MINISTRY OF HEALTH
MANATŪ HAUORA

New Zealand Government

Policy Options for the Regulation of Electronic Cigarettes

Consultation submission

Your details

This submission was completed by: *(name)* Joel L. Nitzkin, MD, MPH, DPA

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Organisation *(if applicable)*:

Position *(if applicable)*:

(Tick one box only in this section)
Are you submitting this:

X as an individual or individuals (not on behalf of an organisation)?

☐ on behalf of a group, organisation(s) or business?

(You may tick more than one box in this section)
Please indicate which sector(s) your submission represents:

☐ Commercial interests, including e-cigarette manufacturer, importer, distributor and/or retailer

☐ Tobacco control non-government organisation

☐ Academic/research

☐ Cessation support service provider

☒ Health professional

☐ Māori provider

☐ Pacific provider

☐ Other sector(s) *(please specify)*:

(You may tick more than one box in this section)
Please indicate your e-cigarette use status:

☐ I am using nicotine e-cigarettes.

☐ I am using nicotine-free e-cigarettes.

☐ I currently smoke as well as use e-cigarettes.

☒ I am not an e-cigarette user.

☐ I have tried e-cigarettes.

Privacy

We intend to publish all submissions on the Ministry's website. If you are submitting as an individual, we will automatically remove your personal details and any identifiable information.

If you do not want your submission published on the Ministry's website, please tick this box:

☐ Do not publish this submission.

Your submission will be subject to requests made under the Official Information Act. If you want your personal details removed from your submission, please tick this box:

☒ Remove my personal details from responses to Official Information Act requests.

If your submission contains commercially sensitive information, please tick this box:

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Declaration of tobacco industry links or vested interest

As a party to the global tobacco control treaty, the World Health Organization Framework Convention on Tobacco Control, New Zealand has an obligation to protect the development of public health policy from the vested interests of the tobacco industry. To help meet this obligation, the Ministry of Health asks all respondents to disclose whether they have any direct or indirect links to, or receive funding from, the tobacco industry. The Ministry will still carefully consider responses from the tobacco industry, and from respondents with links to the tobacco industry, alongside all other submissions. Please provide details of any tobacco company links or vested interests below.

I have no direct link to any of the relevant industries – cigarette, e-cigarette or pharmaceutical. I have an indirect link by virtue of the role I play as Senior Fellow for Tobacco Policy for the R Street Institute. R Street is a moderate, right-of- center libertarian think tank in Washington DC that respects the role of government to protect health and the environment, but objects to what they perceive to be governmental over-reach not justified by protection of the community. They do not accept governmental funds, but do accept support from anyone in the private sector. My role at R Street is to advise them on tobacco policy, not to serve as a spokesman for policy recommended by others.

Please return this form by email to:

ecigarettes@moh.govt.nz by **5 pm, Monday 12 September 2016**.

If you are sending your submission in PDF format, please also send us the Word document.

The Author: I am a public health physician, board certified in Preventive Medicine as my Medical Specialty. I have served as a local health director and state health director (USA) and President of two American public health organizations. I have been active in tobacco control since the 1970's, but never as program staff. My involvement with the e-cigarette issue began in 2007, when on behalf of the American Association of Public Health Physicians, I reviewed and advised them on the then newly introduced American tobacco control law. I was appalled at what I perceived to be provisions protecting the cigarette industry (primarily Altria/Philip Morris) and provisions all-but-prohibiting introduction into the market of lower risk tobacco products and provisions prohibiting manufacturers to claim lower risk than cigarettes, even with extremely strong evidence of such reduced risk.

Consultation questions

Although this form provides blank spaces for your answers to questions, there is no limit to the length of your responses; you should take as much space as you need to answer or comment. Feel free to enlarge the boxes or attach additional pages.

Q1 Do you agree that the sale and supply of nicotine e-cigarettes and nicotine liquids should be allowed on the local market, with appropriate controls?

Yes ☒ No ☐

Reasons/additional comments:

The combustible tobacco cigarette is the most addictive and most hazardous of tobacco products, yet is the dominant vehicle for nicotine in Western Society. In the USA, cigarettes kill an estimated 480,000 Americans per year, with numbers of deaths from all other tobacco products combined so few in numbers that none are tracked by federal authorities. A range of smokeless tobacco products, e-cigarettes and related vapor products present a risk of potentially fatal tobacco-related illness less than 5% the risk posed by cigarettes, and, currently available evidence shows that e-cigarettes may be reducing teen addiction by diverting teens who would otherwise start smoking to the less addictive e-cigarettes, and even zero nicotine e-cigarettes.

