

[In Confidence]

Office of the Associate Minister Health

Chair, Cabinet

## **Improving the regulatory framework for electronic cigarettes (e-cigarettes) and emerging tobacco and nicotine-delivery products**

### **Proposal**

1. This paper proposes to:
  - a. legalise the sale and supply of nicotine e-cigarettes and e-liquid as consumer products and place regulatory controls on nicotine *and* non-nicotine e-cigarettes and e-liquid, and
  - b. establish a pathway to enable emerging tobacco and nicotine-delivery products to be sold lawfully as consumer products.

### **Executive Summary**

2. At its meeting on 29 June 2016, Cabinet Social Policy Committee (SOC) agreed in principle to nicotine e-cigarettes being lawfully available for sale and supply, with appropriate controls. It directed the Ministry of Health to undertake public consultation [SOC-16-MIN-0073 refers].
3. For smokers, e-cigarettes are significantly less harmful than tobacco. E-cigarettes may also be effective for smoking cessation, but the evidence on this is not fully settled.
4. For non-smokers, e-cigarettes have the potential to cause harm. In particular, there is a lack of clarity about the long-term health risks, and these will not be known until e-cigarettes have been in use for many years. Regular long-term use in non-smokers, who would otherwise not have smoked, is likely to be associated with a small increase in health risks.
5. I propose that Cabinet agree on a set of light-touch proposals to maximise the benefits of e-cigarettes for smokers while mitigating any risks associated with them.
6. I recommend that Cabinet agree to legalise the sale and supply of nicotine e-cigarettes and e-liquid as consumer products, and place the following controls on nicotine and non-nicotine e-cigarettes and liquid:
  - a. prohibit their sale, and supply in public places, to people under the age of 18 years, to protect young people who do not smoke from any potential long-term risks, including nicotine addiction (this does not prevent whānau from providing an e-cigarette to young people of any age who have started smoking or who are regular smokers)
  - b. restrict the use of vending machines to R18 settings to support an age limit of 18 years
  - c. limit advertising and promotion to point-of-sale display for all retailers and broader in-store display, free samples, discounts etc. in R18 retail settings

- d. prohibit vaping in legislated smokefree areas to help preserve cultural norms around the undesirability of smoking
  - e. develop light-touch product safety requirements (e.g. notification process, ingredients, manufacture, labelling, packaging).
7. I also propose that Cabinet agree that the scope of the regulatory scheme should encompass emerging tobacco and nicotine-delivery products, to provide a pathway for their regulation as consumer products. I will report back to Cabinet later this year on detailed proposals for the regulation of emerging tobacco and nicotine-delivery products.
8. Effect will be given to these proposals through an amendment to the Smoke-free Environments Act (SFEA).

## **Background**

9. Currently, the sale and supply of nicotine e-cigarettes is unlawful, while smoked tobacco, which is considerably more harmful for users, can be sold legally. Users obtain nicotine e-cigarettes through importation and illegal, local sales.
10. At its meeting on 29 June 2016 [SOC-16-MIN-0073 refers], SOC agreed, in principle, to nicotine e-cigarettes being lawfully available for sale and supply, with appropriate controls. It also agreed that products that make a therapeutic claim should be regulated under the Medicines Act 1981. The Ministry of Health was directed to consult publicly on this proposal.

### *Tobacco control in New Zealand*

11. New Zealand has long had a comprehensive tobacco-control programme, which includes:
- a. excise duties on tobacco
  - b. smokefree indoor workplaces and other public places
  - c. prohibitions on sales to under 18-year-olds
  - d. prohibitions on advertising, including sponsorship and display of products
  - e. support for smokers to quit
  - f. standardised packaging, which is currently being implemented.
12. Smoking rates and tobacco consumption have declined in recent decades. However, 4,500 to 5,000 New Zealanders still die prematurely each year from a smoking-related illness.
13. The *New Zealand Health Survey 2015/16* found that 14 percent of adults are daily smokers. Māori are more likely to smoke than others (35.5 percent smoke daily). Pacific peoples also have relatively high rates of smoking (24.4 percent).
14. The *2015 Year 10 (14-15 year olds) Survey* shows that daily smoking rates for all Year 10 students are continuing to decrease, but disparities remain:
- a. the daily smoking rate for all students was 2.4 percent (2.8 percent in 2014)
  - b. the daily smoking rate for Māori students was 6 percent (7 percent in 2014); 8 percent of Māori girls and 4 percent of Māori boys smoked daily.

