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Removing the nicotine from tobacco: The key component of the current Smokefree Bill

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Aotearoa New Zealand's Smokefree Environments and Regulated Products (Smoked Tobacco) Amendment Bill includes three key policy measures from the Smokefree Aotearoa 2025 Action Plan: denicotinisation of cigarettes and tobacco, large reductions in outlets selling tobacco, and the introduction of a Smokefree Generation policy. In a previous blog we summarised the evidence for and against denicotinisation. This blog updates the evidence, describes why this policy is so pivotal, and discusses implementation issues.

The draft Smokefree Aotearoa 2025 Action Plan (Action Plan) published in April 2021 proposed mandating the removal of virtually all nicotine from smoked tobacco products. Denicotinised (sometimes called very low nicotine cigarettes, VLNCs) are defined as cigarettes having less than 0.4mg nicotine per gram of tobacco.[1]

Our blog in April 2021 summarised the case for denicotinisation as follows:

- Theory and logic suggests denicotinisation will greatly reduce the addictiveness and appeal of smoked tobacco products, and accelerate the decline in smoking prevalence equitably;
- Extensive supporting evidence, notably from randomised controlled trials (RCTs), show that people who smoke and are provided with denicotinised cigarettes find these products less appealing and satisfying, and are more likely to make quit attempts and stop smoking;
- Concerns that denicotinisation would result in compensatory smoking and increased exposure to toxins have proven unfounded;
- Aotearoa is a highly favourable context to mandate denicotinisation because less hazardous non-combustible nicotine products (subsidised nicotine replacement therapy, such as patches, and vaping products) are widely available.
- The Action Plan creates a uniquely favourable context in which denicotinisation will be supported by other robust policies, including reduced retail availability of tobacco products and the smokefree generation policy, and by enhanced smoking cessation support;
- Denicotinisation is technically feasible and acceptable, with high levels of support, including among people who smoke.

The Ministry of Health's analysis of submissions to the consultation on the draft Action Plan revealed most submitters supported denicotinisation. Submitters holding strongly positive views included community groups, Pacific, Māori and iwi/hapū groups; government organisations; smokefree researchers and practitioners; and health care organisations. More negative responses were largely confined to small and medium retailers, vape retailers, and tobacco manufacturers.

Current state of the evidence

Important developments in the evidence base strengthen the case for denicotinisation being the single most important measure included in the Action Plan.

Recent studies, including two comprehensive reviews,[1 2] provide further evidence for denicotinisation's likely effectiveness and information to guide implementation. These studies give greater confidence that denicotinisation is feasible and equitable. For example, randomised controlled trials (RCTs) have found people using denicotinised cigarettes from groups with high smoking prevalence, such as people experiencing poor mental health or with lower socio-economic status (SES), are more likely to make a quit attempt and quit smoking. These studies found no increase in possible adverse effects like increased (compensatory) smoking, stress and anxiety or use of alcohol and other drugs.[3-5] These findings enable us to reject claims tobacco companies and others with commercial vested interests have made to oppose denicotinisation.

Some other recent key findings include:

- An RCT compared experiences among people who smoke and had a history of anxiety and mood disorders randomised to receive denicotinised or regular cigarettes. It found reduced cigarette consumption and markedly increased quit rates in the denicotinised cigarettes group, but no differences in measures of anxiety, mood and stress.[4]
- An RCT with low SES participants found participants using denicotinised cigarettes smoked fewer cigarettes, reduced their exposure to carcinogens, and had increased

quitting compared to participants using regular cigarettes. High rates of attrition and non-compliance among the denicotinised cigarette users suggest having alternative sources of nicotine available is important with a denicotinisation policy.[5]

- An RCT found that people randomised to denicotinised cigarettes were less likely to drink alcohol daily or engage in binge drinking than people randomised to using regular cigarettes.[3]
- An RCT comparing gradual vs immediate reduction in nicotine levels found that there was a greater reduction in cigarettes smoked among participants randomised to the immediate reduction group.[6]
- A qualitative study with people who smoke who could only access denicotinised cigarettes found that most thought they would smoke more but did not. Some participants felt less addicted and more in control of their smoking. Many thought that if only denicotinised cigarettes were available, they would stop smoking, switch to vaping, or seek illicit regular cigarettes or tobacco.[7]
- Studies in diverse US populations[8-11] and among people who smoke or have recently quit in the New Zealand ITC study,[12] have found that the pivotal role of nicotine in addiction is generally understood. However, these studies also revealed common misperceptions, such as that nicotine is the main cause of cancer and other serious smoking-related diseases. This suggests people who smoke may falsely believe denicotinised cigarettes are substantially less harmful to smoke than regular cigarettes or vaping products.

Modelling studies add more evidence. We reported in a previous blog findings from a preliminary modelling study using estimates of impact based on expert elicitation and evidence from NZ studies. Prompt implementation of denicotinisation (March 2023) was projected to dramatically reduce overall daily smoking prevalence to 3.1% by 2025, and to 7.7% for Māori. Māori daily smoking prevalence was projected to reach 5.2% (close to the <5% smokefree goal) in 2025 with additional mass media expenditure and Quitline cessation support. More sophisticated modelling, reported in the regulatory impact statement[14] reached similar conclusions and also found denicotinisation results in substantial reductions in Māori vs non-Māori health inequities.[15]

Implementation recommendations

Hatsukami et al[1] have proposed best practice for implementing a denicotinisation strategy. The table summarises their key points and proposes how the policy could be operationalised in NZ.

