



Reducing nicotine in smoked tobacco products: A pivotal feature of the Smokefree Aotearoa proposals

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Richard Edwards, Janet Hoek, Nick Wilson, Chris Bullen

The NZ Government has published a discussion document outlining an Action

Plan for the Smokefree Aotearoa 2025 goal and has invited submissions on its proposals. This blog is one of a series examining key aspects of the plan to help inform the debate and submissions. Here we examine the proposal to reduce the nicotine in smoked tobacco products to very low levels. We conclude this strategy is likely to have a profound impact on smoking prevalence and, if implemented as part of a comprehensive plan, gives a realistic prospect of achieving a Smokefree Aotearoa.

Why reduce nicotine to very low levels?

The <u>action plan proposes</u> reducing nicotine in smoked tobacco products to very low levels and mandating that these are the only smoked tobacco products available for sale in New Zealand. This innovative policy could profoundly reduce smoking uptake by adolescents and young people by minimising the risk that young people who experiment with smoking become addicted to nicotine. It could also prompt and support people who smoke to quit, and decrease relapse among people who, having quit smoking, occasionally smoke a cigarette.¹⁻³ It aligns with the 2010 Māori Affairs Select Committee inquiry findings which recommended reducing the additives and nicotine in tobacco as one of the measures to help achieve the proposed Smokefree 2025 goal.⁴

What are the arguments and evidence in support of this proposal?

This measure tackles a major gap in the current regulatory regime for tobacco products: that the design and constituents of smoked tobacco products are unregulated, allowing the tobacco industry a free rein to develop and market products. The consequence is that tobacco products are now highly addictive, palatable and appealing (e.g., with high nicotine content and added sugar and flavourings), in spite of the disastrous health consequences these impose on most users. ⁵ These attributes make it difficult for people who smoke to quit and stay quit, and mean young people who experiment with smoking are much more likely to progress rapidly to regular smoking and long-term addiction. ⁷

The proposed policy has a compelling logic; researchers and indeed the tobacco industry have long known that nicotine is the main cause of the addictiveness of smoking and that people who smoke do so mainly to obtain nicotine.⁸

"To lower nicotine too much might end up destroying the nicotine habit in a large number of consumers and prevent it from ever being acquired by new smokers."

Quote from British American Tobacco Company internal document, June 1959 10

Several reviews and commentaries and many individual studies, ¹⁻³ lave investigated the impact of very low nicotine cigarettes (VLNCs), which are generally defined as having around 0.4 mg or less nicotine per gram tobacco or per cigarette. Investigators have generally concluded that most people who smoke and who are provided with VLNCs find

these cigarettes unsatisfying and as a result often cut down on the number of cigarettes they smoke, have similar or lower biomarkers of exposure to toxins, experience fewer withdrawal effects, and make more quit attempts and are more likely to successfully quit. A preliminary New Zealand study found that VLNCs without filters were less acceptable that those with filters to people who smoke³⁴ – suggesting possible synergy with another policy proposed in the action plan – banning filters. These studies likely underestimate the impact of mandating VLNCs as the only available product, as participants usually still had access to non-VLNCs, and there is evidence of substantial non-compliance.³⁵⁻³⁷

Similar impacts have been found in marginalised groups, such as people with mental health conditions,³⁸ where smoking prevalence is much greater. A large New Zealand trial which investigated the impact of adding VLNCs to Quitline smoking cessation support found no difference in impact on quitting between Māori and non-Māori participants.²⁸ Preliminary analyses of participants in the TAKe study, a cohort study of Māori people who smoke, found over half said they would quit smoking (40%) or switch to e-cigarettes (14%) if VLNCs were the only available smoked tobacco product.³⁹ This provides further evidence for the potentially profound impact of a mandated VLNC policy. Evidence suggesting substantial impacts of VLNCs and a VLNC policy in diverse population groups suggests these interventions could reduce disparities in smoking prevalence and associated health inequities.

What is the likely impact of a VLNC policy?

Modelling studies suggest that a mandated VLNC policy would result in substantial reductions in smoking prevalence and population health gains.^{40 41} A historical modelling study estimated that had the tobacco industry introduced VLNCs when the health effects of smoking were established in the 1960s, millions of lives would have been saved.⁴²

What are the arguments against this measure?

Critics have advanced three main arguments against a mandated VLNC policy.

First, they have <u>expressed concerns</u> that lowering the nicotine content of smoked tobacco products may result in **"compensatory" smoking,** where people smoke more cigarettes or puff more intensely to obtain an adequate nicotine dose. However, numerous studies have found that VLNCs, at worst, elicited limited "compensatory" smoking for a few days, after which people who continued smoking typically showed a sustained <u>reduction</u> in the number of cigarettes smoked. These findings are highly plausible, given neither increasing the number of cigarettes smoked nor more intensive and frequent puffing can provide an effective dose of nicotine because the levels of nicotine in VLNCs are around 25 times lower than in a standard cigarette.

Second, some commentators have argued that removing the nicotine from cigarettes amounts to **prohibition** or cigarettes infringes excessively on smokers' autonomy.⁴³ Such arguments are misplaced in a context like NZ, where harm-reduced alternative nicotine products like e-cigarettes are easily available. Rather, as over 80% of people who smoke express regret that they ever started to smoke, state they intend to quit and have tried to quit in the past,⁴⁶ removing the addiction that is the major barrier to quitting will increase rather than compromise their autonomy.

