

In Confidence

Office of the Associate Minister Health

Chair, Social Policy Committee

Regulation of smokeless tobacco and nicotine-delivery products

Proposal

- 1 This paper seeks approval to prepare and issue drafting instructions for a pre-market approval regime, under the Smoke-free Environments Act 1990 (SFEA), to enable smokeless tobacco and nicotine-delivery products to be sold lawfully as consumer products, subject to them being approved and meeting other regulatory requirements.

Executive Summary

- 2 At its meeting on 27 March 2017, Cabinet agreed to legalise nicotine e-cigarettes (which are considered to be around 95 percent less harmful than smoked tobacco) with 'light-touch' regulation, including product notification.
- 3 At the same time, Cabinet invited the Associate Minister of Health to report to Cabinet's Social Policy Committee on detailed proposals for a pathway for emerging tobacco and nicotine-delivery products to be regulated as consumer products in the future.
- 4 A range of smokeless tobacco and nicotine-delivery products are marketed internationally. Little is known about the health risks of the majority of these products. Some may be significantly safer than tobacco smoking while others may be as or more harmful. Products that are significantly safer should be available as an alternative option for smokers. However, because the risks associated with these products are uncertain, manufacturers and importers should demonstrate their safety before they can be marketed in New Zealand.
- 5 I propose that a pre-market approval process be implemented to ensure the quality, safety and reduced-risk profile of any such products sold in New Zealand. This is a sensible approach to take to products that are of unknown and potentially high risk. An abbreviated process should be undertaken for products that, for example, have already been approved by a trusted overseas regulator.
- 6 I also propose that smokeless tobacco and nicotine-delivery products be subject to the following regulatory requirements, consistent with Cabinet's recent decisions on e-cigarettes:
 - a. prohibit sale, and supply in a public place, to those under the age of 18 years
 - b. restrict sale via vending machines to R18 settings
 - c. prohibit use in legislated smokefree areas of products that resemble smoking (ie, some products, such as snus if it was approved, could be used in these places).
- 7 In addition, manufacturers and importers of e-cigarettes/e-liquid and nicotine-delivery products should be required to provide annual sales information to the Director-General of Health, similar to existing requirements for tobacco products (including smokeless tobacco).

This will support monitoring of the impact of policies to increase smokers' access to reduced harm products.

- 8 A review of the enforcement regime is proposed to develop flexible, modern offences and penalties.
- 9 The new regulatory regime should be cost recovered from industry, consistent with the Treasury's *Guidelines for Setting Charges in the Public Sector* (the Treasury's Guideline). Further work is needed, in consultation with industry, to accurately determine costs and establish initial fees and levies.
- 10 It is proposed that effect be given to these proposals through an amendment to the SFEA.

Background

- 11 On 27 March 2017 [CAB-17-MIN-0122 refers], Cabinet agreed to regulate e-cigarettes and e-liquid as consumer products under the SFEA. At the same time, it agreed that the regulatory scheme for e-cigarettes be sufficiently broad in scope to provide a pathway for emerging tobacco and nicotine-delivery products to be regulated as consumer products in future. The Associate Minister of Health was invited to provide detailed proposals.
- 12 As smoked tobacco products can be lawfully sold and distributed under the SFEA and decisions have been taken about e-cigarettes and e-liquid, this paper is only concerned with smokeless tobacco and nicotine-delivery products (excluding e-cigarettes and e-liquid).

