Potential new regulatory options for e-cigarettes in New Zealand

Nick Wilson, Richard Edwards, Janet Hoek, George Thomson, Tony Blakely, Frederieke Sanne van der Deen, Brent Caldwell, Julian Crane

ABSTRACT
While e-cigarette usage has grown rapidly in New Zealand and around the world, the scientific evidence base regarding the net benefits and risks of these types of products at the population level remains uncertain. The health-based policy experience is also minimal. Here, we analyse plausible future regulatory options for e-cigarettes that the New Zealand Government could explore, and that further research could help clarify. These options include: (1) a full free market (an option we doubt is desirable for multiple reasons); (2) controlled increased access through: (a) pharmacy only, (b) pharmacy only plus sales by prescription/to licensed vapers; (c) additional controls through non-profit supply/distribution (eg, public hospital pharmacies); (3) increased restrictions compared with current (eg, adopting a complete ban on self-imports and use). In addition, we consider mechanisms to improve product quality and safety, and argue that policy makers should take great care when regulating e-cigarettes, given the scientific uncertainty and the role of commercial vested interests.

Globally, the market for e-cigarettes, or electronic nicotine delivery systems (ENDS), is highly dynamic and rapidly evolving. There are numerous different product types, including non-electronic forms, and many of the new types look highly dissimilar to smoked cigarettes. However, in this article, for simplicity, we use the most familiar term: ‘e-cigarettes’. Alongside dedicated independent producers of e-cigarettes, the tobacco industry has also been entering the market with its own heavily promoted e-cigarette products. Given the evolving situation, we aimed in this Viewpoint to explore a range of regulatory options that the New Zealand Government could consider further to ensure that e-cigarettes make a positive contribution to the achievement of the smokefree nation 2025 goal.

The current New Zealand situation
The current status of e-cigarettes in New Zealand parallels Australia and Canada. That is, such products cannot be legally sold if they contain nicotine unless they meet regulatory standards for achieving a therapeutic purpose: ie, as a pharmaceutical-grade smoking cessation product as per Medsafe requirements. Nevertheless, e-cigarettes with nicotine and nicotine-containing ‘e-liquid’ can be legally imported for personal use in New Zealand. Shops can sell the e-cigarette devices and e-liquids not containing nicotine, but some may have been selling e-liquids containing nicotine as well, albeit illegally.

At present, the extent of imports is unknown. Yet, the level of use by New Zealand youth suggests a considerable volume, with growth from 7% to 20% in ever-use of ‘electronic cigarettes’ during the 2012–14 period. Among adult New Zealand smokers in 2013, e-cigarette usage in the last two weeks ranged from 8% (in non-quit attempters) to 15% (in serious quitters). For 2014 data, the ‘current use’ amongst adults was reported at 0.8% overall and 0.9% in Māori. Increasingly, there are advertisements for e-cigarettes in New Zealand (eg, the display of posters in shop windows, transit advertising, New Zealand-based websites, and a radio campaign by NZVapor.com in May 2015), some of which have features likely to encourage experimentation among youth and non-smokers. Strong views in favour of liberalising
access to e-cigarettes are apparent in public responses to a blog post detailing potential new options around regulating e-cigarettes in New Zealand (in a related forerunner piece to this Viewpoint article).

**Potential benefits and harms of e-cigarettes**

The published scientific literature on e-cigarettes/ENDS is now large and growing rapidly. For example, we identified 128 review articles in PubMed when searching for relevant terms ('review' and 'e-cigarette'/'electronic cigarette' in May 2015), and multiple systematic reviews exist (eg, six since January, 2014). Recently, the United States Preventive Services Task Force concluded that there are insufficient data on the effectiveness of electronic cigarettes to determine whether the devices can help smokers quit. The literature may also be influenced by authors with a ‘conflict of interest’ eg, one systematic review reported conflicts of interest in 34% of 76 included studies. However, to briefly summarise this large literature, it is probably reasonable to say there is no scientific consensus on how the total potential benefits of e-cigarette availability compare to the total potential harms in the longer term.

