

12 September 2016

Ministry of Health  
PO Box 5013  
Wellington 6145

By email: [ecigarettes@moh.govt.nz](mailto:ecigarettes@moh.govt.nz)

## **Policy Options for the Regulation of Electronic Cigarettes**

Dear Sir/Madam

The New Zealand Medical Association (NZMA) wishes to provide feedback on the consultation document '*Policy Options for the Regulation of Electronic Cigarettes*'.<sup>1</sup> The NZMA is New Zealand's largest medical organisation, with more than 5,500 members from all areas of medicine. The NZMA aims to provide leadership of the medical profession, and to promote professional unity and values, and the health of all New Zealanders. Our submission has been informed by feedback from our Advisory Councils and Board.

### **General Comments**

1. We note that, after considering evidence and concerns about e-cigarettes, the Government has agreed, in principle, to nicotine e-cigarettes being legally available for sale and supply in New Zealand, with appropriate legislative and regulatory controls. As noted in the consultation document, the long-term risks and benefits of e-cigarettes are uncertain. There is ongoing scientific debate about whether e-cigarettes are an effective tool for smokers who want to quit. At the same time, there is general scientific consensus that the exclusive use of e-cigarettes is significantly less harmful than smoking. There are also some concerns that the availability of these products could undermine current tobacco control initiatives (though there are countervailing views that e-cigarettes could contribute to tobacco control initiatives).

2. Given the above considerations, we take the view that a cautious, yet pragmatic, approach to e-cigarettes is warranted. We are supportive, in principle, of making e-cigarettes legally available in New Zealand (though there are differing views on what form this availability would take). Our support for making e-cigarettes available is strictly contingent on an appropriate regulatory regime that ensures due care for unintended harms and risks. We elaborate on our

---

<sup>1</sup> Policy Options for the Regulation of Electronic Cigarettes: a consultation document. Ministry of Health. Wellington. August 2016. Available from <http://www.health.govt.nz/system/files/documents/publications/policy-options-e-cigarette-regulation-consultation-aug16.pdf>

views in our responses to the specific questions below. We also believe it vital for the Ministry to closely monitor the emerging evidence relating to e-cigarettes, both in New Zealand and overseas, and for the Government to be in a position to modify proposed legislative/regulatory/policy responses as necessary.

## **Specific Comments**

### ***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?***

3. We agree that nicotine e-cigarettes and nicotine liquids for such devices should be legally available in New Zealand, subject to the appropriate controls being in place. Key controls include prohibiting sale and supply to people under 18 years and the introduction of requirements for quality control. We elaborate on the most important aspects of a regulatory regime in our answers to questions 3 to 8.

4. There are mixed views on *how* e-cigarettes and nicotine liquids should be made legally available. At one end of the spectrum, some have argued that they should be available only as a harm reduction product to current smokers who want to quit, either by the requirement for a prescription or by restricting their sale to a limited number of licensed specialist shops (with stipulations about proximity to schools, and training for staff in cessation support). However, others do not believe that these products or their liquids should be prescribed, and support their general sale and supply, subject to a rigorous regulatory regime that prevents sale to young people.

5. Internationally, medical profession views diverge on the use of e-cigarettes as a quit or harm-reduction tool. In a 2015 position statement, the Australian Medical Association recommends that “E-cigarettes must not be marketed as cessation aids as such claims are not supported by evidence at this time”.<sup>2</sup> By contrast, a recent report by the Royal College of Physicians, recommends that “in the interests of public health it is important to promote the use of e-cigarettes, NRT and other non-tobacco nicotine products as widely as possible as a substitute for smoking in the UK”.<sup>3</sup> If nicotine-containing e-cigarettes are to be promoted as a smoking cessation aid, then we suggest there is a need to ensure they receive the appropriate regulatory approval under the Medicines Act (or its replacement).

### ***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?***

6. We are not aware of other nicotine-delivery products but in light of the rapid innovation in the area of alternative nicotine products, we agree that the regulatory regime be future-proofed to ensure it covers all existing and future nicotine-delivery products.