Smokeless tobacco and nicotine-delivery products

- 13 A range of smokeless tobacco and nicotine-delivery products, which are currently unlawful in New Zealand, are promoted as being (potentially) less harmful alternatives to smoked tobacco. These include:
 - a. heated tobacco products (eg, IQOS)
 - b. snus (small sachets of tobacco that are placed in the cheek or under the lip), moist snuff, dissolvables, and nasal tobacco
 - c. inhaled nicotine.
- 14 Some of these products use devices to heat and vaporise tobacco or nicotine liquid, gel or wax etc, some devices combine the use of tobacco and these other forms of nicotine.
- 15 Some of these products are likely to be safer than smoked tobacco, as combustion causes most of the harm associated with smoking. However, at present, little is known about the health risks associated with the majority of these products; some may be much safer, but others may be as or more harmful than smoking tobacco.
- 16 Some devices which can be used to heat and vaporise tobacco and other forms of nicotine can also be used for illicit drugs. The Misuse of Drugs (Prohibition of Cannabis Utensils and Methamphetamine Utensils) Notice 2014 prohibits the importation of specified drug utensils. Such utensils would not be eligible to be approved as smokeless tobacco or nicotine-delivery products.
- 17 There are also products regulated under the Medicines Act 1981 (nicotine-replacement therapies), which are wholly or principally for smoking cessation. I propose to keep these

under the Medicines Act 1981. Interface issues will be worked through during the drafting phase and clarified in one or both acts.

Comment

- 18 If a smokeless tobacco or nicotine-delivery product is significantly safer than smoked tobacco, it should be available as an alternative for smokers. It is also important, however, that any newly-marketed products do not attract non-smokers, particularly children and young people, or detract from our smokefree objectives.
- 19 Currently, an amendment to the SFEA would be needed each time a reduced-harm product or class of products were to be legalised and regulated as a consumer product (ie, the process we are currently going through with e-cigarettes).
- 20 I have considered three alternatives to amending the SFEA each time we consider that a reduced-harm product should be lawfully marketed:
- a. by regulations made under the SFEA - this would still require a Cabinet decision, but would avoid the need for a Parliamentary process to amend the SFEA
 - b. by manufacturers and importers obtaining a pre-market approval from a regulator (similar to processes for medicines and psychoactive substances)
 - c. by manufacturers and importers notifying a regulator of their intent to market a product and self-certifying that regulatory requirements are met (similar to processes set out in the Natural Health and Supplementary Products Bill).
- 21 I propose that the Committee agree to implement a pre-market approval regime for smokeless tobacco and nicotine-delivery products. This option is the best fit with the nature of this market where risks are uncertain and potentially high, technology and products are rapidly evolving, and the evidence on the risks and benefits is likely to change over time.
- 22 Compared with a notification process, pre-market approval ensures that the evidence on the risks and benefits associated with a product is assessed before it is marketed, but will not unnecessarily delay the time it takes products to get to market. An abbreviated process should be used where a product has already been approved by a trusted overseas regulator (e.g. the United States' regulator has approved Swedish snus, so the New Zealand process to consider this product should take that into account).

Pre-market approval

- 23 The manufacturer or importer would be required to apply to a regulator for approval to sell or distribute a product (including devices, where relevant). I propose that the broad parameters be specified in the Act and the detail set out in regulations. Information required to support an application would include:
- a. reports, investigations and so forth, into safety of the product (including in relations to smoking)
 - b. reports, investigations and so forth, on the impact of the product on public health (particularly populations with high smoking prevalence or at high risk of smoking such as Māori, Pasifika, young people) such as:
 - i. smokers switching
 - ii. relapse in ex-smokers
 - iii. uptake by non-smokers, particularly young people