A potential benefit of e-cigarettes is that they could offer smokers another therapeutic option to help them quit smoking, and may thus increase quit rates at a population level. E-cigarettes might be particularly important for smokers who have tried existing therapies without success. They also may be an appealing method that prompts smokers who have not tried to quit previously to do so. But, it is not clearly known how effective this approach to quitting is and the extent to which those who quit remain addicted to e-cigarettes (eg, high nicotine exposure from e-cigarettes may prevent ‘nicotine cessation’). Another potential benefit of e-cigarettes is that they may provide a possible substitute source of nicotine with much lower adverse health effects among those who cannot, or do not wish to, end their nicotine dependency. Nevertheless, the long-term safety of using e-cigarettes is not established and there are potential downsides to long-term dependency on them (eg, the financial costs, stigma of being ‘drug dependent’, and users having to go outside of any ‘vaping-free zones’ etc). Even so, given that the health impacts on users are likely to be much less than for tobacco cigarettes, for many users long-term dependency on e-cigarettes might not amount to being that different from the inconvenience of caffeine dependency.

E-cigarettes could also have important adverse effects, including reducing quit rates among smokers and increasing smoking uptake among youth. Examples of how e-cigarettes might potentially reduce quitting rates by smokers, or lead them to relapse, include: (i) the ability to use e-cigarettes to cope with withdrawal symptoms in smokefree environments might remove the impact of such environments to motivate people to quit smoking (and thus result in long term ‘dual use’); (ii) smokers may try to quit unassisted using e-cigarettes, rather than seeking support from quitlines or other cessation services, resulting in reduced quit success; or (iii) seeing people using e-cigarettes may provoke urges to smoke in smokers, resulting in increased smoking or relapse among ex-smokers. Furthermore, the novelty of e-cigarettes may be attractive to youth and to curious non-smoking adults. Thus e-cigarettes may potentially form a gateway to (or ‘back to’ for ex-smokers) tobacco smoking, or could result in new nicotine addiction that would not otherwise have occurred, particularly among youth and young adults. In addition, the use of e-cigarettes (especially those that are ‘cigarette-like’ in appearance) could potentially ‘renormalise’ smoking behaviour in general. There are also concerns about nuisance and potential health impacts from ‘second-hand’ exposure to the aerosol from e-cigarettes for non-users. Less directly, there is also the risk that discussions about the regulation of e-cigarettes may give the tobacco industry a formal place at the policy table where they could do more to undermine tobacco control policy more generally.

**Plausible regulatory options for New Zealand**

In the face of the issues and uncertainties around the net benefits and harms of
e-cigarettes at a population level, we provide a list of plausible regulatory options for nicotine-containing e-cigarettes in New Zealand in Table 1 and follow this with more detailed comments. To inform this list, we reviewed recent literature on regulatory options for e-cigarettes, including an expert survey,17 an ethical analysis,18 a New Zealand-specific policy analysis,19 and other international work.1,2,20-22 Nevertheless, much of the international literature is of limited value when considering e-cigarettes in the context of a country: (i) which is an island nation with strong border controls; (ii) in which nicotine-containing e-cigarettes cannot currently be legally sold (in contrast to many other jurisdictions considering regulatory frameworks where such e-cigarettes are already widely available); and (iii) where the Government has a smokefree nation goal for 2025.23

**Table 1:** A list of plausible options for changing the regulation around nicotine-containing e-cigarettes in New Zealand.

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<thead>
<tr>
<th>Policy goal/s</th>
<th>Direction of policy (restrain/liberalise)</th>
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<tr>
<td>1</td>
<td>To increase access to e-cigarettes (full free market).</td>
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<tr>
<td>2a</td>
<td>To increase access to e-cigarettes as a quitting aid or long-term nicotine maintenance product in those who cannot quit nicotine eg, pharmacy-only sales.</td>
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<td>2b</td>
<td>As above for pharmacy-only sales, but with tighter access requirements (eg, ‘licensed vapers’ or as ‘prescribed’ by a registered health professional).</td>
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<tr>
<td>2c</td>
<td>As above but for very tight control on e-cigarettes to minimise profit-driven risks eg, only public hospital pharmacy as the outlet.</td>
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<td>3</td>
<td>Fully minimise any risk of harm from e-cigarettes to everyone (ie, assuming no net benefit from e-cigarettes) via a complete ban on importation and use.</td>
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This option would involve a change in existing New Zealand law to allow e-cigarettes with nicotine to be made widely available with no regulatory oversight (eg, towards the situation as currently largely exists in the US and various European countries). However, this seems to be an undesirable option in the New Zealand setting at present, for the following reasons:

