

In Confidence

Office of the Associate Minister of Health

Chair, Cabinet

Supporting smokers to switch to significantly less harmful alternatives

Proposal

- 1 This paper proposes to better support smokers to switch to significantly less harmful alternative products through:
 - 1.1 amending the Smoke-free Environments Act 1990 (SFEA) to improve smokers' access to quality vaping and smokeless tobacco products, while protecting children and young people from the risks associated with them.
 - 1.2 improving publicly available information on vaping.
- 2 These proposals align with the Government's priorities of equity and child health, including the focus area of the Child and Youth Wellbeing Strategy: *Children and young people and their families and whānau are empowered to make healthy lifestyle decisions for children and young people.*

Executive Summary

- 3 This paper focuses on one aspect of a broader programme of work towards achieving Smokefree 2025 – improving the regulation of vaping and smokeless tobacco products. I will report to Cabinet on the broader programme of work as it progresses.
- 4 Many people want to quit smoking, but this can be difficult, especially for those who face complex challenges in their lives. However, many smokers who find it hard to quit may be able to switch to much less harmful alternatives, such as vaping.
- 5 There is scientific consensus that vaping is significantly less harmful than smoking. It is likely that vaping also helps smokers to quit smoking but the evidence for the effectiveness of vaping as a stop-smoking tool is still emerging.
- 6 Vaping products can benefit smokers who are able to switch, however, they are not risk-free. In particular, the long-term health impacts are inadequately understood. Appropriate regulation is, therefore, important: products need to comply with safety requirements and access and promotion should be restricted to adults.
- 7 There are concerns that vaping may be a 'gateway' to smoking for young people. There is no robust evidence for this. Most young people who vape daily are smokers or ex-

smokers and smoking among young people is continuing to decline, even while experimentation with vaping is increasing.

- 8 Amendments to the SFEA are proposed, including to:
 - 8.1 clarify that all nicotine vaping liquid is covered by the SFEA and extend coverage to include nicotine-free vaping liquid, and vaping and smokeless tobacco product devices and components
 - 8.2 enable the prohibition of flavours and colours that attract children and young people to vaping and smokeless tobacco products
 - 8.3 prohibit vaping and the use of similar tobacco devices in legislated smokefree areas, with an exemption for specialist R18 retailers
 - 8.4 enable product safety requirements to be set for vaping and smokeless tobacco products
 - 8.5 implement a product notification system to support post-market action where concerns arise with a product
 - 8.6 introduce adverse reactions reporting and monitoring, product recalls, and suspensions and cancellations of product notifications.
- 9 A review of the enforcement regime is proposed, including the development of up-to-date offences and penalties.
- 10 The costs of establishing and running the regulatory regime are proposed to be recovered from industry through fees and levies, consistent with The Treasury's Guidelines for Setting Charges in the Public Sector.
- 11 A small number of minor clarifications and tidy-ups to the SFEA are also proposed as follows: to clarify an internal area of a premise where smoking is prohibited vis-à-vis an open area where smoking is allowed; clarify allowable content for manufacturers' price lists; and repeal the provision allowing tobacco advertising and sponsorship for multi-national sporting events taking place in New Zealand.
- 12 Once decisions are made by Cabinet, drafting instructions can be issued to Parliamentary Counsel Office with a view to having a Bill ready to introduce to Parliament in the first half of 2019.
- 13 In addition to regulatory change, the Health Promotion Agency is working with the Ministry of Health to develop a public information campaign on vaping. This will have an emphasis on supporting Māori women, who have New Zealand's highest smoking rates.

Background

New Zealand's Smokefree 2025 goal

- 14 New Zealand has a goal to be smokefree by 2025. This is generally agreed to mean that fewer than five percent of New Zealanders will smoke daily. Achieving this will be challenging: a recent study modelled the impact of a business-as-usual approach and projected smoking rates to reduce to 8.1 percent for non-Māori and 20 percent for Māori by 2025. Māori were not projected to reach five percent until 2061.

15 There is an opportunity to better support smokers to switch to significantly less harmful alternatives, however, we will need to improve:

15.1 the regulation of vaping and smokeless tobacco products

15.2 information available to the public and smokers.

Supporting smokers to reduce their harm from tobacco

16 While many people want to quit smoking, it can be very hard to do so, particularly for those who face complex challenges in their lives. Some people feel that smoking is their only pleasure, even if they want to quit, and need support beyond 'quit smoking' interventions.

17 There is evidence, based on recent research with Māori women, on what works to support smokers to deal with the many complex problems they face, including smoking. The Ministry of Health is using this evidence to develop a new approach to contracting stop-smoking services that provide holistic support to individuals and their families.