- c. a detailed description of the product
 - d. ingredients and emissions (where relevant).
- 24 For medicines (including nicotine replacement therapy), information on the quality, safety and efficacy of the product must be submitted to Medsafe for review, in line with relevant international pharmaceutical requirements and guidelines. The assessment process proposed for smokeless tobacco and nicotine-delivery products would be similar, although efficacy of the product for smoking cessation would not be assessed and the product's potential broader impact on public health would be taken into consideration.
- 25 Other aspects of the regime would include:
- a. a prohibition on sales to those under the age of 18, advertising restrictions, monitoring of sales patterns, and product safety requirements (which are discussed below)
 - b. establishment of advisory committees to support the regulator in its decision-making
 - c. ability for the regulator to set conditions as a pre-requisite for giving approval (eg, to require in-market monitoring of consumer behaviour) and to declare approved products to be/not to be subject to the prohibition on use in legislated smokefree areas
 - d. appeals of regulator decisions
 - e. suspensions and cancelations of product approvals (eg, for providing false or misleading information, subsequent evidence of harm, failing an audit), provisions for voluntary withdrawal by applicant, and recalls
 - f. auditing of manufacturing facilities (the regulator should have the ability to recognise other specified authorities for this purpose)
 - g. the potential for export certification if requested
 - h. post-market activities (eg, monitoring, compliance, adverse reactions monitoring), including duties on approval holder to, for example, provide information, report adverse reactions etc.
 - i. the payment of regulatory fees and levies
 - j. protection from liability for the regulator, his or her delegate, and advisory committee personnel.
- 26 Further work is needed, in consultation with industry, on requirements when a product is modified and the type of modifications that would trigger a new product application (eg, a modification that impacts on the quality, safety or performance of the product).

Importation of products

- 27 The SFEA prohibits the importation for sale of any tobacco product for oral use other than smoking. This will need to be changed to allow the importation of approved products for sale. This will impose a regulatory burden on the customs service which will need to distinguish between approved and unapproved products. The Ministry of Health (the Ministry) and Customs will work together to minimise this burden.
- 28 There are no provisions in the SFEA that restrict importation for personal use, for example, via online sales. I do not propose to change this. Current border control arrangements will be unchanged.

The regulator (Director-General of Health)

- 29 I propose that the Director-General of Health be the regulator. The Ministry would assess applications to approve smokeless tobacco and nicotine-delivery products, manage the notification process for e-cigarettes and e-liquid, provide public access to registers of products (except information which is commercially sensitive) and be responsible for surveillance, auditing and enforcement.

Principles

- 30 I propose that the following principles apply to the performance of functions, powers and duties undertaken by the regulator under the SFEA (these principles should also apply to manufacturers, importers and other parties where appropriate):
- a. regulation of products should be proportionate to the risks associated with their use
 - b. product information should be accurate, true to label, and tell consumers about any risks, including side-effects, of using the product
 - c. regulatory activity and decision making should aim to assist in preventing or reducing the impact of smoking, particularly on young people and populations with high smoking prevalence.

Powers and duties of the regulator (Director-General of Health)

- 31 I propose applying the SFEA's existing regulatory powers and duties for tobacco products (including smokeless tobacco), with any necessary modifications, to nicotine-delivery products and e-cigarettes/e-liquid, where relevant (and subject to drafting).
- 32 I also propose that any new powers and duties be included in relation to new functions, including the notification/self-certification regime for e-cigarettes/e-liquid products and the proposed pre-market approval regime for smokeless tobacco and nicotine-delivery products.

Sales to under those under the age of 18

- 33 To protect young people from potential long term health risks associated with use of these products, including nicotine addiction, I propose that the Committee agree to prohibit sale, and supply in a public place, to those under the age of 18, consistent with controls on tobacco products and recent decisions on e-cigarettes and e-liquid. This would also apply to businesses selling products online and restricting the sale of approved products via vending machines to R18 settings.

Use in smokefree areas

- 34 I propose that the Committee agree to prohibit the use of smoking and vaping-like products in legislated smokefree areas, as use of these products around children and young people has the potential to erode our cultural norms around smoking-like behaviour. This is consistent with recent decisions on e-cigarettes. It would mean, for example, that a heated tobacco product like IQOS could not be used in a smokefree area, but a product such as snus could be used, if approved.
- 35 The regulator should also have the ability to declare, when approving a product, that it is or is not subject to this prohibition. This would help deal with uncertainty around the margins of the category of prohibited products. It also helps to future-proof the legislative changes.