- It seems fundamentally problematic for society to allow a highly addictive drug (such as nicotine) to be sold in unregulated environments without health professional advice and support for quitting. The existence of widespread tobacco outlets (dairies, supermarkets and petrol stations) can be considered a historical anomaly in New Zealand that needs urgently to be fixed by other measures, such as licencing and a phase-down process for retail outlets.24

- Existing tobacco outlets (especially dairies) appear to chronically break the law around tobacco sales (eg, 64% breaching regulations in one survey and extensive evidence of sales to underage youth25-28). The current New Zealand regulatory machinery seems to take a relatively low key approach to enforcement around tobacco sales to youth and progress on developing a retail licensing system has been extremely slow. In contrast, a more controlled potential outlet (such as pharmacies) are probably much less likely to break the law and monitoring compliance would be easier, given the smaller numbers of pharmacies compared to other outlets (for example, there are around 980 pharmacies compared to an estimated 5,000 plus tobacco retail outlets29).

- In the wake of the recent sale of synthetic cannabis and ‘party pills’ from outlets on New Zealand high streets (albeit now discontinued in 2014), it seems likely that some policy-makers could be risk averse around any further liberalisation of ‘drugs’ (which is how e-cigarettes may be perceived if sold in outlets such as dairies or more specialist stores selling recreational drug paraphernalia).
Option 2a: Policy goal of increasing access to e-cigarettes as a quitting aid or long-term nicotine maintenance product in those who cannot quit nicotine (e.g., pharmacy-only sales)

This option would permit nicotine-containing e-cigarettes to be sold, but in a relatively controlled and medicalised way. For example, this product could be sold only by health-focused outlets such as pharmacies, alongside pharmaceutical-grade smoking cessation products (such as nicotine replacement therapy) and only for those e-cigarette products that met specified quality and marketing standards (Table 2). This option might require an amendment to the Smoke-free Environments (SFE) Act to permit sales and to remove e-cigarettes from Medsafe jurisdiction (as per fluoride when added to drinking water which is now specifically defined as not being a medicine and is therefore now under Medsafe jurisdiction\(^2\)). At the same time the new SFE Act amendment could include tight marketing restrictions and restrictions on sales to youth for e-cigarettes; e.g., under 18 years (Table 2). If careful monitoring showed this approach did not advance public health and the smokefree nation 2025 goal, then it would be politically much easier to discontinue pharmacy sales than to manage product withdrawals from a wider variety of retailers as in Option 1 (given that pharmacists are health professionals with specified ethical standards). Nevertheless, for some policy-makers this option might pose risks of over-liberal uptake of e-cigarettes relative to Option 2b, below.

Option 2b: Policy goal as above but with tighter access requirements (e.g., ‘licensed vapers’ or as ‘prescribed’ by a registered health professional)

The goal of this option would be as per Option 2a above, except with a requirement for a vaper’s licence\(^22\) or as ‘prescribed’ by a registered health professional or registered QuitCard provider. This would better target e-cigarette usage to those wanting to use them to help quit tobacco or to those who have failed to quit after multiple attempts and need to use e-cigarettes as a long-term nicotine maintenance product. Aspects of the proposed ‘smokers’ licence’ system\(^3\) could also be used for vapers. Pharmacists selling e-cigarettes could also be required to deliver brief cessation advice at the same time as selling e-cigarettes; this approach could help to more fully medicalise e-cigarettes (as a quitting aid or maintenance treatment for chronic nicotine dependency). Tighter controls on marketing could mean that all marketing is banned, or limited to government ‘approved’ informational brochures attached to each package of e-cigarette products sold (Table 2).

Option 2c: Policy goal to have very tight control on e-cigarettes to minimise profit-driven risks

By excluding any profit motive from the retail sector, there may be less chance of any commercial interest undermining the intent of any new law on e-cigarettes (e.g., via viral marketing on the internet). To minimise this risk, a government purchaser and distributor (e.g., Pharmac or a new organisation) could purchase e-cigarette products internationally and then supply them through government-owned settings (e.g., pharmacies in public hospitals). However, the latter approach would require changes as these pharmacies are not currently set up for retailing to the public. Internet sales and self-imports could also be banned with this option. The brand/s of e-cigarettes supplied could be of the highest quality currently on the market and could meet all other quality criteria (Table 2).

