Policy Options for the Regulation of Electronic Cigarettes

Consultation submission

Your details

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☐ Commercial interests, including e-cigarette manufacturer, importer, distributor and/or retailer
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Please indicate your e-cigarette use status:

☐ I am using nicotine e-cigarettes.
☐ I am using nicotine-free e-cigarettes.
☐ I currently smoke as well as use e-cigarettes.
☒ We are not e-cigarette users.

☐ I have tried e-cigarettes.

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Declaration of tobacco industry links or vested interest

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Neither author has competing interests with respect to any of the relevant industries.

Please return this form by email to:

ecigarettes@moh.govt.nz by **5 pm, Monday 12 September 2016**.

If you are sending your submission in PDF format, please also send us the Word document.

The authors

Clive Bates is a long standing advocate of harm reduction approaches in public health. From 1997-2003 he was Director of Action on Smoking and Health (UK) and was one of the founders of the international Framework Convention Alliance of NGOs in 2000, supporting development of the WHO Framework Convention on Tobacco Control. He has since been a senior civil servant in the UK government and United Nations, and now runs a small consultancy and advocacy practice, Counterfactual.

David Sweanor is a Canadian lawyer who has worked on tobacco control policies since 1983. This work included 1990 testimony before a New Zealand legislative committee looking at replicating the tobacco advertising restrictions he had played a leading role in achieving in Canada. He has also testified before numerous other national legislative committees, drafted legislation, worked with numerous bodies (including the WHO and World Bank) on issues of tobacco and health. He has appointments with the University of Ottawa and University of Nottingham and has been widely published on issues of tobacco, nicotine and health.

Consultation questions

Although this form provides blank spaces for your answers to questions, there is no limit to the length of your responses; you should take as much space as you need to answer or comment. Feel free to enlarge the boxes or attach additional pages.

Q1 Do you agree that the sale and supply of nicotine e-cigarettes and nicotine liquids should be allowed on the local market, with appropriate controls?

Yes ☒ No ☐

Reasons/additional comments:

Policymakers must base decisions with real-world life-or-death consequences on a dispassionate view of the evidence, and the scientific evidence now suggests that nicotine e-cigarettes and liquids, generically referred to as electronic nicotine delivery systems (ENDS), could be a benefit to millions of smokers.

- Smokers who switch to ENDS are likely to avoid at least 95% of the major smoking-related risks for cancer, heart disease and respiratory illness, and probably substantially more than that [1]. They will also experience significant short-term gains in health and wellbeing and, in high tobacco tax jurisdictions like New Zealand they are likely to be financially better off. No government should deliberately try to deny smokers this option – now adopted by millions of smokers world-wide.
- It is unethical to deny a smoker access to products that are much safer than the dominant product on the market, cigarettes [2]. Outside the field of tobacco and illicit drugs, there are no precedents for banning safer alternatives to widely used products.
- The availability of ENDS is not an alternative to conventional anti-smoking policy but complementary. By providing smokers with an easier way of responding to the pressures of high taxes and other measures, the overall tobacco control policy will become both more responsive and more humane. This is particularly important where smoking is concentrated at high levels in poorer communities, such as the Maoris.
- There is no credible evidence to suggest that ENDS undermine tobacco control, induce young people to smoke, or reduce the rate that adults quit smoking. The evidence, when examined dispassionately, shows what a neutral observer would expect unless presented with evidence to the contrary: people use much safer products to reduce their health risks or to quit smoking.
- ENDS are an effective tool for switching from smoking at no cost to the public purse – the individual smokers bear the costs.
- A widespread switch to ENDS would reduce exposure to second-hand tobacco smoke. E-cigarettes pose no material risk to bystanders [3].
- The quality of products available from reputable manufacturers is now very high and they are on widespread sale in the European Union, North America and throughout Asia without any major problems.
- There is a growing international experience with the regulation of ENDS as consumer products, and, by changing its approach, New Zealand has the opportunity to take a leadership role in these developments.
- It would be better for New Zealand to have its own legitimate and properly regulated supply

chain and to have responsible producers contributing corporate and sales taxes as appropriate, and less international internet trade in high strength liquids.

