

[In Confidence]

Office of the Associate Minister Health

Chair, Cabinet Social Policy Committee

Electronic-cigarettes: policy options and approval to consult

Proposal

- 1 The Committee is asked to agree that the Ministry consults publicly on proposals to adjust the legal status of e-cigarettes, allowing their availability with appropriate controls.

Executive Summary

- 2 E-cigarettes are a relatively new and evolving product. The existing regulatory provisions in the Smoke-free Environments Act 1990 (SFEA) and the Medicines Act 1981 (Medicines Act) are not adequate to control them. The legal status of e-cigarettes is confusing and the laws are not routinely enforced because of the lack of clarity. Currently the sale and supply of nicotine e-cigarettes are prohibited while smoked tobacco, which is more harmful for users, can be sold legally. Users obtain nicotine e-cigarettes, a potentially addictive product, through importation and illegal, local sales.
- 3 The risks and benefits of e-cigarettes are uncertain. There is a lack of clarity about long-term product safety, and health risks to users and non-users. It has also been suggested that the availability of these products could undermine tobacco control initiatives. There is ongoing scientific debate about whether e-cigarettes may be another tool for smokers to quit. At the same time, there is general scientific consensus that the use of e-cigarettes is less harmful for smokers if they completely switch.
- 4 I therefore propose to clarify the legal position so that all e-cigarettes (with and without nicotine) are available for sale and supply lawfully in New Zealand, but that sale is restricted to people 18 and over, that advertising of e-cigarettes is restricted, and that the use of e-cigarettes is prohibited in smoke-free places. This will require legislative change.
- 5 I also propose to explore whether other controls for legal, smoked tobacco products should be applied to e-cigarettes and if there is a need for quality control and product safety.
- 6 Public consultation will be required before precise regulatory proposals can be put forward. I propose the Ministry of Health undertakes public consultation on the proposals in this paper, and reports back to Cabinet by the end of October 2016.

Background

What are e-cigarettes?

- 7 E-cigarettes are electrical devices that mimic smoked tobacco products but produce a vapour (rather than smoke) by heating a solution (e-liquid) which the user then inhales or vapes. Vaping is the term that describes the use of e-cigarettes.

- 8 E-liquids are available with or without nicotine and usually contain flavouring agents. There are many different flavourings available including flavours such as chocolate, candy floss, popcorn and tobacco.
- 9 E-cigarettes have been available on the international market since 2005. Early on, most e-cigarettes looked like smoked cigarettes but these have evolved into a range of products – from those that looked similar to cigarettes (first generation) to refillable tank systems (second generation) and devices with large batteries and adjustable power (third generation).

First generation



Second generation



Third generation



Evidence

- 10 Even though nicotine is a psychoactive, addictive substance which in large quantities can be lethal, the long-term use of small quantities of nicotine in Nicotine Replacement Therapy products (NRT - such as gum, patches and lozenges) does not seem to pose harm.
- 11 The scientific consensus is that the use of e-cigarettes is less harmful for smokers than continuing to smoke, and that short-term use is associated with few adverse effects. Vapers often report they vape because they want to reduce the harm from smoking tobacco.
- 12 A 2014 Cochrane review on the use of e-cigarettes for smoking cessation and reduction found that the quality of the evidence overall is low and only based on two randomised control trials¹. The review concluded that e-cigarettes appear to help smokers reduce their cigarette consumption when compared with placebo electronic cigarettes and nicotine patches however further studies are required to reach conclusive results.
- 13 In 2015 Public Health England commissioned and published an expert review report called *E-cigarettes: an evidence update*². This review concluded that e-cigarettes are significantly less harmful to health than smoked tobacco and have the potential to help smokers quit smoking.
- 14 The Royal College of Physicians published their report *Nicotine without smoke: Tobacco harm reduction*³ earlier this year. This report provides a fresh update on the use of harm reduction in

¹ http://www.cochrane.org/CD010216/TOBACCO_can-electronic-cigarettes-help-people-stop-smoking-or-reduce-the-amount-they-smoke-and-are-they-safe-to-use-for-this-purpose

² McNeill A et al. E-cigarettes: an evidence update - a report commissioned by Public Health England (2015) https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/457102/E-cigarettes_an_evidence_update_A_report_commissioned_by_Public_Health_England_FINAL.pdf

³ <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0>

tobacco smoking, in relation to all nicotine products that are not smoked, in particular e-cigarettes. It concludes that, for all the potential risks involved, harm reduction through smokers completely switching to e-cigarettes has huge potential to prevent death and disability from tobacco use, and to hasten our progress to a tobacco-free society.