Option 3: Policy goal to fully minimise any risk of harm from e-cigarettes via a complete ban on importation and use

This option would not only involve maintaining current New Zealand restrictions that ban the sales of e-cigarettes containing nicotine, but it could also ban the self-importation of e-cigarettes and their use in public places. Furthermore, it could potentially enhance enforcement around illegal sales of nicotine cartridges and e-liquid (e.g., increased monitoring and penalties). This option might be favoured by those who suspect that
nicotine-containing e-cigarettes were to become legally available in New Zealand.

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<th>Policy goal/s</th>
<th>Brief details and comments</th>
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<td>Reducing potential harm and nuisance to others from vaping (and to limit normalisation of vaping)</td>
<td>Amendments to the SFE Act could ensure that there is complete consistency with restrictions on vaping ie, making it illegal to use e-cigarettes in any designated smokefree environment. This measure may reduce public confusion between vaping and smoking, reduce normalisation of vaping, and avoid nuisance impacts on those who simply dislike exposure to vaped aerosol. Such an amendment could provide an opportunity for a wider upgrade of the SFE Act, to build on the success of the ban on smoking in school grounds. For example, it could include a nationwide ban on smoking and vaping: in cars with children, within 10m of children’s playground equipment, in all stadiums, and on all sports fields. In contrast, the use of a nicotine-containing metered dose inhaler might still be permitted in such environments given that this would appear like a typical therapeutic inhaler in shape and function, and the aerosol delivered would be unlikely to disperse beyond the user to affect others.</td>
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<tr>
<td>Increased product quality</td>
<td>Quality controls (possibly under a revised SFE Act) to maximise effectiveness as a quitting aid/substitute (in terms of nicotine levels) and to minimise any health risks could ensure that there were no or minimal contaminants in those e-cigarettes allowed to be sold. Indeed, there are already brands that use pharmaceutical-grade manufacturing processes for their e-liquid with good manufacturing practices (GMP) certification. Furthermore, new regulations under the SFE Act could allow for the quality standards to be gradually tightened over time (eg, annually). Some informative New Zealand work on e-cigarette product testing has already been reported by Laugesen. Such an incremental approach to quality improvement would probably improve access to e-cigarettes in the short-term, relative to the far more demanding options of manufacturers trying to: (i) meet the existing regulatory requirements under the Medicines Act as outlined by Medsafe; or (ii) meet the requirements under the new Psychoactive Substances Act (as suggested elsewhere) but probably only after nicotine was included into the scope of this relatively new and untested legislation. Nevertheless, this ‘quality upgrade’ option may not be a particularly feasible policy option in the sense that it would require the development and annual review of quite complex quality standards, testing of products and an enforcement regime. It is not clear if the New Zealand Government would put adequate resourcing into any of these measures.</td>
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<td>Ensuring quality issues around legal sales</td>
<td>Quality criteria for legal sales of e-cigarettes could include use of age limits (18+ years, as is currently for tobacco in New Zealand), and the use of child-resistant packaging (as per New York State law). Also, all manufacturers could be required to have warning labels (eg, that quitting smoking completely and then quitting e-cigarettes is best for health; that nicotine is highly addictive), to give information on levels of all ingredients, and to not make unproven health claims. No cross-branding practices could be allowed (eg, a ban on the use of tobacco industry logos on e-cigarettes) and marketing could be tightly regulated, including a possible requirement for standardised (plain) packaging. We note the particular need for care with marketing controls given evidence of e-cigarette advertising that appeals to young people and glamorises use; and the experience that alcohol advertising in New Zealand has become very difficult to control again once it became liberalised in the late 1980s. We also note that optimal regulation around approved designs of e-cigarettes could be very difficult to achieve, as there are complex potential advantages and disadvantages of different products: eg, refillable ‘tank’ devices have the potential advantage of lowering costs for users (relative to tobacco smoking).</td>
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<tr>
<td>Encourage smokers to switch to e-cigarettes through price mechanisms</td>
<td>Price signals may help to achieve shifts in usage between tobacco products. Therefore if the policy goal of shifting users from smoking to the use of e-cigarettes was favoured, it would seem desirable to have a large price gap between untaxed e-cigarettes (taxed with only the routine Goods and Services Tax (GST)) relative to smoked tobacco sold elsewhere. This gap could grow if the excise tax on the former kept increasing as part of a national endgame strategy (and taxes on tobacco are a particularly important and cost-effective tobacco control strategy in themselves).</td>
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adequate regulation of e-cigarettes is too hard for the New Zealand political and policy-making system (as discussed further below). But, if illegal sales of e-cigarettes became even more significant and hard to control, the viability of this approach could be eroded. Nevertheless, a large illegal market might be relatively unlikely, given the notable decline of the synthetic cannabis market after such products effectively became illegal in New Zealand. Furthermore, the illegal tobacco market in New Zealand remains small, despite high tobacco prices.