- There is no reason to protect the cigarette trade in New Zealand from competition from superior low-risk products or erect regulatory barriers to entry that are so severe that only tobacco companies have the resources to enter the market, if any company does.

Misrepresentation of scientific findings by some academics and the media have combined to exaggerate risks but understate the benefits of e-cigarettes. There are no precedents for banning safer products while leaving the most dangerous products widely available. On the contrary, ENDS will *support* a tobacco control agenda by giving smokers options to respond to increasing taxes and other controls on smoking. ENDS offer far safer options to smokers than coping with high taxes by switching to buying cigarettes on the black market.

[1] Royal College of Physicians, *Nicotine without smoke: tobacco harm reduction*, London 28 April 2016 [link] section 5.5 page 87.

[2] Hall W, Gartner C, Forlini C. Ethical issues raised by a ban on the sale of electronic nicotine devices. *Addiction* 2015; **110**:1061–7 [link]

[3] Burstyn I. Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks. *BMC Public Health*, 2014 [link]

Q2 Are there other (existing or potential) nicotine-delivery products that should be included in these controls at the same time? If so, what are they?

Yes ☒ No ☐

Reasons/additional comments:

In a revised approach, New Zealand should take the opporunity to develop a coherent regulatory framework that accommodates *all* recreational nicotine products (i.e. competitors to cigarettes) that do not involve combustion of tobacco. This includes all forms of smokeless tobacco, heated tobacco products, lozenges, inhalers, disolvable films etc. Such a framework should allow for and encourage innovation in nicotine products that are much less dangerous than smoking.

Q3 Do you think it is important for legislation to prohibit the sale and supply of e-cigarettes to young people under 18 years of age in the same way as it prohibits the sale and supply of smoked tobacco products to young people?

Yes ☐ No ☒

Reasons/additional comments:

This measure is probably necessary, but only as a compromise to secure public and political consent for a changed approach. Domestic politics is outside our competence, so we have focussed on the public health and consumer protection rationale and suggest the measure is unlikely to be beneficial.

It cannot simply be assumed that imposing age restrictions on ENDS is a good public health measure. It is an intervention in a complex 'ecosystem' of youth risk behaviours in which there is extensive teenage non-compliance with various adult-imposed prohibitions related to illicit drugs, tobacco, alcohol and other risk behaviours. It is quite possible or even likely that raising costs and barriers to access of ENDS for adolescents will mean that more young people continue to smoke when they might otherwise be diverted from harmful smoking to much less harmful ENDS use. This is likely because evidence from other jurisdictions suggests adolescent e-cigarette use is heavily concentrated in young smokers or those who have the 'risk factors' for smoking and that teenage smoking is declining in a way that is consistent with ENDS displacing cigarettes [1][2]. If these young people use e-cigarettes instead of smoking, then there is net public health benefit. Ideally, ENDS policy would be designed in a way that can distinguish between three categories young people who may use ENDS:

- those who would otherwise smoke (incurring a large benefit if they switch to ENDS)
- those would never use any form of nicotine but could be attracted to ENDS use (incurring a small detriment if they start). In most jurisdictions, this group is very small.
- those using zero-nicotine liquids. United States data suggests this is the overwhelming majority, with only 20% of 12th graders having used nicotine the last time they used an e-cigarette [3].

There is a danger of making well-meaning but crude interventions that add to overall harm once the response has worked through to the totality of youth risk behaviours.

Most young people will not become ENDS users whatever the policy, but for those who are 'at risk' of becoming nicotine users, the pattern of use of ENDS and cigarettes may have critical long-term implications. In designing policy, the priority is to reduce the number of young people who emerge into adulthood from a period of adolescent experimentation with a consolidated dependent smoking habit - this being the basis on which teenage smoking causes long-lasting harm. To the extent that ENDS use can intervene to displace such smoking, they have high and long-lasting health benefits. There is no evidence that ENDS act as gateway to smoking. On the contrary, it is far more likely that they are functioning as an 'exit' rather that entry to smoking [4].

