EDITORIAL

CHALLENGES IN PHARMACEUTICAL REGULATION

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The emergence of a wide range of pharmaceutical products with various uses calls for the tightening of the regulatory process by the local National Medicines Regulatory Authority (NMRA). In Kenya, the NMRA is the Pharmacy and Poisons Board (PPB). The regulatory process requires that all pharmaceutical products have their pharmacological efficacies, safety and toxicological profiles clearly established before being registered for distribution and consumption in the market. Since all drugs are poisons, proper regulation and registration is to ensure end-user and patient safety.

Challenges still face the regulatory process as the market is infiltrated by unscrupulous business people and quacks who sell products to consumers with total disregard to the consequences that follow thereafter. The matter worsens as drugs such as antibiotics that should be prescription-only medicines find their way along the roadside, in shops, and are being hawked in buses and stages to unsuspecting clients. The sellers of such unregulated products have mastered the art of convincing their customers and tapping into their desperation by selling them hope through their harmful products. It is not uncommon to find products that are advertised to enhance sexual performance, treat infertility and other gynecological problems, or cure HIV and cancer, being the best sellers. Most of these are supposedly herbal remedies, though a huge number are products of, or related to, conventional medicines.

The field of cosmetics is yet another area that requires strict regulation because many products that purport to lighten skin, enhance certain body parts, and promote weight loss, among other claims, are readily found in the mainstream market. Some of these products are laced with harmful ingredients such as mercury and hydroquinone in quantities that are beyond those recommended for dermatological use. Furthermore, these products are not necessarily subjected to quality control processes, and they do not meet the labelling requirements of pharmaceutical products, nor do they bear the relevant warnings. The use of such unregulated products found in the market results in the end-users experiencing harmful effects of the products.

The PPB must enhance their market regulation to restore sanity and ensure consumer safety, whether through increased juridical enforcement or review of the existing legal framework. Other relevant stakeholders such as regulatory affairs pharmacists of the different Pharmaceutical companies should ensure that the products they submit for registration consideration meet the set requirements and their quality are assured. Outlets in the retail sector should have qualified personnel practicing ethically, stocking and dealing only in those products duly registered by the PPB. This fight is a tough one and is expected to be long drawn, but all the relevant stakeholders must be ready and willing to join in to win.