Health Coalition
Aotearoa

Discussion paper on vaping and e-cigarette regulation

March 2020

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The Smokefree Expert Advisory Group of the Health Coalition Aotearoa, New Zealand

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Introduction

In November 2018, the Associate Minister of Health announced in a Cabinet Paper the Government's intention to *"amend the Smoke-free Environments Act 1990 (SFEA) to improve smokers' access to quality vaping and smokeless tobacco products, while protecting children and young people from the risks associated with them"*. (Salesa, November 21 2018)

On the 24th February 2020 a specific proposal was introduced to Parliament as the Smokefree Environments and Regulated Products (Vaping) Amendment Bill ('the Bill'). The Bill aims to amend the Smoke-free Environments Act 1990 to bring the provisions of the Act up to date and to ensure that all regulated products (tobacco smoking products, heated tobacco products, herbal smoking products, smokeless tobacco products, and vaping products) are adequately covered. There will be a a period of consultation on specific aspects of the proposed regulation through the Health Select Committee process, before the Bill is passed.

The Smokefree Expert Advisory Group (SEAG) is an advisory sub-group of the Health Coalition Aotearoa (HCA), an umbrella organisation for the NGO, healthcare and academic sectors established to achieve the shared vision of health and equity in Aotearoa/New Zealand. The SEAG provides expert advice about the achievement of the Smokefree Aotearoa goal and related matters.

Members have expertise in all aspects of smokefree policy and practice, and include people drawn from the NGO, health, academic/ research and practitioner sectors. Members of SEAG are listed at the end of this document.

Members provide advice based on their expertise and individual views. Statements of the SEAG may not reflect or represent the views of the organisations and institutions from which members are drawn.

Scope and purpose of this document

This discussion paper sets out some possible principles and options addressing key regulatory questions about e-cigarettes, devices that are designed to deliver inhaled

nicotine to the user without the combustion of tobacco. The use of e-cigarettes, hereafter referred to as electronic nicotine delivery systems (ENDS), is referred to as *vaping*.

We hope this document will inform the debate about vaping and ENDS regulation, and prove useful to individuals or organisations preparing submissions.

The primary focus of this paper is on the regulation of electronic nicotine delivery systems (ENDS - vaping products and e-cigarettes). Other alternative nicotine delivery systems (ANDS) such as 'Heat not Burn' (HNB) heated tobacco products are briefly considered

An issue that needs to be determined in more detail is whether regulations should be the same for all types of ENDS and ANDS (and for different classes of vaping device/product), or different.

For most areas, we have been able to agree a preferred regulatory approach, but for others this has not been possible. Where consensus has not been reached this reflects legitimate differences in opinion and uncertainties resulting from limitations in the evidence-base, rapidly evolving contexts, behaviours and products. Where consensus was not possible we have outlined the approaches that were preferred by different members of SEAG.

Conduct of the debate about e-cigarette and vaping product regulation

The evidence-base for the personal and population health impacts of ENDS and ANDS is incomplete, evolving rapidly, and characterised by substantial uncertainty.

Regulatory approaches should be informed by the totality of the evidence, giving greater weighting to evidence from high quality studies and systematic reviews when available. Evidence from the New Zealand setting is also particularly relevant to take into consideration because of our unique history, epidemiology and context with regard to tobacco use and tobacco control.

However, some degree of ongoing uncertainty and differences in opinion are to be expected because:

- products are evolving rapidly
- evidence is always incomplete
- some evidence is of poor quality
- findings from single studies are often given unwarranted attention
- even high quality research can be interpreted in different ways
- new evidence is constantly emerging.

There is general agreement that ENDS are very likely to be less harmful than smoked tobacco products, and probably substantially so. However, there is uncertainty about some key issues, including:

- the degree to which different products are harmful and their relative harm compared to smoked tobacco products
- the potential of these products to act as a gateway to use of combustible tobacco products, especially among children
- their potential to contribute to achieving the Smokefree 2025 goal.

This uncertainty has fuelled debates in the tobacco control community in New Zealand and elsewhere, in particular debates about the optimal regulatory approach that will maximise public health benefits and minimise harms.