### *E-cigarette use in New Zealand*

15. E-cigarettes have emerged on the international market over the last decade or so, as an increasingly popular option for smokers trying to quit smoking.
16. They are electrical devices that mimic smoked tobacco products, but produce an aerosol or vapour by heating a liquid which the user inhales. Liquids (or e-liquids) come with and without nicotine, in a wide range of flavours.
17. The use of e-cigarettes is growing rapidly in New Zealand, as it is in other countries. In 2014, 20 percent of Year 10 students reported ever using, or experimenting with, an e-cigarette compared with 7 percent in 2012.
18. In 2014, 13 percent of adults reported ever using an e-cigarette, and 1 percent reported current use. There is a strong relationship between smoking status and e-cigarette use, with smokers more likely to report having tried or currently using an e-cigarette.

### *Direct health risks and benefits of e-cigarettes*

19. There is scientific consensus that e-cigarettes are significantly less harmful than smoked tobacco. It is likely that e-cigarettes also help smokers to quit smoking, but the evidence is of low quality. A number of studies are underway and more evidence on the effectiveness of e-cigarettes as a smoking-cessation support will be available over the next few years.
20. E-cigarettes either lack many of the toxicants found in cigarette smoke or, where present, these are typically lower than in tobacco smoke, and at levels considered a negligible risk to health. Where toxicants were found to be present at high levels, this was due to e-cigarette use outside of normal operation (e.g. high levels of some toxicants can be generated at extremely high temperatures).
21. A wide range of flavours are used in e-cigarettes. Although these are generally considered safe when ingested orally, little is known about the risks of inhaling these. There is some evidence that some flavours have a greater degree of toxicity than others.
22. The most commonly reported adverse effects associated with short-term use of e-cigarettes include mouth and throat irritation and dry cough, typically mild to moderate in severity.
23. Nicotine is highly toxic at certain exposure levels and there are a small number of reports of nicotine poisoning in children, including from e-liquid. However, evidence from short and long-term use of nicotine replacement therapy suggests that the use of small quantities of nicotine is associated with few risks. The addiction potential of nicotine in e-cigarettes appears to be low, at least with current technology.
24. The long-term effects of vaping are difficult to predict and will not be known for many years. Some of the toxins detected in e-cigarette vapour may increase the risks of lung cancer, chronic obstructive pulmonary disease, cardiovascular disease and other smoking-related diseases. The magnitude of such risks is likely to be substantially lower than those of smoking, and extremely low in absolute terms.
25. E-cigarette vapour contains particles that have been identified as evidence of potential risk to others. To date, there are no case reports of harm caused by exposure to second-hand vapour. However, if any risks are present, they would not become evident for some years.

26. In summary, there are some health risks associated with e-cigarettes. These are much smaller than the risks associated with tobacco smoking and can be mitigated by product safety standards. Smokers who switch to vaping will experience a significant reduction in health risks. Non-smokers who start vaping will likely experience a small increase in health risks.

#### *Impact of e-cigarette use on tobacco-control initiatives*

27. Concerns have been raised in the literature and by commentators that the increasingly visible use of e-cigarettes could undermine tobacco control through:
- a. vaping being seen as a normal activity, eroding cultural norms about smoking being undesirable
  - b. more people becoming addicted to nicotine via e-cigarettes, which may act as a gateway to smoking, particularly with respect to young people.
28. To date, there is no robust data to show that the increase in e-cigarette use has had a negative impact on tobacco control, via the gateway effect or any other mechanism. E-cigarettes do, however, show promise as a tool to help smokers quit smoking.

#### *Emerging tobacco and nicotine-delivery products*

29. There are products, other than e-cigarettes, which are marketed as less harmful alternatives to smoked tobacco, that are unlawful under the SFEA. Examples are heat-not-burn products (e.g. Philip Morris' IQOS) and snus (teabag-like pouches of tobacco which slowly release nicotine when tucked under the lip or in the cheek). Technological development is rapid and new products will undoubtedly continue to emerge.

