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Nicotine electronic cigarette sales are permitted under the Smokefree Environments Act

Summary—Here we (ML and End Smoking NZ) canvass some new thinking on tobacco and nicotine law. End Smoking NZ is a charitable trust dedicated to end the sale of traditional tobacco-containing tobacco products for smoking by 2020. Before this can be done, it is essential to free up access for smokers to effective, safer nicotine products. These products, we find, could theoretically, probably be sold now for recreational use under the Smokefree Environments (SFE) Act. For example, nicotine-containing electronic cigarettes (which simulate smoking, by vaporising nicotine into a mist without burning tobacco or creating smoke) could provide safer alternatives to cigarette smoking. Allowing time for regulations for safety reasons, which we support, it should be possible to permit approved brands of nicotine electronic cigarettes by 2011. This is better than waiting years until such brands can be approved as medicines.

Findings—Tobacco products in the SFE Act 1990, we find, are defined broadly, as products of tobacco, made from tobacco, whether or not they contain tobacco. Since nicotine is manufactured exclusively from tobacco, the nicotine in nicotine 'cigarettes', including nicotine electronic cigarettes, fits the SFE Act definition of tobacco product. This means nicotine-containing electronic cigarettes, can be sold, and sold for recreational or pleasurable purpose under the SFE Act, without negating the powers of Medsafe to approve and license the sale of medicinal nicotine products under the Medicines Act 1981. Some products, perhaps with different brand names, could eventually finish up obtaining approval under both Acts.

Current situation—Smoking cessation is a Ministry of Health priority, but the Ministry's enhanced cessation programme now embarked on, aided by substantial use of subsidised medicinal nicotine, is not expected to prevent more than a minority of smoking or cigarette-attributable deaths in the next few decades. A raft of new policies and products are needed to reduce cigarette smoking more rapidly.

For tobacco addicts, medicines have their limitations. Most smokers, most of the time, do not want medicines or to see the doctor about their smoking. Indeed, most probably regard themselves as healthy. Even when they quit, only 30% use medicinal nicotine. Smokers want to smoke, except for a few days per year when under half make a serious quit attempt. It is mostly nicotine they smoke for. An electronic cigarette emits about 100 times less toxicant than a regular cigarette. So why not let them inhale their nicotine without the toxic smoke?

Most drugs of pleasure, whether legal or not, attract regulation, and need a regulatory "home". Until now, we all assumed nicotine for human consumption only had only one home - the Medicines Act 1981. This has meant all nicotine must perforce be medicinal, whereas patently, it is not. Currently, non-nicotine electronic cigarettes can be sold, but any nicotine-containing electronic cigarette for sale must first be approved as a medicine –an expensive process, and none is, so far. Some are imported for personal use. In reality, 99% of nicotine is non-medicinal, inhaled for pleasure and

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regulated under the SFE Act. Inhaling vapour from a simulated cigarette for pure nicotine pleasure, subject to safety checks, could in fact gratuitously assist in reducing smoking mortality and morbidity, just as methadone is used successfully to treat heroin addiction.

The proposal—We propose that nicotine-containing electronic cigarettes be on general sale by the 2011 at the latest, under the SFE Act. This timetable allows for passage of the necessary Regulations in 2010, enabling testing and shop sales in 2011, which would:

- Be popular with smokers;
- Provide safer choices for smokers;
- Provide a cheaper, safer, alternative for smokers facing rising prices;
- Reduce consumption of tobacco cigarettes;
- Provide in future, a permanent alternative to continued cigarette sales.

The Minister of Health with suitable regulation of e-cigarettes, would be able to do what no previous Minister of Health has been able to do, that is, promise 100-fold risk reduction for continuing "smokers", something impossible, even with the strictest regulation, of commercial tobacco cigarette smoke.

For human consumption, it seems clear, we now have two Acts for nicotine, depending on how the purchaser wants to use the product – for recreational or medicinal purposes:

The SFE Act provides for recreational (non-medicinal) use of nicotine, General sale of cigarettes and electronic cigarettes is permitted, but no therapeutic claims can be made. No dose is prescribed.

The Medicines Act provides for the medicinal use of nicotine by various routes; and allows therapeutic claims, for example, about giving up smoking (example, nicotine patch). Some sales may be restricted to pharmacies, as with current medicinal nicotine inhalers. Guidance on dose and duration of treatment is given.

Definition of a tobacco product—"Tobacco product means any product manufactured from tobacco and intended for use by smoking, inhalation, or mastication; and includes nasal and oral snuff; but does not include any medicine (being a medicine that is sold or supplied wholly or principally for use as an aid in giving up smoking."

The definitional wording suggests that it is *the intention of the seller or supplier* that determines whether it is wholly or principally for use as an aid in giving up smoking. Thus the seller cannot make claims that it helps smokers quit.

Regulations to control for possible hazardous substances in nicotine electronic cigarettes—The Smokefree Environments Act at Section 31, permits Regulations to limit or remove hazardous substances or additives of concern. Although in the one brand studied (Ruyan), few hazardous substances were identified, and only in small amount, this cannot be assumed to apply to all brands without a monitoring system. Regulations should ensure ongoing, regular and random monitoring, and could be financed from charges on the brands to be licensed for sale.

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