BIZCOMMUNITY

Complementaries of the season

By Neil Kirby

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Complementary medicines, long unregulated in South African law, are now formally included in the General Regulations ("the General Regulations") promulgated in terms of the Medicines and Related Substances Act No. 101 of 1965, as amended ("the Medicines Act").

The Minister of Health published regulations in the Government Gazette on 15 November, 2013, formally incorporating complementary medicines into the Medicines Act and the General Regulations. Consequently, a formal system of regulation now applies to complementary medicines. Therefore, manufacturers, importers, distributors and retail agents will have to comply with the amended regulations under the Medicines Act in respect of complementary medicines.

A complementary medicine is now formally defined in law as follows. "... 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; and
- (c) is used in accordance with the practice of the professions regulated under the Allied Health Professions Act, 1982 (Act No. 63 of 1982)". (Emphasis added.)

The definition of complementary medicine, unlike the definition of "medicine", which appears in section 1 of the Medicines Act, is inserted into the regulations. In addition, the definition uses the word "and" after subsection (b), which means that the legislature intended for us to read the components of the definition conjunctively. Therefore, a substance that fails to meet one of the requirements of the definition is not considered to be a complementary medicine. This has important consequences for the application of the definition and its scope and ambit in respect of those substances currently available in the South African marketplace. An interesting component of the definition is the reference to the Allied Health Professions Act No. 63 of 1982 ("the AHPA"). The AHPA regulates certain health care professionals, including chiropractors, homeopaths and acupuncturists. The precise scope of practice of the Allied Health Professions, governed by the AHPA, will have to be scrutinised in order to determine whether or not substances are used by those professions, the nature of the substances used and how those substances now conform with the definition of "complementary medicine". Based on this analysis, any substance that is not used by a profession regulated by the AHPA is not a complementary medicine.

How the regulations are to be implemented

That having been said, the amendments to the regulations in terms of the Medicines Act include a detailed section relating to how the regulations are to be implemented in respect of complementary medicines and various timeframes applicable to the implementation of the regulations. A new regulation 48C sets out the particular requirements of how the regulations will

begin to apply to complementary medicines. Therefore, labelling provisions, currently applicable to medicines, will be applicable to complementary medicines on or about 15 February, 2014. As at 15 November, 2013, certain categories of complementary medicines have to be registered. These categories are set out in amended regulation 48C(2) and are identified as antiviral agents, oral hypoglycaemics, cardiac medicines and cytostatic agents - in accordance with regulations 48C(2)(a)(i). A further category of now complementary medicines is identified for registration purposes in regulation 48C(2)(b)(i). These substances are identified as slimming preparations, male sex hormones, female sex hormones and androgen-oestrogen combinations "claiming sexual stimulation and sexual dysfunction" are required to be registered within 24 months of the date of the publication of the regulations, i.e. by November 2014. However, these substances would have to be formally incorporated into the definition of "complementary medicine" to the extent that they are used by one of the professions governed by the AHPA. Currently, it is not certain which of the professions governed by the AHPA claim use of these substances as part and parcel of the professional scope of practice of that profession.

The next category of complementary medicines identified in regulation 48C(c)(i), and which must be registered within 30 months of 15 November, 2013, are described as substances "claiming immune stimulation or expressions of similar connection and medicines falling in pharmacological classification 17 (medicines acting on muscular system) and pharmacological classification 22 (vitamins) claiming to be sport supplements and exceeding the upper limit of vitamins and minerals as published by [the Medicines Control Council] ... ". Once again, questions relating to how the aforementioned substances are used by professions governed by the AHPA arise.

The last category identified in regulation 48C(2)(d) are all of the remaining complementary medicines that fall into pharmacological classifications set out in in the regulations, which must be registered by no later than December 2019.

Significant consequences for the complementary medicines industry

The formal regulation of complementary medicines has significant consequences for the complementary medicines industry in so far as that industry is now required to conform with the provisions contained in the regulations to the Medicines Act. Such a change in the law means significant changes in the business structures and the manner in which business is conducted by persons operating within the complementary medicines sector in South Africa. In addition, there are requirements on persons who are involved in the complementary medicines sector to ensure that they not only ensure compliance with the amended regulations, but also legislation such as the Consumer Protection Act No. 68 of 2008 and its regulations based on a more careful analysis of how that consumer legislation intersects and interacts with the Medicines Act and its now amended regulations.

All of that having been said, there seems to be a significant disconnect between the new definition of "complementary medicine" and the substances regulated by regulation 48C. Such a disconnect calls into question the legality of the amendments to the regulations - an aspect that may deserve closer investigation.

ABOUT NEIL KIRBY

Neil Kirby is director: health care and life sciences law of Werksmans. He is the chair of the Medicine and Law Committee of the International Bar Association. Kirby has been named

as a leading lawyer in Dispute Resolution by Chambers Global: The World's Leading Lawyers for Business (2008 - 2013), and has published numerous articles in his various fields of speciality.

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