- 15 In summary, there is emerging evidence that, if smokers switch completely to e-cigarettes, these products are a significant harm reduction tool but there is not yet enough data to assess the role of e-cigarettes as a smoking cessation tool.

The status quo

Ministry advice

- 16 The Ministry of Health has to date taken a precautionary approach and advised that there is not yet enough evidence to be able to recommend e-cigarettes as an aid to stop smoking. People are advised to use approved smoking cessation medicines, such as NRT to stop smoking and seek behavioural support from stop smoking services such as Quitline.
- 17 The Ministry monitors emerging research and is developing guidance for health professionals and stop smoking support workers on how to support smokers who want to use e-cigarettes to quit smoking.
- 18 Only approved medicines can be sold for smoking cessation support in New Zealand. At this time no company has met the requirements under the Medicines Act 1981 to have an e-cigarette approved to support smokers to quit.

Regulatory framework

- 19 The regulatory regime covering e-cigarettes in New Zealand, primarily the SFEA and the Medicines Act, was developed before the emergence of e-cigarettes. The Medicines Act and the SFEA regulate the sale, advertising and use of e-cigarettes and the liquids used in e-cigarettes. The SFEA regulates the sale, supply and advertising of tobacco products. E-cigarettes containing nicotine derived from tobacco are considered to be oral tobacco products, which are prohibited.
- 20 E-cigarettes are available for sale and supply in New Zealand and currently this is illegal if:
- the product contains nicotine derived from tobacco (breach of the SFEA)
 - therapeutic claims are made about them (whether or not they contain nicotine), for example, to assist with smoking cessation and they do not have a Medsafe approval for therapeutic use (breach of the Medicines Act).
- 21 The SFEA provides that products that look like smoked tobacco products (toy tobacco products) and that can be used to simulate smoking, must not be sold to persons under the age of 18. Apart from this requirement, nicotine-free e-cigarettes can be sold freely in New Zealand.
- 22 The use of e-cigarettes in smoke-free places is not prohibited by the SFEA. However, organisations and/or work places can prohibit the use of e-cigarettes as part of their own smoke-free policies. For example, they are prohibited on airlines and in Wellington City Council's smoke-free areas.

- 23 Under the Medicines Act and the SFEA, people can import nicotine-containing e-cigarette products for their own use. These imported products cannot be supplied, sold or given away to anyone else.

What is the problem with the status quo?

- 24 Currently the sale and supply of nicotine e-cigarettes are prohibited while smoked tobacco can be sold legally even though evidence is suggesting that smoking tobacco is more harmful for smokers than using e-cigarettes.
- 25 However concerns have been expressed about e-cigarettes, including the promotion of products which appeal to young people and non-smokers, product safety and quality control, the impact of vaping on others, the potential environmental impacts and the increasing role of the tobacco industry.

Enforcement

- 26 There is anecdotal evidence of illegal sales of nicotine e-cigarettes and nicotine e-liquid on the local market and the number of retailers and suppliers importing, supplying, selling and promoting nicotine e-products domestically is rising.
- 27 In 2012 the Ministry commenced enforcement action against an importer and distributor of nicotine-containing e-cigarettes in New Zealand. The company disputed the Ministry's legal interpretation and indicated it would defend the case on the grounds of an insufficient legal basis to ban sales.
- 28 The Ministry wrote to other New Zealand-based importers and distributors in 2013 informing them that they were breaching the law by distributing and selling nicotine-containing e-cigarettes.
- 29 Due to the lack of clarity in the legal position of e-cigarettes, the Ministry has been unable to carry out enforcement actions against a retailer due to difficulty of legal definitions and the adequacy of evidence. Enforcement action can only be taken if there is clear evidence that the retailer has been selling e-cigarettes for therapeutic purposes or products containing nicotine derived from tobacco.