The best package of policy options for New Zealand?

Given the complexities around e-cigarettes, we have not attempted to reach any consensus, or even a majority view, on the ‘most recommended’ option/s for the New Zealand Government to consider. However, it seems logical for policy-makers to consider carefully the pros and cons of all the listed options, and to do so in the light of the smokefree nation 2025 goal. The best long-term option for New Zealand should ideally be informed by on-going local research and careful monitoring of sales, use, product quality, and health effects. Hence the various surveys used in New Zealand should continue to collect data on e-cigarette usage. There may also be potential lessons from the international experience with e-cigarettes and from other drug domains, such as international alcohol regulation and cannabis regulation (eg, as seen with various US states, Uruguay and Portugal). Indeed, the optimal evidence-based policy response may well change over time and so regulatory flexibility seems desirable. Furthermore, the goal of an e-cigarette regulatory regime should be to help end the current tobacco epidemic, and to help achieve the smokefree nation 2025 goal. The selected approach should therefore be implemented in tandem with enhanced tobacco control measures, eg, increasing tobacco taxes, restricting access to tobacco sales, and even reducing the nicotine content in tobacco.

Additional reasons for caution when developing any new regulations

As we have outlined above, there is scientific uncertainty around e-cigarettes, therefore great care is required in crafting any new regulations. Other factors, which we outline below, should also make policy-makers cautious.

Firstly, policy-making around tobacco and nicotine seems very difficult, both internationally and in New Zealand. For example, New Zealand still has no licensing of retail tobacco outlets; no operationalised controls on tobacco product ingredients (including sugar, menthol, rum, and other flavours); no ban on duty-free sales of tobacco; and no restrictions on smoking in cars containing children. Furthermore, New Zealand is not moving quickly to implement standardised (plain) packaging; and the legal situation around smoking in the ‘outdoor’ areas of hospitality settings remains problematic (eg, see this survey). Other product-related examples of regulatory deficiencies in New Zealand include: still permitting advertising of prescription medicines; the lack of virtually any controls on the sales of vitamins and supplements (though some new legislation is pending); the weak regulations around alcohol sales and marketing; and the tortuous process of phasing out leaded petrol. These examples collectively provide a warning on the suboptimal health-related policy-making processes in New Zealand.

Secondly, some of the options outlined assume quality standards may be developed, implemented and enforced. We are not sure whether New Zealand has adequate infrastructure to do this at present. If not, it might be necessary to piggy-back on European Union or US Food and Drug Administration (FDA) standards or similar (either of which may come with its own set of problems).

Thirdly, some participants in the e-cigarette domain have commercial vested interests. For example, e-cigarette companies and some tobacco companies that own e-cigarette brands. The tobacco industry continues to be
influential in New Zealand, has historically opposed effective tobacco control measures, and, at an international level, continues to undermine evidence-based policy. Irresponsible advertising of e-cigarettes in the US is also well described. For these reasons, the tobacco industry should be excluded from discussions regarding e-cigarette regulation, and submissions from any tobacco company should be viewed by the Government with considerable scepticism.

Fourthly, any liberalisation of e-cigarette supply (with its risks) may reduce pressure on the Government to introduce and implement a comprehensive strategy to achieve the smokefree nation 2025 goal (with such elements outlined by the Māori Affairs Select Committee). Such a comprehensive strategy is likely to be the most important step that the Government can take to end the epidemic of tobacco-use related deaths in New Zealand.

Conclusions

Any further regulation of e-cigarettes in New Zealand will require careful analysis and re-opening the regulatory toolkit is not risk-free (ie, increasing access to e-cigarettes may be a benefit, but may also generate new problems that outweigh the benefits). This is especially so given the genuine scientific uncertainties and the vested commercial interests involved. Nevertheless, policy-makers may wish to consider further the pros and cons of the regulatory options outlined in this article.

Competing interests: Nil

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