### ***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?***

7. Yes, we consider it of paramount importance that legislation prohibits the sale and supply of e-cigarettes to young people under 18 years. This precaution is necessary for the following reasons: i) the evidence about potential health harms of e-cigarettes, particularly over the longer term, is inconclusive; ii) nicotine is an addictive and psychoactive substance, although the degree

---

<sup>2</sup> Australian Medical Association. Tobacco smoking and e-cigarettes. December 2015. Available from <https://ama.com.au/position-statement/tobacco-smoking-and-e-cigarettes-2015>

<sup>3</sup> Royal College of Physicians. Nicotine without smoke: Tobacco harm reduction. London: RCP, April 2016. Available from <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0>

of dependency on e-cigarettes is likely to be similar to that with other NRT products; iii) nicotine e-cigarettes are being promoted in ways that appeal to children (eg, the use of cartoons and highly sexualised imagery) and their use is being depicted as ‘cool’, although the effectiveness of such advertising may be less than supposed.<sup>4</sup>

***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?***

8. We note some calls for limiting commercial marketing of e-cigarettes to point of sale (to avoid exposure to children and young people). There is uncertainty over whether or not e-cigarettes may be a so-called ‘gateway’ product to smoked tobacco products.<sup>5</sup> However, there is emerging evidence that exposing children to e-cigarette advertising may not increase the appeal of smoking tobacco cigarettes.<sup>6</sup> We are aware of some advertisements for e-cigarettes overseas that are offensive for various reasons, including sexualisation or deliberate criticism of smokefree environments.<sup>7</sup> We strongly believe that there should be restrictions on these types of egregious advertisements.

***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?***

9. There are mixed views on whether vaping should be prohibited in designated smokefree areas. While there is currently a lack of evidence to demonstrate immediate harms from second-hand vape, there are still grounds to support a ban in designated smokefree areas. These include uncertainty over whether or not e-cigarettes may be a so-called ‘gateway’ product (the evidence for this is very unclear), concerns over the addictive nature of nicotine, and concerns about e-cigarettes becoming ‘cool’ and used by industry to normalise smoking.

10. A compromise solution, as mooted by the National Smokefree Working Group (NSWG)<sup>8</sup> (with whom we agree), could be to ban e-cigarettes in all indoor workplaces and public places (consistent with the 1990 SmokeFree Environments Act), all schools and in selected outdoor locations such as areas where children predominate (eg, playgrounds and parks) but to allow e-cigarettes in other smokefree areas at local discretion. Clear signage should indicate where vaping is permitted, and these areas should be separate from “smoking permitted” areas.

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

11. With the exception of the requirement for graphic health warnings, we consider that all of the other controls in the SFEA for smoked tobacco products might apply to e-cigarettes. These controls might include the following: prohibition on displaying products in sales outlets; restriction on use of vending machines; requirement to provide annual returns on sales data; requirement to disclose product content and composition; regulations concerning ingredients (eg, nicotine content and/or flavours); requirement for annual testing of product composition; prohibition on free distribution and awards associated with sales; prohibition on discounting; prohibition on advertising and sponsorship; requirement for standardised packaging.

---

<sup>4</sup> Petrescu DC, et al. What is the impact of e-cigarette adverts on children's perceptions of tobacco smoking? An experimental study. *Tob Control*. 2016 Sep 5. pii: tobaccocontrol-2016-052940. Available from <http://tobaccocontrol.bmj.com/content/early/2016/08/12/tobaccocontrol-2016-052940.full.pdf+html>

<sup>5</sup> National Smokefree Working Group. E-cigarettes and their potential contribution to achieving the Smokefree 2025 goal. Background Paper. 18 August 2016. Available from <https://aspire2025.files.wordpress.com/2016/08/nsfwg-e-cig-and-their-potential-contribution-to-achieving-smokefree-2025.pdf>

<sup>6</sup> Petrescu DC, et al. 2016

<sup>7</sup> National Smokefree Working Group. E-cigarettes and their potential contribution to achieving the Smokefree 2025 goal. Background Paper. 18 August 2016. Available from <https://aspire2025.files.wordpress.com/2016/08/nsfwg-e-cig-and-their-potential-contribution-to-achieving-smokefree-2025.pdf>

