

Laws change for complementary and alternative medicines in SA

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Our clients who manufacture, distribute, import or export complementary and alternative medicines are affected by new draft legislation which brings these products under the ambit of the Medicines and Related Substances Act No.101 of 1965.



Under the Act, complementary medicines are now defined as any substance or mixture of substances that:

- a) Originates from plants, minerals or animals
- b) Is used or intended to be used for, or manufactured or sold for use in assisting the innate healing power of a human being or animal to mitigate, modify, alleviate or prevent illness or the symptoms thereof or abnormal physical or mental state
- c) Is used in accordance with the practice of the professions regulated under the Allied Health Professions Act, 1982 (Act No. 63 of 1982)

Manufacturers of complementary and alternative medicines are now required to submit their products to the Medicines Control Counsel (MCC), who will evaluate these substances for safety, efficacy and quality before either registering them or rejecting the application.

Distributors, importers and exporters of these products will also be required to apply for licenses to conduct these activities.

The consequences for the informational packaging industry are that we will have to comply with the new regulations pertaining to labelling, packaging inserts and patient information leaflets. This provision will come into force as from 15 February 2014.

Further implementation of the amended regulations will take place in phases, with deadlines for the registration of specific categories of complementary medicines scheduled for 6 months, 24 months and 30 months from the publication date.

Until such time as a complementary medicine has been successfully registered, it will have to contain the following notice:

"This medicine has not been evaluated by the Medicines Control Council. This medicine is not intended to diagnose, treat, cure or prevent any disease."

Pyrotec PackMedia endeavours to keep our clients updated on new developments pertaining to this legislature. Should you have any questions, please do not hesitate to [contact us](#).

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