Q2 Are there other (existing or potential) nicotine-delivery products that should be included in these controls at the same time? If so, what are they?

Yes ☒ No ☐

Reasons/additional comments:

Snus, moist snuff, chewing tobacco, and likely heat-not-burn tobacco products, and other smokeless options. While we have no information on how teens would react to them, everything we know about how tobacco causes addiction and potentially fatal illness tells us that they likely present less than 5% the risk posed by cigarettes.

Q3 Do you think it is important for legislation to prohibit the sale and supply of e-cigarettes to young people under 18 years of age in the same way as it prohibits the sale and supply of smoked tobacco products to young people?

Yes ☒ No ☐

Reasons/additional comments:

Three reasons: 1. Teens are more prone to become addicted to cigarettes and other addictive products than adults. 2. There is some animal evidence that nicotine might inhibit normal brain development in adolescents. 3. The nicotine, per se, may be hazardous to pregnant women, in terms of prematurity and stillbirth.

Q4 Do you think it is important for legislation to control advertising of e-cigarettes in the same way as it controls advertising of smoked tobacco products?

Yes ☐ No ☒

Reasons/additional comments:

Controls on advertising are certainly in order to minimize use by teens. Such controls, however should be far less stringent that for cigarettes. Health warnings other than the potential for addiction would be inappropriate, and "plain packaging" would be inappropriate.

Rather than model regulation of e-cigarette advertising on cigarette advertising, it should be modelled on the marketing of the over-the-counter nicotine replacement therapy pharmaceuticals (gums, patches, lozenges, etc).

Q5 Do you think it is important for the SFEA to prohibit vaping in designated smokefree areas in the same way as it prohibits smoking in such areas?

Yes ☐ No ☒

Reasons/additional comments:

Smoking is prohibited in non-smoking areas to prevent bystanders from being exposed to toxic smoke so concentrated that it can increase the risk of heart attack, and possibly some forms of cancer. The vapour exhaled by e-cigarette users poses no such hazard. While it does contain traces of some toxic chemicals, the concentrations are so low that it is not measurable over background levels in most indoor environments.

Q6 Do you agree that other controls in the SFEA for smoked tobacco products should apply to e-cigarettes? For example:

Control	Yes	No	Reasons/ additional comments
Requirement for graphic health warnings	☐	☒	Theoretical risk is trivial
Prohibition on displaying products in sales outlets	☐	☒	It should be more readily available and more readily marketed than cigarettes
Restriction on use of vending machines	☒	☐	Access by teens
Requirement to provide annual returns on sales data	☒	☐	Progress and use should be tracked in a manner similar to the tracking of cigarette sales to document public health benefit or lack thereof.
Requirement to disclose product content and composition	☒	☐	As with any consumable consumer product
Regulations concerning ingredients (eg, nicotine content and/or flavours)	☒	☐	Since e-cigarette vapour is inhaled, the purity of the ingredients deserves attention. Nicotine content should be kept well below toxic levels, but not limited because of an unjustified concern of recruiting non-smoking teens.
Requirement for annual testing of product composition	☐	☒	
Prohibition on free distribution and awards associated with sales	☐	☒	Sampling should be allowed in vape shops to adult customers.

Prohibition on discounting	☐	☒	
Prohibition on advertising and sponsorship	☐	☒	
Requirement for standardised packaging	☒	☐	e-cigarette liquids for consumer use should be in child-resistant containers
Other	☒	☐	The laws should permit vape shops to custom-mix liquids to meet customer needs and preferences, but with regulations similar to restaurant regulations to assure attention to sanitation, hygiene and quality of ingredients used

Q7 Do you think it is important for legislation to impose some form of excise or excise-equivalent duty on nicotine e-liquid, as it does on tobacco products?

Yes ☐ No ☒

Reasons/additional comments:

E-cigarettes should be seen as potentially beneficial to current smokers and as products that are very unlikely to lead to long term harm for non-users. This being the case, taxation of e-cigarettes should be based on how taxes are levied on over-the-counter nicotine replacement therapy pharmaceutical products (gums, patches, lozenges, etc).

Q8 Do you think quality control of and safety standards for e-cigarettes are needed?