The first evaluation studies from the United States of age restriction measures have highlighted the possible unintended consequences. For example, two recent papers [5][6] suggest negative effects from e-cigarette age restrictions - increases in smoking. Given the government wishes to introduce this measure, the burden of proof should rest with the government to show that it will not cause harm. If it does proceed with the measure, the government should carefully evaluate the impact, subject the measure to periodic review and make sure enforcement action is proportionate to harm.

[1] ASH (UK) Fact sheet: Use of electronic cigarettes among children in Great Britain, May 2015 [link]

[2] Singh T, Arrazola RA, Corey CG, et al. *Tobacco Use Among Middle and High School Students — United States, 2011–2015*. MMWR Morb Mortal Wkly Rep 2016;65:361–367. [link]

[3] Miech R, Patrick ME, O'Malley PM, Johnston LD (2016) What are kids vaping? Results from a national survey of US adolescents. Tob Control tobaccocontrol-2016-053014. [link]

[4] Royal College of Physicians, *Nicotine without smoke: tobacco harm reduction*, London 28 April 2016 [link] Key recommendations

[5] Friedman AS. How does Electronic Cigarette Access affect Adolescent Smoking? *J Health Econ* Published Online First: October 2015. [pubmed]

[6] Pesko MF, Hughes JM, Faisal FS. The influence of electronic cigarette age purchasing restrictions on adolescent tobacco and marijuana use. *Prev Med (Baltim)*, February 2016 [pubmed]

Q4 Do you think it is important for legislation to control advertising of e-cigarettes in the same way as it controls advertising of smoked tobacco products?

Yes ☐ No ☒

Reasons/additional comments:

This question is really two questions:

(1) should legislation control e-cigarette advertising?

(2) should such controls be applied in the same way as advertising of smoked tobacco products?

It would have been helpful to have the option to answer 'yes' to the first and 'no' to the second. The government should resist the easy temptation to apply equivalent controls to tobacco cigarettes and to e-cigarettes. They are *not equivelent* - cigarettes kill one in two long term users prematurely and around 5,000 people die annually in New Zealand from smoking-related disease. Cigarette smoking is a habit usually started in adolescence that consolidates into dependence. In contrast, e-cigarettes are likely to be at least 95% lower risk than smoking (and probably substantially lower than that figure) and there is currently no evidence that they will be a cause of material loss of life at all, though most experts allow for that possibility. E-cigarettes are a substitute for smoking used predominantly by people who smoke or who, in the absence of e-cigarettes, would be likely to smoke. E-cigarettes are thus part of the *solution* to the problem of cigarette smoking. It does not follow, therefore, that a policy designed to address the problem of smoking related disease should be applied symmetrically to a much safer alternative that forms part of the solution.

The problem with an advertising ban or heavy advertising restrictions is again one of unintended consequences. Viewed in terms of market dynamics, banning the advertising of a disruptive low-risk entrant (e-cigarettes) amounts to a regulatory protection of the dominant and highly harmful incumbent product (cigarettes). There is no reason for the government of New Zealand to protect the cigarette trade or to prolong the dominance of cigarettes in this way.