## **Comment**

#### *Public consultation*

30. The Ministry of Health has consulted publicly on:
- a. legalising nicotine e-cigarettes as a consumer product (provided a therapeutic claim is not made)
  - b. placing regulatory controls on nicotine and non-nicotine e-cigarettes as follows:
    - i. prohibiting sale to those under the age of 18 years
    - ii. restricting the use of vending machines
    - iii. restricting advertising, including sponsorship and display of products
    - iv. prohibiting vaping in legislated smokefree areas
    - v. whether any other regulatory controls on tobacco products should apply.
  - c. regulatory controls on product safety
  - d. whether there are any other nicotine-delivery products that should be included in these controls at the same time.
31. The Ministry of Health received 250 submissions, including from individuals, businesses, academics and health service providers. The consultation outcomes are outlined below.

*Policy proposals for e-cigarettes and e-liquid*

32. I have considered the risks and concerns associated with e-cigarettes, the developing evidence, international regulatory approaches and the outcome of recent public consultation in New Zealand. I now propose that we proceed to regulate nicotine and non-nicotine e-cigarettes and e-liquid as consumer products, with appropriate controls.

*Legalise the sale and supply of nicotine e-cigarettes and e-liquid*

33. I propose that Cabinet confirm its in-principle decision to make the sale and supply of nicotine e-cigarettes lawful as consumer products, subject to a range of regulatory controls, as discussed below. This would increase smokers' access to nicotine e-cigarettes as a safer alternative to tobacco. The proposed controls would manage any risks associated with increasing access to nicotine e-cigarettes.
34. The vast majority of submitters (98 percent) agreed that the sale and supply of nicotine e-cigarettes should be allowed, with appropriate controls. There was no significant difference between people who stated they use e-cigarettes (vapers) and those who don't (non-vapers).

*Prohibit the sale, and supply in a public place, of nicotine and non-nicotine e-cigarettes and e-liquid to under-18s*

35. I propose that the Committee agree to prohibit the sale, and supply in a public place, of nicotine and non-nicotine e-cigarettes and e-liquid to those under the age of 18 years.
36. This proposal protects young people from any potential long-term health risks associated with e-cigarette use, including nicotine addiction. It also contributes to maintaining an environment in which smoking-like behaviour is not seen as normal or desirable.
37. This proposal only affects the sale, and supply in a public place. It does not stop whānau from giving e-cigarettes to younger people for any reason, including because they consider e-cigarettes will support their rangatahi to be smokefree.
38. Nicotine replacement therapy is available to young smokers from the age of 12 years. If an e-cigarette was approved as a medicine for smoking cessation, then it could also be provided to young smokers from the age of 12 years. To date, there have been no applications in New Zealand to approve an e-cigarette as a stop-smoking medicine (one has been approved in the United Kingdom, but it has not been marketed).
39. The Ministry of Health will update its information, including the *New Zealand Guidelines for Helping People to Stop Smoking* to include clear messages about e-cigarettes, for example, that they are a safer option for smokers and, although the legal age of sale is 18 years (subject to Cabinet's decision on this), whānau can provide them to young people if, for example, they consider it will support their rangatahi to be smokefree.
40. The majority of submitters (87 percent) agreed that there should be a prohibition on the sale, and supply in a public place, of all e-cigarettes to persons under the age of 18 years. There was no significant difference between vapers and non-vapers.

*Prohibit the use of vending machines for nicotine and non-nicotine e-cigarettes and e-liquid*

41. I propose that the Committee agree to prohibit the use of vending machines for nicotine and non-nicotine e-cigarettes and e-liquid, except in R18 settings. This supports the proposed age limit of 18 years.
42. Submitters were generally supportive (69 percent) of restrictions on the use of vending machines, primarily to maintain a prohibition on sales to under-18s.

*Place limits on promotion/advertising of nicotine and non-nicotine e-cigarettes and e-liquid*