Promotion to young people

- 30 There is some overseas evidence to suggest that promotion of e-cigarettes targets young people and that some e-cigarette flavours (such as chocolate, strawberry and mint) may particularly appeal to young people. Anecdotal evidence shows that nicotine and nicotine-free e-cigarettes are being sold to minors. There is concern young people's experimentation with and use of e-cigarettes may lead to nicotine addiction and/or have a gateway effect, leading to young people taking up smoking.
- 31 There is evidence of an increase in New Zealand young people trying e-cigarettes⁴:

⁴ It is important to note that survey questions in general did not make the distinction between nicotine and non-nicotine e-cigarettes and the relative consumption of these products is unknown.

- a 2014 survey found an increase in the percentage of Year 10 students having tried e-cigarettes, up from 7 percent in 2012 to 20 percent in 2014⁵.
- in another 2014 survey, 21 percent of students reported having tried an e-cigarette (most of them were non-smokers).

Product safety and quality control

- 32 There are no health and safety or quality controls for e-cigarettes available on the local market or from internet sales, which may put users and children who might access these products at risk, for example:
- there are no restrictions on the level of nicotine content or other potentially harmful ingredients
 - labelling of product content has been reported to be at times lacking or inaccurate
 - there are often no health warnings on products about potential risks of vaping during pregnancy, accidental nicotine poisoning and the need to keep products out of reach of children
 - there is no requirement for products to have child-proof containers which may lead to accidental poisoning.

Impact of vaping on others

- 33 There is insufficient evidence to assess the impact of long-term passive exposure to vaping.
- 34 There are concerns that the increasingly visible use of e-cigarettes may increase the risk of renormalisation of smoking behaviour and initiation to smoking, especially by young people.
- 35 Vaping is not regulated in smokefree places although organisations can include e-cigarettes in their smokefree policy. E-cigarette vapour can produce vaping clouds and smells which may be a nuisance to bystanders, especially in enclosed spaces.

Environmental impact

- 36 There is limited information on the impacts associated with the production, the usage, and the disposal of e-cigarette devices (eg, batteries) and their liquid. As the use of e-cigarettes increases, the potential chemical waste (such as lead and nicotine) and electronic waste (such as batteries and devices) is likely to become problematic. There are currently no disposal requirements in place for these products.

Tobacco industry involvement

- 37 There are indications that tobacco industry involvement has been increasing over the last few years⁶, however we do not have information available to quantify their current market share.

⁵ White J. et al. Tripling Use of Electronic Cigarettes Among New Zealand Adolescents Between 2012 and 2014. *Journal of Adolescent Health* 56 (2015), pp 522-528.

⁶ Example: *Tobacco industry's investment in non-cigarette nicotine products* by Tobacco Control Research Group at the University of Bath http://www.tobaccotactics.org/images/3/3b/Ecig_investment_timeline_Sept_2014.pdf

- 38 New Zealand is a Party to the WHO Framework Convention on Tobacco Control (WHO FCTC). A report on e-cigarettes to the sixth WHO FCTC Convention of Parties in 2014 included observations and considerations of the role of the tobacco industry - "The e-cigarette market, initially dominated by companies with no links to the tobacco industry, is increasingly owned by the tobacco industry. All main transnational tobacco companies sell e-cigarettes and one of them is launching legal proceedings over patents against its rivals. The increasing concentration of the e-cigarettes market in the hands of the transnational tobacco companies was considered to be of grave concern in light of the history of the corporations that dominate that industry"⁷.

What are other countries doing?

- 39 Overseas jurisdictions have applied their existing legislation to regulate e-cigarettes resulting in differing positions on e-cigarettes: for example, banning them from sale; regulating them as medicines, tobacco products and/or consumer products; or having very little regulation at all.

Policy objectives

- 40 I have considered the range of problems and concerns, the evolving evidence and international developments related to e-cigarettes and believe there is a need to review the current regulatory framework.
- 41 I propose the following policy objectives for the regulatory framework for e-cigarettes:
- harm reduction
 - harm prevention
 - product safety.