<sup>8</sup> Ibid

12. In saying the above, however, we recognise the risks of people not accessing e-cigarettes to the extent they might, and hence the lost health opportunities from people remaining on, or starting, cigarette smoking itself. The evidence either way is highly unclear.<sup>9</sup> In addition, vapour is not smoke (with different lung deposition patterns and uptake), and we are aware of some *in vitro* evidence suggesting heavy vapour use is no more harmful on lung epithelia than air.<sup>10</sup>

***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?***

13. No. The availability of a fiscal instrument such as an excise duty would be a useful lever to influence patterns of consumption if e-cigarettes are made available and as more evidence about their use emerges. However, we agree with the stance of the NSWG to maintain the status quo,<sup>11</sup> ie, no additional tax or excise duty applied to nicotine-containing e-cigarettes and e-liquids, and for review if there is evidence of substantial uptake of nicotine-containing e-cigarettes by non-smoking children and young people and with commensurate increased uptake of cigarette smoking. Excise tax on nicotine-containing e-juice could reduce accessibility to those groups that may benefit the most from e-cigarettes as an alternative to smoking cigarettes (eg, Māori and Pacifica).

14. If any such regimens were to be introduced, then the excise structure would need to reflect the differences in harm between smoking cigarettes (most harmful), vaping nicotine-containing e-cigarettes (considerably less harmful than smoking), vaping non-nicotine products (possibly negligible harm),<sup>12</sup> and not smoking / not vaping (the least harmful). Regimens would need to discriminate between e-juice that contains tobacco product and that which does not, or if nicotine has been derived from tobacco (which we understand is how laws are currently being circumvented in the USA).

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

15. Yes, we believe that quality control of, and safety standards for, e-cigarettes are definitely needed. Currently, there are concerns about the long-term effects of e-liquids, the safety of some e-liquid flavours, and the effects of e-cigarettes on pregnant women and their foetuses. There are also concerns around the lack of standards and regulations for nicotine levels which can vary widely. As such, we are in favour of regulations setting the requirements and standards for the following: childproof containers; disposal of e-cigarette devices and liquids; safety of devices in terms of their ability to prevent accidental burns, explosions and spillage; good manufacturing practice; purity and grade of nicotine; registration of products; a testing regime to confirm product safety and contents; maximum allowable volume of e-liquid in retail sales; maximum concentration of nicotine e-liquid; mixing of e-liquids at (or before) point of sale.

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

16. In addition to the controls identified in paragraph 11, we suggest that the following measures are necessary if e-cigarettes are to be made available: licensing of e-liquid suppliers/producers to facilitate monitoring; appropriate pharmacovigilance to detect unforeseen health consequences; controls around the components of e-liquids (eg, butyric acid has the potential for lung toxicity if vaped in large doses); further research with respect to the use of e-cigarettes as a form of nicotine replacement therapy; further research with respect to associations

---

<sup>9</sup> Ibid

<sup>10</sup> Neilson L, et al. Development of an *in vitro* cytotoxicity model for aerosol exposure using 3D reconstructed human airway tissue; application for assessment of e-cigarette aerosol. *Toxicol In Vitro*. 2015 Oct;29(7):1952-62

<sup>11</sup> National Smokefree Working Group. E-cigarettes and their potential contribution to achieving the Smokefree 2025 goal. Background Paper. 18 August 2016. Available from <https://aspire2025.files.wordpress.com/2016/08/nsfwg-e-cig-and-their-potential-contribution-to-achieving-smokefree-2025.pdf>

<sup>12</sup> *In vitro* evidence suggests heavy vapour use is no more harmful on lung epithelia than air (Neilson L, et al. 2015)

between the uptake of e-cigarettes and the incidence of cigarette smoking and of new cigarette smokers, alongside population risks of cumulative vaping.

17. Finally, given that evidence on the potential benefits and harms of e-cigarettes is still equivocal, but is emerging at a rapid rate, we recommend that any regulatory arrangements are subject to ongoing and comprehensive review of all evidence, including outcomes in terms of the impacts on tobacco smoking rates. It is vital to ensure that the government retains the flexibility to implement more stringent measures to control the availability of e-cigarettes should future evidence emerge of harm.

We hope that our feedback has been helpful and look forward to learning the outcome of this consultation.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Steve Child', written in a cursive style.

Dr Stephen Child  
NZMA Chair