Yes ☒ No ☐

Quality standards for the manufacture of e-liquids have been proposed and are being periodically updated by the American E-Liquid Manufacturing Standards Association (www.aemsa.org). Many manufacturers already adhere to these standards, but, because this is a voluntary rather than governmental organization, they have no way of mandating compliance.

Additional comments:

Area of concern	Yes	No	Reasons/additional comments
Childproof containers	☒	☐	For the protection of infants and small children in the home. Hazard to children is minimal and likely limited to vomiting. The childproof containers should minimize parent anxiety, calls to poison control centres and emergency room visits because of the anxiety.
Safe disposal of e-cigarette devices and liquids	☒	☐	The main issue is the lithium battery. This should be reflected in the disposal guidelines. Other than that, there should be no disposal concerns.

Ability of device to prevent accidents	☒	☐	Governmental authorities should consult with industry experts on how best to minimize, if not eliminate the risk of explosions and fires.
Good manufacturing practice	☒	☐	
Purity and grade of nicotine	☒	☐	Should be pharmaceutical grade
Registration of products	☒	☐	
A testing regime to confirm product safety and contents purity	☐	☒	
Maximum allowable volume of e-liquid in retail sales	☐	☒	
Maximum concentration of nicotine e-liquid	☒	☐	For e-liquids for consumers, limited only that they are well below toxic levels (not limited to prevent teen recruitment)
Mixing of e-liquids at (or before) point of sale	☒	☐	Should be permitted, but regulated as noted above.
Other	☒	☐	Given the continuing rapid evolution of vapour products, an advisory committee should be formed by which e-cigarette industry experts can meet with public health authorities on a regular basis to discuss new products, surveillance data and changes that might be appropriate for both regulations and public communications.

Q9 Are there any other comments you would like to make?

Two sets of issues have been largely neglected to date. The first is the potential public health benefits of adding a tobacco harm reduction component to current public health programming, with e-cigarettes as a major, but not the only harm reduction modality. To facilitate this, and as documentation to support statements made above, I urge reading of one or both of two papers I generated two years ago, that continue to be supported by more recent research. The first was written for legislators and attorneys in Washington, DC, with a more detailed explanation of how I, as a public health physician, came to advocate on behalf of e-cigarettes. This paper can be downloaded from http://www.rstreet.org/wp-content/uploads/2014/07/20140630FDLI-EcigForum.pdf . The second, written for a medical and scientific audience can be downloaded from http://www.mdpi.com/1660-4601/11/6/6459.

The second set of issues has to do with the tendency within the public health community to condemn the use of all non-pharmaceutical tobacco-related products on the basis of tradition and bias within the public health community, without regard to the scientific evidence and real-life experience in favor of major personal and public health benefits. A discussion of this issue can be found at http://ntr.oxfordjournals.org/cgi/reprint/ntw104?ijkey=iflKpog6Q2x9V5z&keytype=ref

The thinking of American and most, if not all, international public health authorities is that there can be no personal or public health benefit to any nicotine delivery product not licensed as a drug. While readily admitting that e-cigarettes are far less hazardous to the user than cigarettes, there is no consideration of the possibility that this difference in risk could possibly offer public health benefits. For this reason, American authorities do not attribute any of the remarkable recent reductions in adult and teen smoking to e-cigarettes. The voluminous research now being funded by the American Food and Drug Administration (FDA), working through the National Institutes of Health (NIH) is almost entirely intended to document potential personal and public health harms and risks of e-cigarettes and to gather baseline data against which progress in reducing e-cigarette use might be measured. The only significant exception to this rule seems to be limited to research into e-cigarette efficacy for short-term smoking cessation, if one uses e-cigarettes according to pharmaceutical protocols.

This mindset by public health authorities makes balancing risks and benefits by regulators problematic, if one starts with the premise that potential benefits are not to be considered.

Additional information on sales and use

Q10 Can you assist us by providing information on the sale of e-cigarettes in New Zealand (for example, size of sales or range of products for sale on the local market)?

Sorry, can't help you on this question.

Q11 Would the Ministry of Health's proposed amendments have any impact on your business? If so, please quantify/explain that impact.

no

Q12 If you are using nicotine e-cigarettes: how long have you been using them, how often do you use them, how much do you spend on them per week and where do you buy them?

How long have you been using them?	How often do you use them?	How much do you spend on them per week?	Where do you buy them?
never tried one			