18 The emergence of vaping products, and other significantly less harmful alternatives to smoking, provides smokers with more choice. Many smokers who find it hard to quit may be able to switch to less harmful and often much cheaper alternatives.

19 The benefits to a smoker of switching include reducing the direct risks to their health and to their children's health from second-hand smoke, reducing the likelihood that their children will become smokers, and increasing their disposable income.

Evidence on the risks and benefits of reduced-harm tobacco products

20 Debates on the risks and benefits of reduced-harm tobacco products have focused on:

20.1 the role of vaping and smokeless tobacco products in reducing the harm from smoking and in helping people to stop smoking

20.2 whether vaping acts as a gateway to tobacco smoking for children and young people

20.3 the safety of products.

Harm reduction and support for smoking cessation

21 The tar and toxins in tobacco smoke, rather than the nicotine, are responsible for most of the harm associated with tobacco use. Vaping and smokeless tobacco products do not combust and are, therefore, highly likely to be much less harmful than smoking.

22 There is scientific consensus that vaping is significantly less harmful than smoking (around 95%). It is likely that vaping can also help smokers to stop smoking, but the evidence for vaping as an effective stop-smoking tool is still emerging. A number of large studies are underway and more information will be available over the next year.

23 A range of smokeless tobacco products are also used internationally as alternatives to smoked tobacco, for example:

23.1 heated tobacco products (devices that heat, rather than burn, tobacco sticks)

- 23.2 snus (tobacco, often in small sachets, that is placed in the cheek or under the lip), chewing tobacco and dissolvables.

Potential impact of vaping on children and young people

- 24 There is concern that experimentation may lead to regular vaping and then to smoking (ie, vaping acts as a gateway to smoking). However, there is no robust evidence to support this concern.
- 25 Two major reviews have been published this year that address this issue. The National Academy of Sciences in the United States and Public Health England considered the same evidence and concluded that there is an association between ever vaping and ever smoking at a later point in time. Both reports acknowledge that the studies included in the reviews have limitations and that it is not possible to conclude that vaping causes smoking.
- 26 Last year, the British Medical Association (BMA) concluded that current data on vaping and smoking does not support a gateway effect, noting that smoking has continued to decline over the same period that vaping has become increasingly available. This is the case in New Zealand, the United Kingdom and the United States.
- 27 The BMA also noted that the United Kingdom's laws to prevent uptake by children and young people (eg, no sales to under-18s, restrictions on advertising) are likely to have played a role. New Zealand's tobacco laws have similar protections for under-18s.

Vaping and smokeless tobacco product safety

- 28 While it is much less harmful to vape or use smokeless tobacco products than it is to smoke, there are inherent risks associated with the use of these products. These risks relate primarily to the toxicants present in products, however, there is also some risk with malfunctioning devices. These risks can be mitigated through product safety standards (eg, manufacturing standards, ingredients and child resistant closures).

The current regulatory framework

- 29 In *Philip Morris (NZ) Ltd v Ministry of Health* [2018] NZDC 4478, the Court found that Philip Morris's HEETS tobacco stick may be lawfully sold. Crown Law declined permission to appeal. Following this judgment and subsequent Crown Law advice, it is likely that all oral tobacco products (other than those that are chewed or 'parked' in the mouth), may be lawfully sold subject to largely the same regulatory controls that apply to cigarettes¹.
- 30 This adds to the complexity of the existing law, which was designed primarily for smoked tobacco products. I propose to amend the SFEA to address the following concerns:
- 30.1 there is a lack of clarity in the SFEA about which products can and cannot be lawfully sold
- 30.2 there have been significant practical barriers to enforcing the SFEA for vaping products, due to evidential difficulties proving that the nicotine in the product is manufactured from tobacco

¹ Tobacco excise applies to all tobacco products (smoked and smokeless) but not to nicotine vaping liquid.

- 30.3 the SFEA does not apply to vaping liquids that are not manufactured from tobacco or devices, meaning they can, for example, be sold to minors
- 30.4 the SFEA does not prohibit vaping or the use of similar devices in legislated smokefree areas, such as indoor workplaces and schools
- 30.5 the SFEA does not specify minimum product safety requirements, or expressly provide an ability to do so.

Proposals for the regulation of vaping and smokeless tobacco products

Public consultation

- 31 In August 2016, the Ministry of Health consulted publicly on the regulation of vaping products. 250 submissions were received from members of the public, clinicians, academics, vape businesses and tobacco companies. There was very strong support for the lawful sale of vaping products, provided they are appropriately regulated.
- 32 Most submitters (87 percent) supported a prohibition on sales to under 18s; just under half (44 percent) supported a prohibition on vaping in legislated smokefree areas; and a majority (53 percent) supported advertising restrictions of some sort, with 12 percent supporting a ban on all forms of advertising and promotion.
- 33 The public will have another opportunity to submit as part of the select committee process. In addition, consultation will be undertaken by the Ministry of Health in developing the detailed requirements which will be set out in regulations.