We suggest therefore that the conduct of discussions within the HCA SEAG, and for all involved in this debate in the wider tobacco control and public health sectors should be respectful, mana-enhancing, and focus on substantive issues not individuals.

Possible principles to guide policy and regulation

One means of facilitating productive and respectful discussions is to agree on a set of principles that should inform decision-making on regulation and policy. We suggest the following as a starting point for discussion:

- The primary aim of ENDS-related policies should be to support health equity through achieving the Smokefree 2025 goal of minimal smoking prevalence among all population groups in NZ; the policies should not create barriers to achieving a longer term Tupeka Kore goal of eliminating nicotine use as well as tobacco use.[1]
- ENDS-related policy options should be considered and evaluated in the context of the overall policy environment, taking into account complementarity with, and impacts on, other current or potential measures to achieve the Smokefree 2025 goal;
- Smoked tobacco product regulation should always be more stringent than that applied to ENDS because of the greater harm caused by smoked tobacco products;
- ENDS-related policies should aim to:
  - (i) maximise the benefits of ENDS (such as supporting smokers to quit smoking; or for those who cannot quit, to transition completely from smoking to ENDS), and
  - (ii) minimise harms related to ENDS use. This includes minimising: the health risks that ENDS users are potentially exposed to; the initiation of nicotine-containing ENDS by non-smokers (especially children and young people), and potential 'gateway' effects of ENDS use to smoking.
- Priority should be given to ENDS-related policy and regulation that help reduce smoking among Māori, Pacific peoples, families experiencing higher levels of deprivation, people with mental health conditions, and other groups where smoking prevalence is high.
- The Ministry of Health should continue to monitor emerging evidence on ENDS, particularly their potential impacts on smoking prevalence and users' health in New Zealand.
- Policies and regulations should be crafted so as to be able to be updated swiftly in light of new evidence.

[1]Tupeka Kore arose from Māori leaders who proposed a tobacco-free kaupappa in which tobacco use and availability was eliminated for Māori

Scope of the document

This document sets out a preferred option for each regulatory area included in the Bill, as agreed by the SEAG.

In cases where there was substantial disagreement about the preferred approach, more than one option is given.

The regulation of combusted tobacco products such as manufactured cigarettes, roll your own tobacco, cigars and hookah (also called waterpipes and shisha) is not discussed in detail in this paper. However, in line with the principles outlined above, the unanimous view of the SEAG is that combusted tobacco products should be subject to more stringent regulation than ENDs due to the likely greater degree of harm associated with their use.

Members of SEAG noted that an important consideration in determining preferred regulatory options is the broader policy and regulatory environment, particularly the policies and regulations in place for smoked tobacco products. SEAG strongly recommends that a regulatory framework is implemented for all ENDS and ANDS with the aim of minimising the use of smoked tobacco products as rapidly as possible.

Regulatory approaches for different products may have complementary effects and thus may affect the acceptability of specific regulatory approaches. For example, removing nicotine from smoked tobacco products may be feasible to implement and more effective at reducing smoking if less harmful nicotine delivery products, such as ENDS, are widely available for smokers. In addition, if the availability of smoked tobacco products is essentially unregulated, then it is very difficult to justify a more restrictive regulatory policy for (less harmful) ENDs.

Another consideration is deciding which policy levers or approach to use. Members noted that where products and evidence are rapidly evolving, policy interventions may be best introduced using regulations rather than primary legislation. For example, regulations could be introduced through devolved regulatory powers through the Director General of Health or designated regulatory authorities. Such an approach may be preferred to allow more rapid, responsive and timely policy measures.

