

## Legal Status of e-Cigarettes in South Africa

### MEDICINE CONTROL REGULATION

In 2009, the South African Pharmacy Council resolved that it would not endorse the sale of e-cigarettes and referred the matter to the Medicines Control Council (MCC) to determine whether the sale of electronic cigarettes is regulated under medicine control.

(Council Resolutions July 2009: E-Cigarettes. Pharmacia Dec 2009, 17(3):8).

In this regard, a number of changes to the schedules of the Medicines and Related Substances Act, 101 of 1965 (MRA) were recently published by the Minister of Health and are effective immediately.

As has been noted in the Medical Chronicle, May 2012:

“According to Lorraine Osman, head: public affairs at the Pharmaceutical Society of SA (PSSA), all prescribers and suppliers of medicines need to be aware of the changes and the implications for both consumers and healthcare professionals.

#### Scheduling status of nicotine

“In cases where a substance appears in more than one schedule, the default schedule for the substance is the highest schedule in which it is listed,” explained Osmond. All entries of the same substance in lower schedules indicate an exception to the default schedule. To illustrate this point, the scheduling status of nicotine becomes easier to understand if read from Schedule (S) 3 to S1.

S3 states that nicotine, when intended for human medicinal use as an aid to smoking cessation or as a substitute for a tobacco product (as defined in the Tobacco Products Control Act, 1993, as amended), is an S3 substance, except when registered and presented as nicotine gum or lozenges (S0, S2), metered sprays containing 1mg per dose or less (S2), nicotine transdermal patches for continuous application to the skin (S1, S2), oral solid dosage forms containing 2mg or less (S2) or as inhalers containing 10mg or less per cartridge (S2).

“In other words, nicotine is an S3 substance if it is intended as an aid to smoking or as a substitution for a tobacco product,” she said. Exceptions are however made for products that comply with the requirements for sale in a pharmacy as S1 or 2 substances, and for those that may be sold as S0 products, i.e. in general retail outlets.

“One of the interesting aspects of this change is that there has been a lot of debate about whether or not the electronic cigarette (e-cigarette) is now scheduled and may only be sold on a doctor’s prescription,” noted Osmond.

The Pharmaceutical Society of SA requested the Medicines Control Council (MCC) to clarify the scheduling status of nicotine, with particular respect to so-called e-cigarettes.

The response pointed out that nicotine, when sold as a substitute for a tobacco product, will be classified as an S3 substance, unless the product is registered by the MCC after consideration of its safety, quality and efficacy. All other nicotine-containing e- cigarettes that are used as a tobacco substitute, whether registered with the MCC or not, may therefore be sold only on prescription.”

The MCC has now confirmed that electronic cigarettes are subject to medical scheduling and can only be sold at pharmacies, and therefore, at present, the MRA does appear to regulate the sale of electronic cigarettes.

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