be produced in backyards, small industries or even at home.

The Kenyan market is flooded with various generic medicines and it is not always indicative that the products still meet expected quality once they have been granted marketing authorization. Certain loopholes, particularly illegal importation of medicines via the country's porous borders, allow substandard and counterfeit medicines to enter the drug supply chain. These defective medicines may be subject to illegal hawking and sale or may indeed find their way into the authorized supply chain. At their very best, these medicines are ineffective to the patient and at their very worst, they tend to cause harm to the patient, promote development of drug resistance and increase morbidity and mortality rates.

Pharmacy and Poison's Board (PPB) is the national medicines regulatory authority in Kenya and together with the analytical arm of National quality control laboratory (NQCL) and Drug Analysis and Research Unit (DARU) ensure that pharmaceutical products are actively regulated and comply with set specifications for safety and effectiveness. However, these bodies face major challenges in the bid to protect the public from substandard and counterfeit drugs. DARU reported that between 2001 and 2005, 10.7-55.4% of antibiotic medicines failed to meet quality specifications. This finding was probably linked to the emergence of resistance against commonly used antibiotics during this period. In the year 2000, DARU reported identification of Panadol® junior tablets that contained the wrong ingredient (aspirin instead of paracetamol) and faulty packaging.

Concerns about high healthcare costs have resulted in tremendous utilization of generic products. According to the United States Food and Drug administration (USFDA), generics should only be marketed if they are bioequivalent and pharmaceutically equivalent to the originator or original drug. The large numbers of generic products locally may hamper pharmacovigilance efforts allowing the infiltration of substandard and counterfeit medicines. Circulation of substandard drugs is encouraged by the fact that drugs manufactured for export are often not regulated to the same standard as those manufactured for domestic use. In developing countries there is an abundance of small-scale suppliers who may supply the substandard or counterfeit medicines.

Substandard medicines may pose various risks to the population. Product contamination can lead to toxicity and fatalities as highlighted by various cases in literature. In October 2004, a doctor working for Medicines Sans Frontier in Darfur reported that a local donation of ringer's lactate was contaminated with fungal growth. The death of 86 children in Haiti in 1996 after ingestion of paracetamol that contained the anti-freeze diethylene glycol, which led to acute kidney failure in those who ingested it, is another grave example. Recently in Kenya, some batches of gentamycin injection were recalled as they were reported to cause adverse reaction of severe headaches. On the worldwide front, all valsartan medications formulated using drug from a Chinese manufacturer were recently recalled due to contamination of the active pharmaceutical ingredient with a carcinogenic impurity. **The presence of suboptimal amounts of active pharmaceutical ingredient** compromises the treatment causing progression of the disease, antimicrobial resistance, increased morbidity and mortality rates. A study done in Nigeria in 2001 found out that almost half of randomly samples antibiotics and antiparasitics did not comply with the pharmacopoeia limits, containing less amounts of the active pharmaceutical ingredient, thus posing and a threat of development of antimirobial resistance and hence prolonged illness. **The social and economic effects of substandard medicines cannot be ignored.** The patient using these ineffective medicines may lose confidence in health care professionals including their physician and pharmacist and potentially modern medicine as a whole. These patients also suffer from economic losses occasioned by unsuccessful therapy and worsening illness. The spread of substandard medicines also has political ramifications, undermining the governments' investments in health delivery systems and its credibility with respect to providing quality health care.

Constant surveillance of marketed medicines through infrastructure development and capacity building in the country would strengthen quality assurance. For instance, imported drugs should routinely be tested on arrival so as to ensure that commercially available drugs in the market conform with the pharmacopoeial standards.