LOCALISATION AND WIDENING THE AMBIT OF MEDICINAL LAW - *(Tatenda Dumba, Senior Associate)*

As of the 17th of February 2017, the Medicines and Related Substances Act of 2013 ("the Medicines Act") replaced and repealed the Drugs and Related Substances Act Cap 63;04 ("Drugs Act").

The new Medicines Act requires that local, Botswana companies only, may operate in the medicinal industry. It also widens its ambit in respect of the authorisations to be obtained, the regulation of cosmetics and medical devices.

Under the old Drugs Act, there was a registration requirement for the importation, exportation, manufacturing, distribution and selling of the drugs. In terms of the new Medicines Act, the registration requirement has been widened to include the promotion, advertising, storing or dispensing of the drugs in addition to what was previously provided in terms of the Drugs Act. The old Act only provided guidelines in the manner of advertising or promoting drugs but had no explicit requirement to ensure that prior to an entity promoting, marketing such a drug, it must be registered.

The old Drugs Act had no limitations as to which entity could apply for the registration of such a drug, provided the regulatory Authority was satisfied with the entity's standards of good practice. However, in terms of the Medicines Act, there is a limitation imposed on the type of entity that can apply for such a registration. Section 24 (2) of the Act provides that an application to register the medicines shall be made by a company that is registered, licensed or operating in Botswana. The company must be registered in accordance with Botswana's Companies Act, either as an external company or locally incorporated entity.

Essentially, the company has to have a commercial and physical presence in Botswana. This initiative is obviously derived from the citizen empowerment mandate.

A notable feature in the Medicines Act is the new regulation and governance of cosmetics. Cosmetics in terms of the Medicines Act means any substance or mixture of substances manufactured, sold or represented for use by rubbing, pouring, spraying, or applying by any other means to the human body, for the purpose of cleansing, beautifying or altering the appearance or any article intended for use as a component of a cosmetic. Prior to the Medicines Act coming into effect, there were no rules pertaining to the manner of selling, manufacturing, safety and labelling of cosmetics.

To protect the public, in light of the growing trend of use of cosmetics, the Medicines Regulatory Authority has seen it fit that this aspect be regulated. Registration of cosmetics is now a requirement prior to any importation, exportation, manufacturing, distribution selling, promotion, advertising, storing or dispensing of such a cosmetic.

In addition to cosmetics, medical devices are now regulated and governed. The old Drugs Act did not cover medical devices, nor was there any legislation that governed this. In terms of the Medicines and Act, the definition of medicine includes any medical device. Thus, the Medicines Act intends to govern not only drugs but medical devices. Medical devices have been defined as an instrument, apparatus, implement, implant, medical equipment, machine and contrivance. There is a registration requirement for medical devices similar to that pertaining to medicines and an entity applying for such registration in relation to medical devices has to be a resident company in Botswana.

The medicine industry therefore should take heed of these notable changes introduced by virtue of the Medicines Act.