Regulating all nicotine and nicotine-free vaping liquid, devices and other components of vaping and smokeless tobacco products

- 34 The SFEA does not fully apply to vaping and smokeless tobacco products; nicotine that is not manufactured from tobacco (eg, synthetic nicotine), nicotine-free vaping liquids and devices can be sold to minors and used to circumvent laws prohibiting the advertising, promotion and sponsorship of tobacco products.
- 35 I propose that the Committee agree to bring all nicotine vaping liquid, nicotine-free vaping liquid, devices, and other components of vaping and smokeless tobacco products within the scope of the SFEA.

Protecting children and young people from the risks associated with the use of vaping and smokeless tobacco products

- 36 To protect children and young people from addiction and any other risks to their health, I propose to retain the prohibitions on sales to under-18s, promotion, sponsorship and advertising, and the requirement that sale via vending machines must be supervised by the salesperson. In addition, I propose to include a power in the Bill to enable the prohibition of flavours and colours that attract children and young people to vaping and smokeless tobacco products.

Develop tailored requirements for the provision of sales data

- 37 The SFEA requires manufacturers and importers to report annually to the Director-General of Health on volumes of tobacco sold. The reporting requirements set out in the

SFEA are not relevant to vaping liquid. I propose that the Committee agree to amend the SFEA to allow tailored requirements for different product types to be made by regulations.

Use in legislated smokefree areas

- 38 The SFEA prohibits smoking in indoor workplaces and certain public areas, such as schools. These laws were made primarily to protect employees from the known health risks associated with second-hand smoke.
- 39 I propose that the Committee agree to also prohibit vaping and the use of similar devices (eg, heated tobacco products) in legislated smokefree areas. This is a precautionary measure: there is no robust evidence of harm from second-hand vapour, however, increasingly visible vaping in public has the potential to normalise it. I believe it is important to signal that vaping should be viewed only as an alternative product for smokers.
- 40 I propose, however, that the Committee agree to exempt notified specialist R18 retailers from the prohibition on vaping indoors, as users need support and instruction to maximise their chances of a successful switch from smoking to vaping.

Setting product safety requirements

- 41 I propose that the Committee agree to insert into the SFEA an express power to set product safety requirements for vaping and smokeless tobacco products.
- 42 Product safety could be supported through a product notification process; that is, a web-based system administered by the Ministry of Health whereby manufacturers and/or importers notify products prior to marketing and self-certify that regulatory requirements are met. The main advantage is that, if any post-market action is required (eg, recall of a product that is causing harm), the Ministry would know who is accountable. In addition, it gives the Ministry a mechanism to communicate with industry (eg, to notify safety concerns or changes to regulations).
- 43 The regulatory regime should also require adverse reactions monitoring and reporting, allow for recalls of defective or harmful products, suspensions and cancellations of product notifications (eg, for providing false information or later evidence of harm), and the issuing of warning statements.

Offences and penalties

- 44 I propose that the legislation include up-to-date offences and penalties, aligned with similar legislation. The overall approach would continue with the SFEA's:
- 44.1 monetary penalties only, rather than custodial or community-based sentences
 - 44.2 use of infringement notices, which allow instant fines for low-level offending
 - 44.3 generally more lenient penalties for individuals as distinct from bodies corporate or manufacturers, importers or distributors.
- 45 Further work is proposed in consultation with the Ministry of Justice and Parliamentary Counsel Office. I propose to report back to Cabinet on the outcome of this work.

Regulation-making powers

- 46 The SFEA's existing regulation-making powers for tobacco products may need some modification for vaping and smokeless tobacco products. New regulation-making powers will also be needed, for example, to prescribe:
- 46.1 tailored annual sales data requirements for different types of tobacco product
 - 46.2 product safety requirements
 - 46.3 information requirements and other details related to product notifications
 - 46.4 fees and levies related to the establishment and running of the regime.

General review of the Act

- 47 I propose a review of the Act be undertaken as part of the drafting process to ensure that it works together as a whole with the new vaping and smokeless tobacco provisions.

Implementation

- 48 I seek agreement to prepare and issue drafting instructions for a SFEA Amendment Bill to enable the scheme.
- 49 Regulations and other subordinate instruments will need to be made under the SFEA to prescribe any technical and detailed requirements. The Ministry will work with stakeholders on the development of these requirements. I will report back to Cabinet in late 2019 seeking approval of any regulations that are required.