Table: Recommendations for implementation of a denicotinisation policy in Aotearoa NZ (adapted from Hatsukami et al[1])

Implementation issue	Implementation recommendation
Nicotine level in smoked tobacco products	Reduce to ≤ 0.4mg nicotine/g tobacco in *all* smoked tobacco products. *The maximum level should be specified in the final Act to avoid any potential challenges if it is only set out in the regulations.*

Implementation issue	Implementation recommendation
Timeline for introduction of policy	Implement an immediate rather than a gradual reduction in nicotine levels. *A specific date should be set in the final Act (not the regulations) after which only denicotinised tobacco products will be legal to sell. This will avoid any potential confusion that may arise if regular and denicotinised tobacco products are available at the same time.*
Cessation support	Provide affordable and easily accessible cessation support treatments, including medical products. *NZ already provides this support and the Action Plan proposes expanding cessation support alongside increased investment in mass media campaigns, including cessation support and campaigns designed designed by Māori, for Māori.*
Access to alternative nicotine products	Provide people who smoke with access to lower harm nicotine products as potential smoking cessation aids or substitutes for smoking. *Vaping products are already widely available in NZ through hundreds of specialist and generic retailers (though a careful balance should be struck between supporting people who smoke to switch to these products while avoiding uptake among youth).*
Illicit tobacco market	Implement robust surveillance and enforcement policies to minimise the illicit market in smoked tobacco products. *Robust monitoring and enforcement against smuggled tobacco is in place. The Action Plan proposals and recent budget allocations will further strengthen existing processes.*
Adjunct policies	Implement denicotinisation policy within a comprehensive tobacco control programme. *This is the approach taken in the Action Plan, albeit with some policy omissions e.g., no minimum price strategy, no clear action against filters and other product design features, and some gaps in smokefree environment policies.*
Public education	Prior to implementation, educate the public about the rationale and nature of the policy, including outlining the relative harmfulness and addictiveness of regular cigarettes, VLNCs and alternative nicotine products (vaping products, heated tobacco products and NRT).

Implementation issue	Implementation recommendation
Testing and surveillance infrastructure	Develop systems for surveillance, verifying compliance and evaluating impacts of the denicotinisation policy. *In NZ this could include establishing testing systems using local laboratories or sending samples to overseas laboratories, and using the NZ Health Survey and other surveys and research studies to monitor responses among people who smoke.*

Policy developments internationally and locally

International momentum for mandated denicotinisation is growing. In December 2021, the US FDA authorised marketing of two denicotinised cigarette products and in June 2022, the FDA announced it intends to develop a product standard to minimise the nicotine level of smoked tobacco products.

Most importantly, the final Smokefree Aotearoa 2025 Action Plan committed to introduce mandated denicotinisation and the Smokefree Environments and Regulated Products (Smoked Tobacco) Amendment Bill published on 21 June 2022 included denicotinisation. A Technical Advisory Group has already been established.

The proposed implementation process set out in the current Bill includes:

- Denicotinisation will apply to *all* smoked tobacco products (to prevent tobacco companies from developing small cigars and similar products designed to evade limits that apply only to cigarettes);
- Regulations introducing the proscribed nicotine limit must be introduced within 21 months of the Bill becoming law (although the timetable for introducing the policy once the regulations are in place is unclear);
- Smoked tobacco products will require approval to be sold in NZ and tobacco manufacturers/importers will be required to implement an annual testing regime to demonstrate that products meet the standards required for approval.

The outline in the Bill could change if amendments are introduced during the Select Committee and subsequent readings of the Bill.

There should be no major product-related feasibility issues: producing denicotinised tobacco is highly feasible,[16] and some US companies already produce VLNCs and others may follow. Such products could be imported through these companies via branches in NZ or by existing NZ-based tobacco or vaping companies.

What are the priorities?

There are at least four priority actions needed at this point.

Strong advocacy. The health, public health, and smokefree communities need to advocate strongly for this key measure and support its passage through Parliament, by making submissions that outline the benefits denicotinisation will bring to whānau, communities and the general population.

Rapid implementation. The policy should be introduced as soon as practicable, given the urgency of helping people who smoke to quit and preventing additional young people from becoming addicted to smoking. We recommend introducing regulations in 2023, within six months of the Bill becoming law, and implementing the policy during 2024, within 6-12 months of publication of the regulations.

Correct sequencing. Implementing denicotinisation *before* introducing measures to greatly reduce retail availability of smoked tobacco products has a strong logic. The substantial reductions in prevalence and demand that will follow denicotinisation will decrease the importance of smoked tobacco products to retailers, thus increasing the acceptability and feasibility of introducing rigorous retail supply constraints.

Plan now. Detailed preparation should start immediately, so implementation can begin once the Bill has passed into law. We suggest the implementation strategy should include a communications plan (see Table) to explain the policy and its rationale, enhanced measures to monitor and minimise illicit trade (these are already being introduced), and developing a product testing and surveillance regime to ensure all products released for sale comply with the new product standards.

Conclusion

New research and modelling studies add to the evidence strongly suggesting that denicotinisation of cigarettes and other tobacco products is a pivotal measure in the Smokefree Aotearoa 2025 Action Plan; and that this measure will rapidly reduce smoking prevalence and the many inequities smoking causes. The smokefree and public health communities in Aotearoa NZ have a crucial opportunity to help end the smoking epidemic by uniting to support the Smokefree Bill and advocating for rapid implementation of the world-leading measures it sets out.

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