Advertising allows e-cigarette makers to communicate with smokers and to attract them away from smoking. Such advertising should be recognised by the government as free public health advertising that promotes an effective and novel smoking cessation strategy to a group of smokers who may not be responsive to the traditional public health messages. Advertising also provides a return on and stimulus to innovation - there is little point in investment in innovation if it is difficult to communicate benefits with consumers about it. Such innovations may be pro-health, for example, temperature control, user feedback, filling safety and changes in chemical formulation. By its nature, innovation is hard to anticipate, but the means to communicate beneficial innovation to its intended beneficiaries should not be prevented unless there is a good reason, and there is no good reason in the case of ENDS. It is best to think of e-cigarette advertising as 'anti-smoking' but to provide some protections that limit the appeal to children. The following principles should apply:

- **Advertising should be true and fair**. Normal rules that apply to advertising all products should be applied to e-cigarettes and they would be by default. This should address nearly all the concerns about the advertising of these products.
- **Restrictions on themes and media attractive to under-25s**. The UK Committee on Advertising Practice has set guidelines for UK advertising of e-cigarettes that were widely welcomed [1]. These are similar to the restrictions placed on alcohol advertising in the UK. They reflect a balance between protection of young people and the desirability of the commercial freedom to advertise low risk alternatives to smoking.

[1] Committee on Advertising Practice (UK), UK Code of Broadcast Advertising: 33. E-cigarettes Broadcast [link]; UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing (CAP Code): 22. E-cigarettes [link]

Q5 Do you think it is important for the SFEA to prohibit vaping in designated smokefree areas in the same way as it prohibits smoking in such areas?

Yes ☐ No ☒

Reasons/additional comments:

Unless and until some material involuntary risk to bystanders is identified, the decision on whether to permit or prohibit vaping in a property or any part of a property should remain a matter for the owner or manager, not the law. Though many owners/managers may choose to prohibit vaping, the government needs a credible basis to overrule the preferences of owners/managers who would otherwise wish to allow vaping. The case for legally-binding restrictions on smoking rests on the argument that second hand smoke is a cause of material harm. No such case has been made for exposure to e-cigarette aerosol. Even for active ENDS users, the levels of exposure to any hazardous agents are far below occuptational exposure limits, and "*exposures of bystanders are likely to be orders of magnitude less, and thus pose no apparent concern*" [1]. It is easy to envisage many cases where allowing vaping is a reasonable option for the owner/manager to adopt, for example:

1. A bar wants to have a vape night every Thursday
2. A bar wants to dedicate one room where vaping is permitted
3. In a town with three bars, one decides it will cater for vapers, two decide they will not allow vaping
4. A bar manager decides on balance that his vaping customers prefer it and his other clientele are not that bothered – he'd do better allowing it
5. A hotel wants to allow vaping in its rooms and in its bar, but not in its restaurant, spa, and lobby
6. An office workplace decides to allow vaping breaks near the coffee machine to save on wasted smoking break time and encourage smokers to quit by switching
7. A care home wants to allow an indoor vaping area to encourage its smoking elderly residents to switch during the coming winter instead of going out in the cold
8. A vape shop is trying to help people switch from smoking and wants to demo products in the shop…
9. A shelter for homeless people allows it to make its clients welcome
10. A day centre for refugees allows it instead of smoking

There is no reason to believe that the state, acting through legislation, is better placed to make thousands of 'micro-decisions' of this nature than the owners or managers. To justify overriding the preferences of owners/managers, the government needs a credible justification. No such justification exists in the scientific literature concerning 'second-hand vapour' exposure, nor has the New Zealand government made an evidence-based case for such an intervention.

It is quite possible that banning vaping in public places or severely restricting it would have adverse effects on health via three mechanisms. First, by making ENDS use relatively less attractive to smokers and so reducing switching. Second, by forcing those who have successfully switched to join smokers while they vape - potentially promoting relapse from vaping back to smoking. Third, by sending an inappropriate and not evidence-based signal that vaping is as harmful as smoking, which it is not. It would be like extending drink-driving laws to coffee - the public would inevitably draw false conclsuions about coffee.

Rather than overriding the preferences of owners and managers with blunt policy prescriptions, a better role for the government is to provide advice on how to make a vaping policy. This is the approach adopted in England, where the lead public health agency, Public Health England, has produced guidance after an extensive stakeholder consultative exercise [2].

