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Where there's smoke ...?

20 January 2013 - Is an electronic cigarette a tobacco product or a remedial medical product? Does this artificial smoke-free device lessen the stigma of smoking? Are e-cigarettes properly controlled? How does it influence the way tobacco is promoted in the media? Irshad Motala takes a penetrating look at the controversial issue of the regulation and promotion of electronic cigarettes in South Africa.

A. INTRODUCTION

1. In this matter, the author has been asked to discuss and analyse whether electronic cigarettes are regulated in South Africa presently.

2. The author has reviewed various sources, as set out below.

B. THE TOBACCO PRODUCTS CONTROL ACT

3. The Tobacco Products Control Act 83 of 1993 (the Act) likely does not apply to electronic cigarettes because it only regulates "tobacco products".

4. The words "tobacco product" is defined to mean "a product containing tobacco that is intended for human consumption, and includes, but is not limited to, any device, pipe, water pipe, papers, tubes, filters, portion pouches or similar objects manufactured for use in the consumption of tobacco".

5. Therefore, the product must contain tobacco before it falls within the aforementioned definition. In the case of electronic cigarettes, they do not contain tobacco, and therefore do not fall within the ambit of the aforementioned definition.

6. However, section 3(1)(a) of the Act provides that "No person shall advertise or promote, or cause any other person to advertise or promote, a tobacco product through any direct or indirect means, including through sponsorship of any organisation, event, service, physical establishment, programme, project, bursary, scholarship or any other method."

7. The words "advertisement" and "advertise" "in relation to any tobacco product-

   (a) means any commercial communication or action brought to the attention of any member of the public in any manner with the aim, effect or likely effect of-

      (i) promoting the sale or use of any tobacco product, tobacco product brand element or tobacco manufacturer's name in relation to a tobacco product; or

(ii) being regarded as a recommendation of a tobacco product;

(b) includes product placement; and

(c) excludes commercial communication between a tobacco manufacture or importer and its trade partners, business partners, employees and share holders and any communications required by law, and 'advertise' has a corresponding meaning"

8. The word "promotion" in turn "is the practice of fostering awareness of and positive attitudes towards a tobacco product, brand element or manufacturer for the purposes of selling the tobacco product or encouraging tobacco use, through various means, including direct advertisement, incentives, free distribution, entertainment, organised activities, marketing of brand elements by means of related events and products through any public medium of communication including cinematographic film, television production, radio production or the internet, and 'promote' has a corresponding meaning".

9. An argument could be made that users of e-cigarettes are likely to (a) find the use of tobacco products to be acceptable, and (b) by advertising electronic cigarettes, the stigma associated with tobacco products is lessened, and therefore, advertising of electronic cigarettes has the "likely effect" of promoting the sale or use of tobacco products, or alternatively, fostering a positive attitude towards tobacco products.

10. Of course, this argument has not been tested to date, and it must be borne in mind that the aforementioned provisions must be interpreted restrictively. In this regard, any legislation which creates criminal or administrative penalties requires a restrictive interpretation.

(Oilwell (Pty) Ltd v Protec International Ltd and Others (2011 (4) SA 394 (SCA)) [2011] ZASCA 29; 295/10 (18 March 2011) at para 11).

11. The author therefore believes that absent clear evidence that a positive attitudes towards tobacco product or the promotion of the sale and use of tobacco products is caused by the advertising and promotion of electronic cigarettes, the provisions of the Act do not apply.

C. GENERAL ADVERTISING REGULATION

12. The Advertising Standards Authority (ASA) code of conduct may prohibit some of the representations made by the distributors of electronic cigarettes.

13. For example, Part 23 of section 3 of the Code provides:

"Smoking deterrents

No advertisements will be accepted for any smoking deterrent unless the advertiser makes clear that the product offers only assistance and not a cure, and that its success will be dependent upon the willpower of the user."

14. In addition, there is a duty on the advertiser to substantiate any claim made in an advertisement. Part 4.1.1 of section 2 of the Code provides:

"Before advertising is published, advertisers shall hold in their possession documentary evidence as set out in Clause 4.1, to support all claims, whether direct or implied, that are capable of objective substantiation."

15. It therefore follows that in situations where electronic cigarettes are promoted as a safer alternative to tobacco products, and furthermore, as a means to stop smoking, the following should be considered:

a. The advertiser must make it clear that it is merely assistance, and that the willpower of the user is crucial; and

b. The advertiser must also be in possession of documentary evidence to actually substantiate the fact that the electronic cigarette is safer and helps persons stop using tobacco products.

16. In D Beelders v. Smokestik SA CC, (Case No: 15322), ruling handed down on 27 July 2010, a complaint was made against an electronic cigarette distributor on the basis that the aforementioned provisions of the code had been contravened. However, the distributor agreed to withdraw its advertising and the matter was resolved in this manner.

17. Moreover, the Consumer Protection Act 68 of 2008 (CPA) would also probably require that the claims of manufacturers of electronic cigarettes be substantiated, failing which there advertising will be unlawful.

18. In this regard, section 41 of the CPA prohibits "False, misleading or deceptive representations", including cases where suppliers "use exaggeration, innuendo or ambiguity as to a material fact, or fail to disclose a material fact if that failure amounts to a deception", and furthermore, alleging that products "have ingredients, performance characteristics, accessories, uses, benefits, qualities, sponsorship or approval that they do not have".

19. More importantly, section 61 of the CPA makes "the producer or importer, distributor or retailer of any goods is liable for any harm" caused wholly or partially by any product they sell or distribute, including the failure to provide adequate warnings or hazards associated with the goods. The provision also provides that liability attaches regardless of negligence. The "harm" envisaged by the section includes "an illness of any natural person".

20. In light of the above, to the extent that the claims of the manufacturers of electronic cigarettes cannot be substantiated, the aforementioned regulatory framework applies. In addition, if it is factually proven that use of electronic cigarettes is hazardous, the failure to warn in relation to such hazards may be a further ground of liability to the supplier of electronic cigarettes.

D. MEDICINE CONTROL REGULATION

21. 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).

22. 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.

23. 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.
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> Scheduling status of nicotine
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> "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.
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> 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).
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> "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.
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> "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.
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> 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.
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> 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."

24. 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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