43. Advertising is broadly defined in the SFEA and includes:
  - a) point-of-sale display (e.g. behind the counter) and broader in-store display of products
  - b) discounts, free samples, co-packaging, loyalty schemes etc.
  - c) window display and promotion (e.g. notification of availability of tobacco, use of trading names such as 'Joe's Discount Tobacco') on the outside of shops
  - d) sponsorship
  - e) advertising in the broad range of media (e.g. cinema, billboards, radio, television etc.).
44. Tobacco-like controls, which prohibit all promotion and advertising (except notification of availability and price), are not appropriate for e-cigarettes. Smokers need to be able to see what is available if they are to be encouraged to switch.
45. However, advertising should not encourage non-smokers, including children and young people, to vape as nicotine is addictive and vaping is not completely without risk to health and wellbeing.
46. I propose that the Committee agree to allow:
  - a. point-of-sale (i.e. at the cash register, behind the counter, business website) display in all retail outlets; no restrictions are proposed on where e-cigarettes can be sold so this would include, for example, dairies, service stations, supermarkets etc.
  - b. broader in-store display, discounts, free samples, co-packaging, loyalty schemes etc. in R18 retail settings. This would mean that specialist vape shops' ordinary business would not be disrupted (including online sales)
  - c. window display and promotion on the outside of R18 retail settings.
47. Broader advertising, for example, billboards, sponsorship and advertising in the broad range of media, such as cinema, radio, television and internet would be prohibited.
48. The detail of what will be allowed, which would be set out in regulations, will be further consulted on with industry and other stakeholders.

49. The following table compares the proposals for e-cigarette advertising controls with the regulatory controls on tobacco and stop-smoking medicines:

	<b>tobacco</b>	<b>e-cigarettes</b>	<b>medicines*</b>
<b>point-of-sale display</b>	x	✓	✓
<b>in-store display</b>	x	✓ R18	✓
<b>display outside store (e.g. in window)</b>	x	✓ R18	✓
<b>sponsorship</b>	x	x	x
<b>advertising in broad range of media</b>	x	x	✓

\* advertising is permitted under the Medicines Act, consistent with industry advertising codes, and compliance with the requirements of the Medicines Act and its regulations

50. The majority of submitters (53 percent) supported restrictions on advertising, with 12 percent supporting a ban on all advertising. Non-vapers were more likely to support advertising controls than vapers.

*Vaping in smokefree areas legislated under the SFEA*

51. The SFEA prohibits tobacco smoking in indoor workplaces and certain public areas. These laws were made primarily to protect employees from the significant known health risks associated with second-hand smoke. The proposals in this paper do not apply to smokefree areas outside of those legislated for under the SFEA.
52. Many organisations have prohibited vaping in their smokefree areas in the absence of legislation, for example, Air NZ, Parliament, District Health Boards, Wellington City Council.
53. I propose that the Committee agree to prohibit vaping in legislated smokefree areas. Increasingly visible vaping in public areas and around children has the potential to erode our cultural norms around the undesirability of smoking-like behaviour.
54. Just under half of submitters (44 percent) agreed that vaping should be prohibited in legislated smokefree areas. Non-vapers were more likely than vapers to support restrictions (59 percent and 23 percent respectively).

*Product safety*

55. I propose that Cabinet agree that provisions be included in the SFEA to set out product safety requirements in regulations and/or tertiary legislative instruments such as notices or guidelines. These would include requirements for:
- a. manufacturing standards
  - b. safety of ingredients (e.g. maximum concentration of nicotine in e-liquid)
  - c. packaging (e.g. child resistant closures)
  - d. labelling (e.g. safety warnings such as 'nicotine is addictive').
56. To minimise costs to industry, New Zealand should recognise any products marketed lawfully in countries with robust regulatory systems (e.g. the United States and the United Kingdom) and utilise any suitable international standards.

57. Product safety requirements 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 (e.g. recall of a product that is causing harm) the Ministry of Health would know who is accountable.
58. The proposed system would be light-touch, similar to that being implemented to regulate natural health products. Where possible, existing systems will be built upon to minimise costs to government and industry.
59. There were few substantive submissions on product safety for e-cigarettes and e-liquid. I propose that the Ministry of Health work with industry stakeholders to develop and cost detailed proposals.

