Abstract

Background:

The use of herbal medicines is global, with the majority of the world’s population depending on traditional medicines, particularly herbal remedies for their primary healthcare needs. In Kenya, it is estimated that conventional healthcare system provides for approximately 30% of the population, while nearly 70% rely on herbal remedies. Herbal medicines, however, present safety concerns as they carry a relatively high risk of contamination by pathogenic microbes, organic and inorganic pollutants including toxic metals and non-metals, organic, mycotoxins, endotoxins, and agrochemical residues.

Objective: This study was designed to assess the microbial quality of regulated and unregulated herbal medicinal products in diverse Kenyan markets, such as the supermarkets, roadside vendors, retail pharmacies and herbal clinics, for levels of microbial contaminants. Materials and Methods: Thirty samples of registered and unregistered herbal medicinal products were collected by purposive sampling from five Kenyan provinces. Microbial load analysis was performed in accordance to pharmacopoeial methods (BP and USP). Microorganisms were further isolated and characterized using differential and selective media and by biochemical analyses.

Results: All registered products had microbial load below 100 cfu/ml, and complied with BP and USP requirements. However, none of the unregistered samples complied with pharmacopoeial limits for either or both bacterial and fungal load limits. Most of the unregistered samples had microbial loads ranging from $3.00 \times 10^6$ to $1.56 \times 10^{10}$ cfu/ml, thus exceeding by far BP or USP standards. The microbial isolates belonged to fifteen (15) different bacterial genera and seven (7) fungal genera. *Escherichia coli* was the most frequently isolated bacteria from 75% of the unregistered product samples while *Klebsiella pneumoniae*, *Enterobacter aerogenes*, and *Staphylococcus aureus* followed in 70%, 60% and 45% of the samples, respectively. *Salmonella* spp was isolated in 40% of the samples while *Shigella* spp was found in 20% of the samples.

Conclusion: Unregulated herbal medicinal products that are available in diverse Kenyan markets show poor microbial quality and exhibit contamination by pathogenic microorganisms. There is need to extend regulatory control by the drug authorities to herbal medicinal products to enhance microbial quality and safety.