[1] Burstyn I. Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks. *BMC Public Health*, 2014 [link]

[2] Public Health England, Use of e-cigarettes in public places and workplaces, July 2016 [link]

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

Control	Yes	No	Reasons/ additional comments
Requirement for graphic health warnings	☐	☒	There are no established health risks that could be legitimately portrayed in such warnings. The purpose of warnings should be be to inform about legitimate risks and to help consumers make informed decisions about risk behaviours. It should never be to create unwarranted fear in the hope of achieving a particular behavioural response. The danger of such a measure is that it would deter smokers from switching and thereby increase harm.
Prohibition on displaying products in sales outlets	☐	☒	It is important to make it as easy as possible for smokers to switch to vaping. This is a more important public health goal than preventing non-smokers trying vaping, which carries minimal risk. Even if young people use these these products, they are likely to be doing this instead of smoking - so it is not even possible to justify such restrictions on the basis of protecting adolescents.
Restriction on use of vending machines	☒	☐	A vending machine is an unsupervised retail outlet and it would be inconsistent to have age restrictions for sales while allowing sales from vening machines. The exception should be vending machines inside venues with comparable age restrictions. However, it is important to reiterate that it cannot be assumed that restricting access to ENDS, even to young people, is a good policy for public health.
Requirement to provide annual returns on sales data	☐	☒	There is no basis for imposing this requirement and no indication about what would be done with the data and who would have access to it. It is not a suitable alternative to conducting periodic independent systematic surveys of the market for tobacco and nicotine products. For many of the small businesses involved it could easily be an excessive burden.
Requirement to disclose product content and composition	☐	☒	The manufacturers should list ingredients on the pack as part of their disclosure to customers. No further disclosure is justified and no case has been made that the data disclosed will be used for any constructive purpose. The government should avoid placing pointless burdens on any business without a reasoned justification.

Regulations concerning ingredients (eg, nicotine content and/or flavours)	☒	☐	It is dificult to answer this with a yes/no response because it depends on what the regulation is designed to achieve. There is no basis for limiting strength of e-liquids in the range of concentrations used by consumers. In New Zealand this may involve adjusting the classification of nicotine under the Hazardous Substances and New Organisms (HSNO) Act to set a concentration below which the Act does not apply - typically 7-10 percent in other jurisdictions (7.5 percent in the UK [1]). Higher strength liquids may be valuable in at least three circumstances: 1. To help the most heavily dependent smokers find a satisfactory nicotine dose; 2. To help smokers overcome barrier of achieving adequate nicotine dose as they learn the technique of vaping; 3. To support innovation - for example in minaturising products so that they are more acceptable to consumers. There is no reason to limit flavours or flavour descriptors, unless there is a material health concern with an ingredient - for example it is known to be carcinogenic, mutagenic, reprotoxic or a respiratory sensitiser. There is no problem with ingredients that requires an immediate response, but over time the government can develop a regulatory regime for ingredients, for example using a similar approach to that developed in France [2] or Britain [3] or by adopting international standards should they emerge. [1] The Control of Poisons and Explosives Precursors Regulations 2015 [link] [2] AFNOR (France) Electronic cigarettes and e-liquids Part 1: Requirements and test methods for e-cigarettes XP D90-300-[link] and Part 2: Requirements and test methods for e-cigarette liquid XP D90-300-2 [link] March 2015 [3] BSI PAS 54115:2015 Vaping products, including electronic cigarettes, e-liquids, e-shisha and directly-related products - Manufacture, importation, testing and labelling - Guide [link] July 2015
Requirement for annual testing of product composition	☐	☒	No special requirements for annual testing are justified and no justification has been provided.
Prohibition on free distribution and awards associated with sales	☐	☒	There is no justification for restricting marketing designed to encourage smokers to switch from smoking to vaping.

