EDITORIAL

ADULTERATION OF HERBAL PREPARATIONS

Adulteration in the context of herbal medicines is the intentional introduction of extraneous ingredients into a product. The objects of such adulteration include drugs for clinical effectiveness, industrial dyes to modify appearance and substitution to enhance quantities. Historical reviews demonstrate that adulteration is an old vice as recorded by Dioscorides in *Materia Medica*, Pliny the Elder in *Naturalis Historica* and Pomet's, *A Complete History of Drugs*. In the 17th century, King James granted a separate charter to the Apothecaries Guild to distinguish them from general merchants of the Grocers Guild. He remarked that 'the business of the apothecary is a mystery', hence less likely to be influenced by adulteration. The desire to guard against adulteration and sophistication led to the development of specific legislation and pharmacopoeias in various jurisdictions.

Current anecdotal evidence shows adulteration of herbals with contraceptives and phosphodiesterase type 5 (PDE-5) inhibitors. In one case encountered in Nairobi, a herbal product marketed for contraception was found to contain more than ten times the levonorgestrel levels in regular pills. Incidentally, this product was being taken by a breast-feeding mother whose infant daughter started developing precocious symptoms, hence the investigation that revealed contamination with levonorgestrel. In another incident, a herbal aphrodisiac, was analyzed and found to be spiked with tadalafil. Herbal aphrodisiacs seem to be prime targets for adulteration since they are popular among middle aged and older men. This cohort commonly suffer from chronic conditions that contraindicate use of conventional PDE-5 inhibitors, yet adulterated products contain the same.

Numerous research reports on adulteration of herbal pharmaceuticals and food supplements have been published since the turn of the 21st century. Traditional and complimentary medicines have rapidly gained popularity in contemporary society due to the belief that they are efficacious with little or no side effects. Thus, they command a huge market share which fraudsters yearn to exploit. What better way to benefit from their business potential than to disguise allopathic medicines as herbals while their customers stay satisfied with the clinical effects? Traditional Chinese Medicines (TCM) for instance have an established global market hence are attractive and vulnerable to adulteration. On a smaller scale, African Traditional Medicines (ATM) are also undergoing adulteration with allopathic drugs of established efficacy in order to render credence to therapeutic claims. Recent published reports have shown adulteration of TCM and ATM with aphrodisiacs, antihypertensives, antidiabetics, analgesics, weight loss agents, contraceptives among other drugs.

The big question is: 'why are herbal medicines targeted for adulteration'? The answer to this question lies in the regulatory frameworks at play regarding production, distribution and dispensing of herbal medicines. In Kenya, for instance, traditional medicine is controlled by the Ministry of Gender, Sports, Culture, and Social Services which does not have the capacity to effectively regulate the products. This loophole is therefore exploited by unscrupulous vendors and charlatans to deceive the public about unverified and false claims as well as sale of ineffective, falsified or adulterated products. The same can be said for several other African countries.

Detection and verification of adulterated products is achieved through post-market surveillance and subsequent testing. Specific chromatographic and hyphenated testing methods such high performance thin layer chromatography (HPTLC), high performance liquid chromatography (HPLC), gas chromatography (GC), liquid chromatography - mass spectrometry (LC-MS) and gas chromatography - mass spectrometry (GS-MS), are required for these types of analyses. This calls for the establishment of dedicated and adequately equipped specialized laboratories with suitably trained manpower for functionality. Such laboratories normally gain experience with time and build up databases which in turn support timely analysis of suspect samples. The coupling of such analytical expertise with other areas of herbal drug development could provide a basis for self-sustainability through the generation of

intellectual property. This issue of the journal features a research article by Dumba et al. describing the determination of adulterants in aphrodisiac herbals whereby sildenafil, tadalafil and vardenafil were encountered.

Since most adulterated herbal medicines are promoted for chronic diseases, adulterant drugs may induce long-term adverse effects and may result in deaths. It is an opportune time for governments to institute measures to curb the vice of adulteration in order to protect the public. This would involve establishment of a policy and regulatory framework, market authorization system, expert committees, national pharmacopoeias, testing laboratories, and good manufacturing practice (GMP) guidelines. Enactment of enabling legislation for effective regulation and control of herbal drugs, food supplements and traditional medicine practice is also key in this endeavor. Additionally, formal training of traditional medicine practitioners would contribute greatly to professionalism and ethical adherence. These strategies coupled with public education and regular post-market surveillance will improve the herbal medicine landscape to the benefit of all legitimate players.

Controlling the herbal medicines market and curtailing sale of adulterated products requires intensive investment of requisite resources by concerned government agencies. In this regard, it is encouraging to note that the study by Dumba et al. was supported by Makerere University and the National Drug Authority, a government regulatory agency in Uganda.

Prof. Kennedy O. Abuga

Assistant Editor-in-Chief