Promotion and advertising, including sponsorship

- 36 If a product is approved because it is a significantly safer option for smokers, then the full tobacco prohibitions should not apply. I propose that, where appropriate, product categories be exempt from certain provisions prohibiting promotion and advertising and that this be given effect by making regulations. This is consistent with recent decisions on e-cigarettes.

Product safety

- 37 There are inherent risks associated with the use of these products, relating primarily to the toxicants that are present. The nature of these risks will vary between products and are, at present, largely unknown for most products. These risks can be mitigated through appropriate product safety requirements.
- 38 I propose that Cabinet agree that provisions be included in the SFEA to set out product safety requirements in regulations and/or other subordinate instruments. This is consistent with recent decisions on e-cigarettes and would include requirements for:
- a. manufacturing standards
 - b. safety of ingredients (eg, exclusion of unsafe ingredients)
 - c. packaging (eg, child resistant closures)
 - d. labelling (eg, warnings such as 'nicotine is addictive').
- 39 To minimise costs to industry, the regulator should have the ability to take into account any product approvals made by trusted overseas regulators and utilise any suitable international standards.

Annual sales data

- 40 The SFEA requires tobacco manufacturers and importers to provide annual sales data on tobacco products (including smokeless tobacco). This requirement was not considered by Cabinet for e-cigarettes and e-liquid.
- 41 I propose manufacturers and importers of nicotine-delivery products and e-cigarettes/e-liquid be required to provide annual sales data to the Director-General of Health. Together with tobacco sales data, this supports monitoring and evaluation of policies by providing an overall picture of shifting trends in the tobacco market.
- 42 The existing legislative provisions relating to annual sales data for tobacco products are not relevant and I propose that detailed information requirements specific to nicotine-delivery products and e-cigarettes/e-liquid be consulted on with industry and set out in regulations.

Offences and penalties

- 43 I propose that the legislation include flexible, modern offences and penalties, aligned with similar legislation. The enforcement tools would be designed to allow the regulator a wide range of options, meaning enforcement action can be commensurate with the severity of misconduct, and the regulator's approach can be flexible according to circumstances.
- 44 The overall approach would continue with the SFEA's:
- a. monetary penalties only, rather than custodial or community-based sentences

- b. use of infringement notices, which allow instant fines for low-level offending
- c. 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 (including smokeless tobacco) should be applied with any necessary modifications to e-cigarettes/e-liquid and nicotine-delivery products, where relevant. New regulation-making powers will be needed, for example, to prescribe:

- a. information requirements and other detail related to product approvals and notifications
- b. annual sales information (for e-cigarettes/e-liquid and nicotine-delivery products)
- c. classes of product exempt from aspects of the prohibitions on promotion/advertising
- d. fees and levies related to the running of the regulatory scheme, for example, for processing applications for pre-market approvals, product notification, etc

Costs and cost recovery

47 In line with the Treasury's Guideline, I envisage a fully cost-recovered regime to reduce reliance on funding from general taxation and as the main beneficiaries of the regulatory scheme are industry players.

48 At this stage, it is not possible to be clear about the costs associated with establishing and running the regime, as there is no accurate information on the likely demand for the regulatory activities. Further work, in consultation with industry, is needed to clarify expected numbers of regulated products and initial fees and levies.

Implementation

49 I seek agreement to prepare and issue drafting instructions for a SFEA Amendment Bill to enable the regulatory scheme.

50 Regulations and other subordinate instruments will need to be made under the SFEA to prescribe any detailed provisions. The Ministry will work with stakeholders (including industry) on the development of these provisions.

Monitoring and review

51 The evidence for the risks and benefits of smokeless tobacco and nicotine-delivery products is still emerging. The Ministry will continue to monitor this evidence, including patterns in the use of products in New Zealand.

Consultation

52 The Ministry has held targeted discussions with tobacco sector stakeholders including health sector agencies, academics, tobacco companies and vape retailers. Most of these stakeholders favoured pre-market approval, with processes to ensure that evidence on the risks and benefits of products was independently assessed.