Prohibition on discounting	☐	☒	There is no justification for managing pricing of products that are alternatives to smoking or denying vendors the option of using promotions to recruit smokers.
Prohibition on advertising and sponsorship	☐	☒	The SFEA (1990) almost completely prohibits advertising and sponsorship of tobacco products, but this should not be extended to e-cigarettes (see response to Q4) and the governmen should reconsider its application to non-combustible tobacco products, which can be used for harm reduction purposes.
Requirement for standardised packaging	☐	☒	There is no justification for inhibiting the marketing of much safer alternatives to cigarettes - this would be a *de facto* regulatory protection of the cigarette trade from competition. As with advertising bans, there is no case for symmetrically applying policies aimed at reducing the harms of smoking to products that, in themsleves, reduce the harms of smoking.
Other	☐	☒	By far the best option is to leave these products to thrive in the market place, as consumers make decisions about reducing their smoking-related risks unhindered by ill-judged government intervention for which unintended harmful consequences are likely to far outweigh any hoped-for benefit. "Do nothing" is usually the most credible option in this environment.

Q7 Do you think it is important for legislation to impose some form of excise or excise-equivalent duty on nicotine e-liquid, as it does on tobacco products?

Yes ☐ No ☒

Reasons/additional comments:

There is no reason to tax nicotine e-liquids beyond the standard 15 percent Goods and Services Tax (GST). Experts argue that the excise regime for recreational nicotine products should create a fiscal incentive to move from high risk to low-risk nicotine products [1]. However, there are three objectives associated with an excise regime for tobacco or rerlated products: public health, low cost of tax administration and revenue raising. Any regime that successfully and proportionately promotes the public health objective would have to adopt a rate so low that the costs of administration would be likely to be significant in relation to the revenue raised. So a first approximation for a suitable rate would be zero, thereby avoiding all the tax administration costs and giving the greatest public health incentive [2].

It is also possible to make a case for a tax *exemption* on the same basis that NRT sold over the counter attracts a reduced rate of sales tax or value added tax in some jurisdictions. For example, in the UK, NRT attracts a VAT rate of 5 percent compared to the standard rate of 20 percent.

[1] Chaloupka FJ, Sweanor D, Warner KE. Differential Taxes for Differential Risks--Toward Reduced Harm from Nicotine-Yielding Products. *New England Journal of Medicine* 2015;**373**:594–7. [link]

[2] Sweanor D, Now is not the time to tax e-cigarette liquids, Irish Times, 26 August 2016 [link]

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

Yes ☒ No ☐

Additional comments:

Area of concern	Yes	No	Reasons/additional comments
Childproof containers	☒	☐	The ISO 8317:2003 standard for child resistent containers should be specified. This could be a requirement under consumer protection legislation, though it is almost universally adopted as standard practice in the industry.
Safe disposal of e-cigarette devices and liquids	☐	☒	The same requirements that apply to batteries or elecrical waste should apply and no further initiative is required.
Ability of device to prevent accidents	☒	☐	It is reasonable to develop standards over time that address aspects of safety: mechanical, thermal, electrical. For example, see French AFNOR standered [1] [1] AFNOR (France) Electronic cigarettes and e-liquids Part 1: Requirements and test methods for e-cigarettes XP D90-300-1 March 2015 [link]
Good manufacturing practice	☐	☒	A better regime would be ISO9001:2008 Quality Management System [link]
Purity and grade of nicotine	☒	☐	The nicotine used should be of pharmaceutical grade. This is near universal practice in the legitimate ENDS industry.
Registration of products	☐	☒	It is unclear what such a registration system would be used for. In the absence of a more robust justification this would be an unnecessary bureaucratic burden to both the manufacturers and the government.
A testing regime to confirm product safety and contents purity	☒	☐	A standard-setting regime is the best way of regulating these products - that includes a standardised testing regime - this would reduce costs, give clear guidance to analytical services companies and increase confidence. It is therefore worthwhile.
Maximum allowable volume of e-liquid in retail sales	☐	☒	There is no basis for imposing a limitation on container volume in retail sales. Hazardous liquids are sold in large quantities (e.g. bleach) and the appropriate safeguards are to specify container standards; warn of dangers; and provide information on what to do in the event of an accident.