Additional amendments

- 50 Given that an amendment to the SFEA will be needed to implement Cabinet's decisions about the regulation of vaping and smokeless tobacco products, there are a small number of relatively minor additional amendments that could be made at the same time to:
- 50.1 enable an assessment methodology, which takes into account air quality, to be provided for in regulations to support a determination by business owners and Smokefree Enforcement Officers of whether a space within a premise is open (where smoking is allowed) or closed (where smoking is prohibited)
 - 50.2 enable allowable content for manufacturers' price lists (which are currently being used to promote incentives schemes to retailers) to be set out in regulations
 - 50.3 repeal the provision which allows an exemption from the SFEA's advertising and sponsorship prohibitions for multi-national sporting events (these exemptions are historic and were designed to allow the Whitbread Round the World Race (now the Volvo Ocean Race) to stop in New Zealand. In 1989-90 a number of yachts that stopped over in Auckland were sponsored by tobacco brands (eg, Rothmans).

Better information for the public and smokers about vaping

- 51 The Health Promotion Agency is working with the Ministry of Health to develop a new public information campaign on vaping. This will have an emphasis on supporting Māori

women, who have New Zealand's highest smoking rates. [REDACTED]

Broader action towards achieving Smokefree 2025

- 52 I am currently in discussion with officials on a broader range of regulatory and non-regulatory options to achieve Smokefree 2025. In addition to re-orienting stop-smoking services, I have sought advice on registering retailers, regulating the contents of products (eg, nicotine levels and flavours), and expanding outdoor smokefree areas.
- 53 In November 2017, Cabinet agreed to an independent evaluation of the impact of tobacco excise increases [CAB-17-MIN-0525 refers]. This evaluation is near completion and I will report its findings to Cabinet towards the end of 2018.

Consultation

- 54 The following departments and agencies were consulted on this paper and their views are reflected: Health Promotion Agency, New Zealand Customs Service, the Ministry of Justice, New Zealand Police, the Ministry of Business, Innovation and Employment (Commerce and Consumer Affairs), Te Puni Kōkiri, the Ministry for Pacific Peoples, Oranga Tamariki – Ministry for Children, The Treasury, and the Department of the Prime Minister and Cabinet.

Financial Implications

- 55 The costs to establish the regulatory scheme, which include human resources and the IT build for the product notification system, are estimated as follows:

	2019/20	2020/21	2021/22
CAPEX	\$450,000	\$600,000	n/a
OPEX	\$180,000	\$230,000	\$60,000

- 56 I also propose that the scheme be fully cost-recovered, in line with The Treasury's Guidelines for Setting Charges in the Public Sector, to reduce reliance on funding from general taxation and as industry is a significant beneficiary of the regulatory scheme. Over time, I anticipate that the costs of establishing and running the scheme will be recovered from the regulated industry.

57 [REDACTED]

- 58 Further work, in consultation with industry, is needed to clarify numbers of regulated products and initial fees and levies. I will report back to Cabinet in late 2019 seeking approval of the detailed policy related to cost and cost recovery, including any regulations.

Legislative Implications

- 59 The proposals in this paper require amendments to the Smoke-free Environments Act 1990, as well as a separate amendment to the regulations made under that act. This Bill is included on the 2018 legislation programme, with a category 5 priority (referral to a select committee in 2018). Officials will prepare a bid to carry it over to the 2019 Legislation programme. The Bill will bind the Crown.

Impact analysis

- 60 The Impact Statement has been reviewed by the Ministry of Health's Papers and Regulatory Committee, which considers that it meets the quality assurance criteria.

Human Rights

- 61 Restrictions on advertising will impact on freedom of expression under section 14 of the New Zealand Bill of Rights Act relating to commercial activity. However, I consider that this would be a justified limitation given the potential public health harm, particularly to children and young people, being addressed.

Gender Implications

- 62 According to the New Zealand Health Survey 2016/17, the rate of daily smokers among men is higher (15.1 percent) than the rate of daily smokers among women (12.6 percent). More Māori women (35.5 percent) smoke than Māori men (29.1 percent).

Disability Perspective

- 63 Smoking is a significant cause of disability in New Zealand. Any impact the proposals have on reducing smoking rates will improve New Zealanders health and independence.

Publicity

- 64 There has been a considerable amount of interest in the Government's intentions for the regulation of vaping products in particular. I intend to publicly announce Cabinet's decisions on proposed amendments to the Smoke-free Environments Act 1990.