- 53 Health sector staff, academics, and the majority of vape retailers suggested that products should only be regulated as consumer products if they were significantly less harmful than smoked tobacco (ie, similar to e-cigarettes), otherwise they should remain unlawful.
- 54 There was a strong view, particularly among some academics, vape retailers and two tobacco companies, that all tobacco products should be treated the same, whether they are smoked or not. There was a general view that nicotine-delivery products should be treated differently from tobacco products.
- 55 The following agencies were consulted on this paper and their views are reflected: New Zealand Customs Service, Ministry of Justice, New Zealand Police, Te Puni Kokiri, Ministry of Pacific Peoples, Ministry for Women, Ministry of Social Development, Ministry for Vulnerable Children/Oranga Tamariki, Environmental Protection Authority, Ministry of Business, Innovation and Employment, and The Treasury. The Department of the Prime Minister and Cabinet was informed about this paper.

Financial Implications

- 56 I propose that the Crown meet the costs of policy advice and that all other costs be met by industry through fees and levies (including set-up costs, which would need to be met up-front by the Crown and recouped over a specified period of time from industry).

Human Rights

- 57 Restricting advertising will impact on freedom of expression relating to commercial activity. However, I consider that this would be a justified limitation given the potential public health harm being addressed.

Legislative Implications

- 58 The proposals in this paper require amendments to the SFEA and Regulations. Consequential and related amendments to the Medicines Act 1981 and Regulations will also be needed to manage interface issues. This Bill is included on the 2017 legislation programme, with a category 5 priority (referral to a select committee in 2017).
- 59 Section 3 of the SFEA states that the act shall bind the Crown. This provision will remain unchanged by the proposed amendments.

Regulatory Impact Analysis

- 60 The Regulatory Impact Analysis (RIA) requirements apply to the proposals in this paper and a Regulatory Impact Statement (RIS) has been prepared and is attached.
- 61 The Regulatory Quality Team at the Treasury has reviewed the Regulatory Impact Assessment "Regulatory Impact Statement: Regulation of smokeless tobacco and nicotine-delivery products" produced by the Ministry of Health and dated 18 July 2017. The review team considers that it meets the Quality Assurance criteria.
- 62 It sets out a regulatory framework aimed at ensuring that smokeless tobacco or nicotine-delivery products cannot be marketed unless they are significantly less harmful than smoked tobacco, and therefore help contribute towards the achievement of *Smokefree 2025*.
- 63 In its future work it will be important to consider: (i) possible ways to inform and encourage online purchasers who will continue unrestricted, to be aware of the risks; (ii) substantial

further work is still required to clarify expected numbers of regulated products and to develop detailed costings, fees and levies, and proposals for cost recovery, as well as the need to design a flexible, modern offences and penalties aligned with similar legislation; and (iii) further work is still needed on monitoring, as acknowledged in the document.

Gender Implications

- 64 According to the *New Zealand Health Survey 2015/16*, the rate of daily smokers among men is higher (15.6 percent) than the rate of daily smokers among women (12.9 percent). More Māori women (36.5 percent) smoke daily than Māori men (34.4 percent).

Disability Perspective

- 65 Smoking is a significant cause of disability. Any impact greater use of reduced-harm products has on reducing smoking-related harm will improve New Zealanders' health and independence.

Publicity

- 66 I intend publicly announce the Government's decisions. I also intend to publish this Cabinet paper and the Regulatory Impact Statement to coincide with this announcement.