Harm reduction

- 42 It is difficult to assess the potential contribution of e-cigarettes to reducing harm from tobacco smoking and the potential contribution these products could make towards Smokefree 2025. For individual smokers, there is a growing consensus, based on evidence, that use of nicotine e-cigarettes is less harmful than tobacco smoking if smokers switch completely to e-cigarettes. There are few known side effects associated with short-term use of e-cigarettes. However, smoking, even at a reduced level, remains significantly harmful for smokers⁸.
- 43 Dual use of e-cigarettes and smoked tobacco products is not well understood. There is no long-term population data available to know whether the products help, delay or hinder dual users to quit smoking, although emerging evidence is showing that they may be useful in helping people to quit.
- 44 If a manufacturer or supplier of e-cigarettes wishes to make a therapeutic claim that their product is an aid to quit smoking, then they need to apply to Medsafe for approval to supply their product as a medicine. Medsafe estimates that such an application may cost between \$7,000 and \$88,000. This involves an assessment of the safety and efficacy of the product. To date no such products have been approved in New Zealand but the first application is in the

⁷ http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10Rev1-en.pdf?ua=1

⁸ Tverdal A, Bjartveit K. Health Consequences of Reduced Daily Cigarette Consumption. *Tobacco Control* 2006;15(6):472–80.

process of being assessed; this product has been granted marketing authority for smoking cessation in the UK.

Harm Prevention

- 45 The evidence about the potential health harms to the wider public is inconclusive because of a lack of data.
- 46 Concerns have been expressed about the promotion of e-cigarettes to young people and the potential risks that vaping in public places poses to both the objectives and enforcement of the SFEA.
- 47 There is some overseas evidence to suggest that advertising of e-cigarettes may be targeting young people. Data shows that the number of young people experimenting with e-cigarettes is growing and some researchers have suggested that e-cigarettes may act as a gateway to smoking for young people.
- 48 There is limited evidence available on the effects of e-cigarette vapour on bystanders. Although available data suggests that second-hand vaping has less harmful effects than second-hand smoking, concerns about vaping in public places are two-fold. First, there is the possibility that vaping behaviour normalises smoking. Second, concerns have been raised that vaping in smokefree places makes it difficult to enforce smokefree laws as it may not be clear, for example, whether someone is smoking or vaping.
- 49 Even though these concerns are unsubstantiated at this stage, it may be warranted – in the light of a lack of data – to apply a precautionary approach whereby the provisions of the SFEA prohibiting sales to minors, restricting advertising, and preventing their use in smokefree places are applied to e-cigarettes.
- 50 Because of this lack of evidence, especially about long-term use, it is difficult to make a robust assessment about whether e-cigarettes help or hinder progress towards the Government's goal of a Smokefree New Zealand by 2025.

Product quality and safety

- 51 There is some preliminary evidence to support the view that e-cigarettes are less harmful for users than if they continue to smoke tobacco, at least in the short term. Evidence of the long-term risks from the use of e-cigarettes and the health effects of second hand exposure to e-cigarette vapour is inconclusive at this point. Concerns relate to:
- long-term effects of e-liquids on users, especially vapourised nicotine, propylene glycol and vegetable glycerine
 - safety of some e-liquid flavours for inhalation
 - effects of e-cigarettes on pregnant women and their foetuses, infants and children, young people, people with respiratory and chronic illness.
- 52 Nicotine is highly addictive and can be poisonous in large amounts. There are potential risks of accidental or unknown exposure to nicotine (addiction) in e-cigarettes through:
- users unknowingly ingesting nicotine through products that are labelled as nicotine-free or do not list nicotine as an ingredient

- unreliable doses of nicotine delivered due to lack of standards and regulations around the manufacture and labelling of products⁹
- children being accidentally poisoned due to there being no requirement for child-proof packaging or warnings about the risks of poisoning.

Considering change - proposals for consultation

53 Given the lack of available evidence that would lead us to definitively conclude how or if e-cigarettes should be made available, I propose making changes that will maximise the potential benefits of e-cigarettes and minimise risks, not only to smokers but also the wider population.

54 It is important to consult on these proposals to ensure that advice from all stakeholders is considered to inform policy development.

55 I intend to consult on the following proposals with respect to e-cigarettes:

- E-cigarettes as therapeutic products: there is not enough evidence to be able to make a policy recommendation that e-cigarettes are useful as an aid to quit smoking.

However, suppliers of e-cigarettes who wish to market them for smoking cessation purposes can, under existing legislation, seek an approval from Medsafe. If approved, based on an assessment of the evidence for safety and efficacy, that particular product may be marketed as a smoking cessation tool.

I propose that the status quo remain.