Proactive release

- 65 Once public announcements have been made, I also intend to publish this Cabinet paper on the Ministry of Health's website.

Recommendations

66 The Associate Minister of Health recommends that the Committee:

- 1 **note** that smokers who find it hard to quit may be able to switch to significantly less harmful vaping or smokeless tobacco products which can benefit their health and save them money
- 2 **note** that vaping and smokeless tobacco products are inadequately regulated

Better information for the public and smokers

- 3 **note** that the Health Promotion Agency is developing a public information campaign on vaping, which will have an emphasis on supporting Māori women who have New Zealand's highest smoking rates

Regulate all nicotine and nicotine-free vaping liquid, and vaping and tobacco product devices and components

- 4 **agree** to include all nicotine and nicotine-free vaping liquid, and vaping and tobacco product devices and components within the scope of the Smoke-free Environments Act

Regulate flavours and colours

- 5 **agree** that provisions be included in the Smoke-free Environments Act to enable the prohibition of flavours and colours that attract children and young people to use vaping and smokeless tobacco products

Tailored annual sales data reporting

- 6 **agree** that the Smoke-free Environments Act be amended to allow tailored requirements to be specified in regulations for the annual sales data that manufacturers/importers provide to the Ministry of Health for different product types

Smokefree areas

- 7 **agree** to prohibit vaping and the use of similar tobacco product devices in legislated smokefree areas (indoor workplaces, early childhood centres, schools)
- 8 **agree** to exempt notified specialist R18 retailers from the prohibition on vaping indoors

Product safety

- 9 **agree** that provisions be included in the Smoke-free Environments Act to enable product safety requirements to be set through regulations for vaping and smokeless tobacco products
- 10 **agree** that manufacturers/importers of vaping and smokeless tobacco products must notify and enter product information and contact details onto a web-based system maintained by the Ministry of Health before they begin selling their products

- 11 **agree** that the regulatory regime include:
- 11.1 adverse reactions reporting and monitoring
 - 11.2 recalls of defective or harmful products
 - 11.3 suspensions and cancellations of product notifications
 - 11.4 the issuing of warning statements about products.

Offences and penalties

- 12 **agree** that further work be undertaken, in consultation with the Ministry of Justice and Parliamentary Counsel Office, on the design of an up-to-date offences and penalties regime

Regulation-making powers

- 13 **agree** to additional regulation-making powers for vaping products and smokeless tobacco, as necessary, to implement the proposals in this paper
- 14 **note** that I will report back to Cabinet in late 2019 seeking approval of any regulations that are required

Additional amendments to the Smoke-free Environments Act

- 15 **agree** to enable an assessment tool, that takes into account air quality, to be provided in regulations to support a determination of whether a space within a premise is an open area or an internal area
- 16 **agree** to enable allowable content for manufacturers' price lists to be set out in regulations
- 17 **agree** to repeal the provision that allows an exemption from the Smoke-free Environments Act's advertising and sponsorship provisions for multi-national sporting events

General review of the Act

- 18 **agree** that Parliamentary Counsel Office may re-draft the Smoke-free Environments Act as necessary to ensure that the Act, as a whole, works together with the new vaping and smokeless tobacco provisions

Cost recovery

- 19 **agree** that the implementation and running of the scheme be fully cost-recovered from industry through fees and levies, consistent with Treasury's Guidelines for Setting Charges in the Public Sector

- 20 [REDACTED]

- 21 **note** that further work is needed, in consultation with industry, to accurately determine the costs, including initial fees and levies, associated with regulating these products
- 22 **note** that I will report back to Cabinet in late 2019 seeking approval of detailed provisions, including regulations, related to cost and cost recovery

Legislative amendment

- 23 **note** that an amendment to the Smoke-free Environments Act 1990 is included on the 2018 legislation programme and I will seek to have this carried over to the 2019 Legislation programme
- 24 **invite** the Associate Minister of Health (Hon Jenny Salesa) to issue drafting instructions to the Parliamentary Counsel Office to give effect to recommendations 4 to 19 above

Further Cabinet reports

- 25 **note** that the Associate Minister of Health (Hon Jenny Salesa) will report to Cabinet towards the end of 2018 on the findings of the independent evaluation into the impact of the tobacco excise increases
- 26 **note** that the Associate Minister of Health (Hon Jenny Salesa) will report to Cabinet on the broader programme of work towards achieving Smokefree 2025 as it develops

Publicity

- 27 **note** the Associate Minister of Health's intention to publish this Cabinet paper on the Ministry of Health's website once Cabinet's decisions are publicly announced.

Authorised for lodgement

Hon Jenny Salesa

Associate Minister of Health