Maximum concentration of nicotine e-liquid	☐	☒	It is counterproductive to limit concentrations at any level below that set for the classification of nicotine as a poison (typically 7-10 percent). Stronger nicotine liquids are valuable to the more highly dependent smokers (and hence those at greater risk), smokers in the early stages of switching to ENDS, and to allow for potential innovations.
Mixing of e-liquids at (or before) point of sale	☐	☒	The personalisation and diversity of the range of liquids available is an important feature of ENDS products - and a feature of their attractiveness relative to cigarettes. The option to mix products at the point of sale is important for a certain type of retail outlet and preferable to consumers buying the same ingredients separately and mixing them at home.
Other	☐	☐	The government should avoid restrictions on internet sales of ENDS products. Internet retailing is particularly important in this business because: • the user population is sparse • the product is highly diverse • the rate of innovation is very high • in the event of excessive domestic restrictions, users will buy internationally from internet retailers, for example, in China

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

When regulating ENDS, the regulator should be preoccupied by the risks of 'unintended consequences'. Because ENDS are substitutes for smoking and uptake driven by consumer appeal, there is a risk that e-cigarette policy will have harmful consequences. The Royal College of Physicians explains [1]:

> *A risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm, eg exposure to toxins in e-cigarette vapour, renormalisation, gateway progression to smoking, or other real or potential risks. However, if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking. Getting this balance right is difficult.*

Governments need to take this insight seriously when considering intervention in markets for tobacco and nicotine. It is very easy to make matters worse, protect the cigarette trade and add to the toll of death and disease. In its impact assessment [2] for the implementation of the European Union Tobacco Products Directive, the UK government noted the potential for unintended harmful consequences, and several specific concerns are drawn out, though not quantified, in the assessment. For example:

- 117. [...] There may also be potential negative health implications if the restrictions on advertising reduce the number of consumers switching from tobacco products to e-cigarettes. [...]
- 207. There is a risk that due to the potential price increase and reduction of choice of e-cigarettes, people will choose to switch back to smoking, thus harming their health. This possibility is considered in the sensitivity analysis.
- 208. There is a risk that a black market will develop with potentially harmful e-cigarette products, due to consumers no longer having the same degree of choice in the legal market.

It is possible to extend this analysis and make a more comprehensive assessment of the possible unintended consequences arising from poorly designed regulation.

Policy	**Likely unintended consequence**
Loss of product diversity	Consumers are unable to personalise the vaping experience or find products that they enjoy and find it less satisfactory, so continue to smoke or relapse
Restrictions on liquid strength	Smokers are unable to sustain a satisfactory nicotine experience during the first stages of switching or while they are learning to vape, so relapse to smoking or give up on vaping
Limits on container and tank size	The experience of vaping becomes more inconvenient and so less attractive. More filling operations are required and the likelihood of running out of liquid is increased.
Ban e-cigarette use in public places	Diminishes value proposition of e-cigarettes to users and 'denormalises' vaping, a much less risky option, and so diminishes the appeal of vaping relative to smoking, May promote relapse in existing vapers if they cannot maintain adequate nicotine levels or if they join smokers outside.
Restrictions on advertising, promotion and sponsorship	Reduces the ability of e-cigarette brands to compete with cigarettes (the market incumbent) and diminishes means to communicate the value proposition to smokers. May reduce means to communicate innovation or build trusted brands. If subjected to excessive control may become dull and sterile, diminishing appeal.
Bans on online sales	Because vaping options are highly diverse, user density still quite low, and technological evolution rapid, the internet-based business model is important to provide the greatest choice and convenience to users. If users are forced to purchase from 'bricks and mortar' outlets but do not have a specialist shop nearby they are likely to see their options limited and vaping relatively less attractive
Policy compliance burdens and other costs - leading to black markets	Black markets develop in response to restrictive or costly regulation or taxation. Black markets can to some extent compensate for poorly designed policy and they are likely to emerge if regulation is unduly restrictive. However, they also cause harms through trade, transit and handling of high strength liquids, product quality, poor labelling, inferior packaging. They may exacerbate risks the policy is meant to mitigate.
Product design restrictions and requirements – testing and paperwork	There are numerous subtle trade-offs in product design between safety and appeal and cost. For example, the perfectly safe product that no-one wants to buy may be worse for health if it means more people smoke. Excessive design regulation can impose high costs, burdens and restrictions, slow innovation and drive good products and firms out of the market through 'regulatory barriers' to entry. Very high spec regulations will tend to favour high volume, low diversity commoditised products made by tobacco or pharmaceutical companies. Regulation can adversely reshape the market and reduce the pace of innovation.
Bans on flavours	All e-cigarettes and liquids are flavoured with something – and this forms a key part of the appeal. Many former smokers report switching to non-tobacco flavours as a way of moving permanently away from smoking. There is a risk that loss of broad flavour categories will cause relapse among e-cigarette users, fewer smokers switching, and emergence of DIY and black market flavours.