Recommendations

67 The Associate Minister of Health recommends that the Committee:

- 1 **note** that, at its meeting on 27 March 2017, Cabinet invited the Associate Minister of Health (Hon Nicky Wagner) to report to Cabinet on detailed proposals for a pathway for emerging tobacco and nicotine-delivery products to be regulated as consumer products in future
- 2 **note** that the Ministry of Health has held targeted discussions with tobacco policy stakeholders, including health sector agencies, academics, tobacco companies, and vape retailers

Authority to market a smokeless tobacco or nicotine-delivery product

- 3 **agree** to establish a pre-market approval regulatory regime for smokeless tobacco and nicotine-delivery products
- 4 **agree** that the detailed requirements be set out in regulations

Regulator

- 5 **agree** that the regulatory powers be vested in the Director-General of Health

Principles

- 6 **agree** that the following principles apply to the performance of any functions, powers and duties under the Smoke-free Environments Act 1990:
 - a. regulation of products should be proportionate to the risks associated with their use
 - b. product information should be accurate, true to label, and tell consumers about any risks of using the product, including side effects
 - c. regulatory activity and decision-making should aim to assist in preventing or reducing the impact of smoking, particularly on young people and populations with high smoking prevalence

Regulation-making powers

- 7 **agree** that the Smoke-free Environments Act 1990's existing regulation-making powers be applied, with any necessary modifications, to smokeless tobacco, nicotine-delivery products, e-cigarettes and e-liquid where relevant
- 8 **agree** to additional regulation-making powers for smokeless tobacco, nicotine-delivery products, e-cigarettes and e-liquid, as necessary, to implement the proposals in this paper

Regulatory controls

- 9 **agree** that the following regulatory controls will apply to smokeless tobacco and nicotine-delivery products:
 - a. prohibit sale, and supply in a public place, to under 18s
 - b. restrict the sale of smokeless tobacco and nicotine-delivery products via vending machines to R18 settings

- c. prohibit the use of smoking/vaping-like products in legislated smokefree areas
- 10 **agree** to provide the regulator with a power to declare products to be/not to be exempt from the prohibition on use in legislated smokefree areas
- 11 **agree** to provide a regulation-making power to exempt product classes from specific aspects of the prohibitions relating to the promotion and advertising of tobacco products

Product safety

- 12 **agree** that provisions be included in the Smoke-free Environments Act 1990 to provide for the setting of product safety requirements for smokeless tobacco and nicotine-delivery products in regulations and/or other subordinate instruments by the Director-General of Health
- 13 **note** that the Ministry of Health will work with industry stakeholders and technical experts to develop detailed requirements for smokeless tobacco and nicotine-delivery product safety

Annual sales data

- 14 **agree** that manufacturers and importers of nicotine-delivery products and e-cigarettes and e-liquid be required to provide the Director-General of Health with annual sales information
- 15 **agree** that the detailed information requirements be set out in regulations, following consultation with industry

Regulatory powers and duties

- 16 **agree** that the Smoke-free Environments Act 1990's existing regulatory powers and duties be applied, with any necessary modifications, to smokeless tobacco, nicotine-delivery products, e-cigarettes and e-liquid, where relevant
- 17 **agree** to additional regulatory powers and duties for smokeless tobacco, nicotine-delivery products, e-cigarettes and e-liquid, as necessary, to implement the proposals in this paper

Offences and penalties

- 18 **agree** that further work be undertaken, in consultation with the Ministry of Justice and Parliamentary Counsel Office on the design of a flexible, modern offences and penalties regime
- 19 **note** that the Associate Minister of Health will report back to Cabinet on the outcome of this work

Cost and cost-recovery arrangements

- 20 **agree** that the implementation and the running of the regulatory scheme be fully cost-recovered in line with Treasury's guidelines
- 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 the Associate Minister of Health will report back to Cabinet on the outcome of this work

Interface with the Medicines Act 1981

- 23 **note** that consequential and related amendments to the Medicines Act 1981 and its Regulations may be needed to ensure the interface is clear

Legislative amendments

- 24 **invite** the Associate Minister of Health to issue drafting instructions to the Parliamentary Counsel Office to give effect to recommendations 3-23 above
- 25 **note** that an amendment to the Smoke-free Environments Act 1990 is included on the 2017 legislation programme, as a category 5 (referral to a select committee in 2017)

Publicity

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

Authorised for lodgement

Hon Nicky Wagner

Associate Minister of Health