- E-cigarettes as consumer products: there is a growing consensus, based on the evidence, that the use of e-cigarettes is less harmful for smokers than smoking if users make a complete switch and do not dual use (use both products).

However, the sale and supply of e-cigarettes containing nicotine derived from tobacco are currently deemed to be unlawful under the SFEA.

I propose to consult on amending the SFEA to make nicotine e-cigarettes lawful as a consumer product and to regulate all e-cigarettes in the same way as legal, smoked tobacco products. I intend to consult on the following proposals with respect to protecting the public from any negative consequences of the use of e-cigarettes:

- prohibit the sale of e-cigarettes to children and young people under the age of 18
- control advertising of e-cigarettes
- prohibit e-cigarettes in smoke-free places in order to:
 - prevent normalising of smoking behaviour
 - strengthen enforcement of the smokefree requirements.

⁹ Cheng, T. Chemical evaluation of electronic cigarettes *Tobacco Control* 2014, **23**, pp 11-17.

56 I propose to consult on whether other controls in the SFEA for smoked tobacco should apply to e-cigarettes, such as health warnings, labels, retail display and taxes.

57 I also intend to consult on the following proposals to enhance the quality and safety of e-cigarettes as consumer products:

- the need and process for setting standards for:
 - ingredients
 - childproof containers
 - disposal of products.

Next steps

58 I will report back to Cabinet by the end of October 2016 on consultation findings and proposals for specific regulatory changes to the SFEA and its regulations. I will also seek approval to issue drafting instructions to PCO for a draft amendment Act and for its draft regulations.

Consultation

59 The following agencies were consulted on this paper and their views are reflected: New Zealand Customs Service, the Ministry of Justice, New Zealand Police, the Environmental Protection Authority, and Consumer Protection within the Ministry of Business, Innovation and Employment. The Department of the Prime Minister and Cabinet was informed about this paper.

Financial Implications

60 There are no financial implications.

Human Rights

61 The proposals in this paper are consistent with the rights and freedoms contained in the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993.

Legislative Implications

62 There are no legislative implications associated with this paper. Cabinet decisions to be made subsequent to proposed public consultation may result in legislative change.

Gender Implications and Disability Perspective

63 Overall, the rate of daily smokers among men has been higher (according to the New Zealand Health Survey 16.1 percent during 2014/15) than the rate of daily smokers among women (13.9 percent). The daily smoking rate of Māori is higher (35.5 percent) than the total population (15 percent) and more Māori women (40 percent) smoke daily than Māori men (30.5 percent).

64 There are no particular matters with respect to disability perspectives.

Publicity

- 65 Publicity will occur around the proposed release of a consultation paper based on decisions in this paper. I intend to proactively release this paper.

Recommendations

The Associate Minister of Health recommends that the Committee:

1. **note** that e-cigarettes are relatively new and evolving products, which are not adequately covered by existing regulatory arrangements
2. **note** that, although there is uncertainty about the risks and benefits of e-cigarettes, there is a scientific consensus that they are less harmful for smokers than smoked tobacco
3. **agree** in principle to nicotine e-cigarettes being lawfully available for sale and supply, with appropriate controls, and to consult on the proposals set out below
4. **agree** to retain the requirement that e-cigarettes making a therapeutic claim, such as aiding smoking cessation, must have Medsafe approval that attests to safety and efficacy
5. **agree** that the Ministry of Health prepares a public consultation paper on e-cigarettes seeking feedback on the following:
 - a. legalising nicotine e-cigarettes as a consumer product, through an amendment to the Smokefree Environments Act
 - b. prohibiting the sale of all e-cigarettes (with and without nicotine) to children and young people under the age of 18
 - c. restricting advertising of all e-cigarettes
 - d. applying the provisions of the SFEA restricting the use of all e-cigarettes in smokefree places
 - e. exploring whether other controls for legal, smoked tobacco products should be applied to e-cigarettes
 - f. exploring the need and processes for quality control and product safety.
6. **agree** that the Associate Minister of Health will approve the release of the public consultation paper
7. **note** that, following public consultation, the Associate Minister of Health will report back to Cabinet by 31 October 2016 on proposals for the regulation of e-cigarettes
8. **note** that subject to decisions taken at the report back stage, these proposals would require amendments to the SFEA Act and to its regulations.

Authorised for lodgement

Hon Peseta Sam Lotu-liga
Associate Minister of Health