Ban refillable systems	This idea has been proposed by tobacco companies for commercial and anti-competitive reasons. It means removing the 'open system' 2nd and 3rd generation products that increasingly dominate the market. Many vapers report these are more effective alternatives to smoking. Any (minor) risks of poisoning, dermal contact, DIY mixing etc have to be set against the likely black market response, and the substantial benefits arising from personalisation and huge extension to the diversity of products available.
Health warnings	Alarmist health warnings, even if technically correct, can be misleading and misunderstood by the public. This has always been the case with smokeless tobacco – warnings do not adequately communicate relative risk and, therefore, understate smoking risks or the advantage of switching. They may obscure more important messages about relative risk compared to smoking that is not provided in official warnings.
Ban sales to under-18s	There is near universal support for this policy. A US study [link] found that in areas where e-cigarette sales to under-18s had been banned the decline in smoking was slower than in areas where it was not banned. However, it is worth noting that NRT is made available to people over 12 years in some jurisdictions – because young smokers also need to quit. It should not be assumed that 'harm reduction' should start at 18.
Prohibit health or relative risks claims	This denies smokers real world truthful information about relative risk and may cause more smoking. It is uncontroversial that e-cigarettes are safer than smoking – the debate is over where in the range 95-100% less risky. This erects high and unnecessary regulatory barrier to truthful communication - and therefore obscures the most important consumer benefit from consumers. The authorities could address this by providing authoritative advice on relative risk - for example of the type provided by Public Health England or the Royal College of Physicians, which could be used in communication with consumers.
Raise taxes on e-cigarettes	This reduces the financial incentive to switch from smoking to vaping unless the tax on smoking is also increased. But these taxes if raised too far will tip users into other forms of unintended behaviour – accessing the black market, switching to rolling tobacco, or create cottage industries producing e-liquids in garages. It may also favour smoking cessation medications that are less effective on average, such as NRT [2] (which in the UK actually receives a VAT *discount*)

[1] Royal College of Physicians, *Nicotine without smoke: tobacco harm reduction*, London 28 April 2016 [link] Section 12.10, page 187

[2] Department of Health, MHRA, Tobacco Products Directive, Impact Assessment,18 April 2016. [link]

[3] Brown J, Beard E, Kotz D, *et al.* Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study. *Addiction* 2014;109:1531–40 [link]

Additional information on sales and use

Q10 Can you assist us by providing information on the sale of e-cigarettes in New Zealand (for example, size of sales or range of products for sale on the local market)?

No information

Q11 Would the Ministry of Health's proposed amendments have any impact on your business? If so, please quantify/explain that impact.

Not appliacable

Q12 If you are using nicotine e-cigarettes: how long have you been using them, how often do you use them, how much do you spend on them per week and where do you buy them?

How long have you been using them?	How often do you use them?	How much do you spend on them per week?	Where do you buy them?
NA	NA	NA	NA