#### *Future-proofing the legislation*

60. Ministers have proposed that the legislative amendments to the SFEA should provide a pathway to allow emerging tobacco and nicotine-delivery products, which are currently prohibited under the SFEA, to be regulated as consumer products. This would provide a simpler process to having to amend the SFEA to legalise products in future.
61. I propose that Cabinet agree that the scope of the regulatory scheme proposed for e-cigarettes should be broad enough to allow for the future regulation of emerging tobacco and nicotine-delivery products as consumer products. A new regulatory authority will need to be established within the Ministry of Health to administer this scheme.
62. In addition, the purpose of the SFEA will need to be amended to encompass these proposals, for example, to incorporate the concept of harm reduction.
63. Product safety requirements could be supported through a comprehensive regulatory regime that ranges from a light-touch product notification process for lower risk, well understood products (such as e-cigarettes) to a more substantial approach for higher risk, less well understood products. Further work is needed to define this approach. Existing New Zealand and international regulatory regimes that provide models for consideration include:
  - a. New Zealand's approach to psychoactive substances (a pre-market approval process with a high burden of proof of safety)
  - b. The United States' approach to new tobacco products (a pre-market approval process which takes into consideration toxicological and behavioural data)
  - c. The European Union's approach to novel tobacco products (a pre-market notification process that requires submission of a significant amount of toxicological and behavioural data)
  - d. New Zealand's approach to natural health products, which is also proposed for e-cigarettes (a light-touch pre-market notification process requiring self-certification against a minimal set of regulatory requirements).
64. Officials will undertake further work, in consultation with stakeholders, on detailed requirements for the regulation of emerging tobacco and nicotine-delivery products. I will report back to Cabinet later this year with detailed proposals.

65. Submitters named a range of products, other than e-cigarettes, that they considered should be included in these regulations. There were divergent views on whether heat-not-burn cigarettes (e.g. IQOS) should be included. Some submitters proposed that a regulatory framework be implemented that would allow for consideration of whether and how emerging products should be regulated in future.

#### *Interface with the Medicines Act*

66. Cabinet has agreed there be no change to the law in respect of e-cigarettes as medicines. If a therapeutic claim is made for an e-cigarette (e.g. it helps people to quit smoking), then that product should be regulated under the Medicines Act [SOC-16-MIN-0073 refers].

#### *Implementation*

67. Effect will be given to these proposals through amending the SFEA. Smokefree enforcement officers, appointed by the Director-General of Health under the SFEA, would be responsible for enforcing any regulatory controls related to sale and supply, advertising and prohibition of vaping in legislated smokefree areas. Costs would be met from within baselines.
68. Regulations and tertiary legislative instruments (e.g. notices, guidelines) will need to be made under the SFEA to prescribe any detailed provisions.

#### *Monitoring and review*

69. E-cigarettes are a relatively new product and the evidence for their risks and benefits is still emerging. The Ministry of Health will continue to monitor this evidence, including changing patterns in the use of e-cigarettes in New Zealand. The Ministry of Health will also continue to monitor other emerging tobacco and nicotine-delivery products.

#### *Next steps*

70. The Ministry of Health will prepare and issue drafting instructions for the legislative amendments needed to give effect to decisions in respect of this paper.
71. Further policy decisions will be needed, together with a second tranche of drafting instructions, to cover detail related to the future-proofing aspect of these proposals, including:
- a. definitions
  - b. requirements for eligibility to lawfully market an emerging tobacco or nicotine-delivery product
  - c. powers and duties of the regulatory authority
  - d. interface with other legislation (e.g. Medicines Act 1981, Misuse of Drugs Act 1975).
72. I propose to report back to Cabinet before the end of 2017 with detailed proposals for the regulation of emerging tobacco and nicotine-delivery products. This will enable full drafting instructions to be issued, with a view to a Bill being ready for introduction in early 2018.
73. The Ministry of Health will work with stakeholders to develop and cost detailed proposals for e-cigarette product safety regulation, as well as on detailed advertising regulations. I will report back to Cabinet in the first half of 2018, well ahead of any legislative change.

## Consultation

74. 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, the Ministry of Business, Innovation and Employment, and The Treasury. The Department of the Prime Minister and Cabinet was informed about this paper.

## Financial Implications

75. There are no financial implications associated with this paper.

## Human Rights

76. 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

77. The proposals in this paper require amendments to the Smoke-free Environments Act 1990, as well as regulations under that Act. Consequential and related amendments to the Medicines Act 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). The Bill will bind the Crown.

## Regulatory Impact Analysis

78. The Regulatory Impact Analysis (RIA) requirements apply to the proposal in this paper and a Regulatory Impact Statement (RIS) has been prepared and is attached.
79. The Regulatory Impact Analysis Team at the Treasury (RIAT) has reviewed the RIS prepared by the Ministry of Health, and considers that the RIS *meets* the quality assurance criteria.
80. RIAT notes that options previously considered by Cabinet on promotion and advertising of e-cigarettes have been withdrawn, and are not discussed in the RIS.
81. As noted, further work on the regulation of emerging e-cigarette and nicotine products will need to take account of the delineation around illicit substances under New Zealand law, which also includes utensils used to consume illicit drugs.