Third, some suggest the proposed policies in the action plan, including mandated VLNCs,

will increase the **illicit and smuggled cigarette market** and home grown tobacco use. Indeed, this seems to be the only argument that the <u>tobacco industry has made</u> against the action plan proposals. These concerns are almost certainly as exaggerated and self-serving as they have been in the past for measures like increases in tobacco taxation and standardised (plain) packs. Reviews of illicit tobacco use have noted the limited number of independent (non-tobacco industry funded) studies, ⁴⁷ but the most recent independent estimate from 2013 was that illicit products made up only 1.8-3.8% of the NZ market. ⁴⁸ Commentators have noted that any increase in illicit trade is likely to be modest and will not undermine the substantial positive effects of the policy in reducing smoking prevalence. ⁴⁹ Furthermore, NZ has very strong border controls and surveillance which, coupled with its relative geographical isolation, make it unlikely that smuggled tobacco will be a major problem. Nonetheless, surveillance and enforcement should be strengthened further, as the action plan proposes.

How practical is a mandated VLNC policy?

The policy has high acceptability among people who smoke. For example, 80% of people who smoke and recent quitters expressed support for mandated VLNCs, provided alternative nicotine products are available.⁵⁰ There is similar evidence of very strong support for this policy in international studies.^{51 52}

Although no other country has yet implemented a VLNC policy, international interest in this policy measure is increasing and the evidence base continues to grow. For example, the US FDA recently announced its intention to introduce a risk-proportionate regulatory framework for nicotine products.¹³ In 2018 the FDA issued an Advanced Notice of Proposed Rulemaking that recommended developing a tobacco product standard for nicotine levels in cigarettes, and that would mandate minimal or non-addictive nicotine levels.⁵³ Recent press reports suggest introducing a mandated reduced nicotine policy for cigarettes is currently under active consideration.

The manufacture of VLNCs is technically feasible through extraction of nicotine from tobacco or use of genetically-engineered low-nicotine tobacco plants as evidenced by the tobacco industry's history of developing reduced nicotine products like *Quest* and *Next* and the existence of current research VLNC products (e.g. manufactured by 22nd Century Group) such as *Magic* and *Spectrum*.¹²

Some,²² though not all,⁵⁴ studies have found that immediate reductions in nicotine content have greater positive effects than a gradual reduction in nicotine levels, so this is likely to be the preferred method of introducing the policy. Concerns tobacco companies operating in NZ may refuse to supply VLNC products and abruptly withdraw from the NZ market could be addressed by the NZ Government developing pre-implementation contracts with international producers of VLNCs that operate independently of the tobacco companies. These arrangements would enable the timely and rapid introduction of VLNCs. The 22nd Century Group has expressed its willingness to support implementation of the action plan policy by supplying VLNCs to NZ.

NZ's regulatory framework also ensures relatively easy access to alternative nicotinedelivery products, such as e-cigarettes and pharmaceutical grade products (gum, patches etc) for people who smoke who wish to use these products to help them quit or to switch too as short or long term alternative nicotine products (if they are unable to quit nicotine use). These two policy approaches are likely to act synergistically to reduce smoking prevalence.^{11 55} For example, VLNCs' impact as a cessation trigger is likely to be greater where alternative less harmful nicotine products are available for people who smoke to switch to (i.e., who cannot quit nicotine use completely).²⁴ Concerns e-cigarettes act as a 'gateway' to smoking among young people would diminish if cigarettes were rendered unappealing because they no longer deliver comparable doses of nicotine to vaping products.

Finally, studies have shown many people who smoke perceive nicotine (rather than by-products of combustion) as harmful and hence may mistakenly perceive VLNCs as less harmful or alternative products like e-cigarettes as more harmful than VLNCs. 50 56-58 This could deter quitting or switching to alternative, less harmful, nicotine sources, although the evidence that will eventuate is unclear. To address this concern prior to and during implementation it will be important to communicate to people who smoke that VLNCs are just as harmful as regular, non-VLNC, cigarettes and advise that nicotine is not the primary toxic constituent of tobacco products.

Conclusion

A mandated VLNC policy for Aotearoa NZ is a critical component of the Government's proposed action plan which will give a realistic chance of achieving the Smokefree 2025 goal, and realising the many benefits of health improvement, enhanced equity, and cost-savings that would follow. There is a compelling logic and growing evidence base supporting this approach, and NZ can potentially draw on ongoing developments with implementation of this policy in the USA. Robust monitoring and evaluation will be critical to assess the policy's impact, and to ensure people who smoke are supported to quit or move to other nicotine sources. Submissions for the action plan are open. We encourage all individuals and organisations who are concerned about enhancing the health of New Zealanders and who support the need to protect future generations and help people who smoke to quit, to make submissions in support of this important measure.

* **Author details:** Richard Edwards, Janet Hoek and Nick Wilson are members of ASPIRE2025 and the Department of Public Health, University of Otago, Wellington. Chris Bullen is based at the National Institute of Health Innovation at the University of Auckland.

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