## Gender Implications

82. 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

83. Smoking is a significant cause of disability. Any impact greater use of e-cigarettes has on reducing smoking rates will improve New Zealanders health and independence.

## **Publicity**

84. I intend to publicly announce the Government's decisions. I also intend to publish this Cabinet paper and the summary of submissions to coincide with this announcement.

## Recommendations

85. The Associate Minister of Health recommends that the Committee:

1. **note** that, at its meeting on 29 June 2016, Cabinet Social Policy Committee agreed in principle to make nicotine e-cigarettes lawful for sale and supply as a consumer product, subject to appropriate controls, and directed the Ministry of Health to undertake public consultation [SOC-16-MIN-0073 refers]
2. **note** that e-cigarettes and e-liquid products that make a therapeutic claim (e.g. to support smoking cessation) must have a product approval under the Medicines Act 1981 [SOC-16-MIN-0073 refers]
3. **agree** that nicotine e-cigarettes (also known as electronic cigarettes or electronic nicotine delivery systems) and e-liquid should be lawfully available as consumer products
4. **agree** to regulate nicotine and non-nicotine e-cigarettes and e-liquid as consumer products under the Smoke-free Environments Act 1990, subject to the controls proposed in recommendations 5 to 13 below

### *Age restrictions*

5. **agree** to prohibit the sale, and supply in a public place, of e-cigarettes and e-liquid to persons under the age of 18 years
6. **note** that this proposed prohibition does not prevent whānau from providing younger people with an e-cigarette if they consider that they would benefit from one
7. **note** that the Medicines Act 1981 provides a legal route for the approval of nicotine e-cigarettes as a medicine, like nicotine replacement therapy, which is available to young people from the age of 12 years

### *Vending machines*

8. **agree** to prohibit the use of vending machines for nicotine and non-nicotine e-cigarettes and e-liquid except in R18 settings

### *Advertising*

9. **agree** to allow the following forms of promotion and advertising of e-cigarettes and e-liquids:
  - a. point-of-sale display (i.e. at the cash register; behind the counter) in all retail outlets, and
  - b. broader in-store display, discounts, free samples, loyalty awards, co-packaging etc. in R18 retail settings (e.g. in specialist vape shops)
  - c. window display and promotion on the outside of R18 retail settings
10. **note** that the Ministry of Health will consult industry and other stakeholders in the development of regulations to give effect to decisions in recommendation 9

### *Smokefree areas*

11. **agree** to prohibit vaping in legislated smokefree areas, consistent with controls on tobacco products under the Smoke-free Environments Act 1990

### *Product safety*

12. **agree** that provisions be included in the Smoke-free Environments Act 1990 to set out product safety requirements for e-cigarettes and e-liquid (e.g. guidelines)
13. **agree** that suppliers of e-cigarettes and e-liquid be required to notify products via a web-based system and self-certify that they meet regulatory requirements
14. **note** that the Ministry of Health will work with industry stakeholders and technical experts to develop detailed requirements for e-cigarette and e-liquid product safety

### *Interface with the Medicines Act*

15. **agree** that consequential and related amendments to the Medicines Act 1981 and its Regulations may be needed to ensure the interface is clear

### *Future-proofing the legislation*

16. **note** that alternative tobacco product technology is rapidly developing and, in future, products other than e-cigarettes may be appropriate for sale as consumer products
17. **note** that many of these products will be unlawful under the Smoke-free Environments Act 1990
18. **agree** that the regulatory scheme for e-cigarettes and e-liquid be sufficiently broad in scope to provide a pathway for emerging tobacco and nicotine-delivery products to be regulated as consumer products in future
19. **note** that further work is needed on detailed proposals for the regulation of emerging tobacco and nicotine-delivery products
20. **agree** that a new regulatory authority be established, within the Ministry of Health, to administer the regulatory scheme
21. **note** that the purpose of the Smoke-free Environments Act 1990 will need to be amended, for example, to include 'to reduce the harm from tobacco products'
22. **invite** the Associate Minister of Health to report back to Cabinet before the end of 2017 on detailed proposals for the regulation of emerging tobacco and nicotine-delivery products

### *Other matters*

23. **invite** the Associate Minister of Health to issue drafting instructions to the Parliamentary Counsel Office to give effect to recommendations 2-20 above
24. **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)

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

Authorised for lodgement

Hon Nicky Wagner

**Associate Minister of Health**