Preferred regulatory options

Supply and availability (place of sale and age restrictions)

1. Place of sale

Government proposals: The Bill proposes the same regulations for ENDS (and ANDS) as for cigarettes regarding where they can be sold (i.e.,they may be sold by any retailer, including dairies, with no requirement for a licence or any other stipulations about retailer facilities, staff expertise etc.).
The Bill differentiates between specialist specialist vape stores (which will require registration as a 'specialist vape retailer'), and generic retailers (who will not require registration). Specialist vape stores are defined as those where at least 85% of the total sales from the retail premises are from vaping products. Such retailers will need to report sales annually to the Ministry of Health.
Specialist vape stores must be R18 and the retailer must take all practicable steps to prevent under-18s from entering. Vending machine sales allowed if supervised by staff, do not make regulated products visible, not located where the public have access, and must have health warnings.

SEAG view: There was unanimous agreement that there should be stepwise introduction of substantial restrictions on the availability of smoked tobacco products (e.g. regulations that progressively limit the number and type of stores that may sell smoked tobacco products and a ban on vending machine sales). These measures are essential to ensure that the relative availability of ENDS is greater than that of much more harmful smoked tobacco products.

In the context of highly restricted availability of smoked tobacco products, there was support for some constraints on where ENDS products could be sold, provided these still resulted in easy availability of ENDS for smokers. The advantages of constrained availability are that it could (i) ensure highly restricted availability for minors and (ii) facilitate the provision of expert advice and support to smokers about the most effective and safe use of ENDs. The main potential downside identified was that ENDS users who ran out of e-liquids/pods etc at times or in locations where ENDS products are not available (more likely in rural communities) may lapse or relapse to smoking.

SEAG members supported the Bill's proposal for registration of specialist vape retailers, but also believe such retailers should be licenced/certified to deliver smoking cessation support.

There were three options discussed by SEAG members for the availability and place of sale of ENDS. These options reflect the diversity of option between members.

Option 1: More constrained: Sale of all devices, starter kits, e-liquids/pods etc limited to:

(i) Licensed specialist R18 vape retailers. Licence to include meeting stipulated standards in relation to staff training (in ENDs products and their use, smoking cessation advice/referral etc), sale of adequate product range, products meeting safety standards, and location e.g. non-proximity to schools and early learning centres.

(ii) Selected/certified community pharmacies. Selection/certification based on meeting stipulated requirements as above (note adequate product range and staff training in use of ENDs and continuing education on new products is essential). Members noted that the feasibility and practicality of pharmacy sales needs exploring further.
(iii) No sales allowed in other stores including dairies, supermarkets and gas stations.
(iv) No vending machine sales.

Option 2: Moderately constrained: Sale of devices/starter kits limited as in option 1, other than in areas where no specialist vape stores or community pharmacies selling devices are available within a reasonable (to be defined) distance, in which case generic retailers could apply for registration to sell a specified range of devices.

(i) Sale of refills for ENDS (e-liquids/pods etc) allowed in other stores including dairies, supermarkets and gas stations, but only with a limited range of flavours e.g. tobacco, mint and menthol.
(ii) Sale of refills for ENDS (e-liquids/pods etc) including all non-prohibited flavours allowed in R18 specialist vape retailers.
(iii) Vending machines allowed to sell refills with limited flavour range (subject to location in R18 premises and supervised operation with age verification). Vending machines should also include other cessation options such as NRT products.

Option 3: Less constrained: Sale of devices, starter kits, and refills for ENDS (e-liquids/pods etc) allowed in all stores, including specialist vape retailers, dairies, supermarkets and gas stations (with age verification).

(i) Sale of refills for ENDs as in option 2
(ii) Vending machines as in option 2 and to include devices, starter kits, and refills for ENDS, plus other cessation options (such as NRT products).

For all of the above options, SEAG members agreed that sales to minors in all settings should be prohibited and subject to rigorous enforcement action.

This is an example of an area where regulations could vary for different products according to likelihood of harms. For example in option (ii), HTP products (including refills) could be restricted to sale in R18 premises and pharmacies, whilst ENDS refills could be sold more widely.

All these options will result in the availability of the most harmful smoked tobacco products being less constrained than vaping products. This anomaly must be addressed by progressively decreasing the availability of smoked tobacco products so that they are less easily purchased than vaping products

2. Minimum age requirements

Government proposals: The Bill bans retailers from selling ENDs and ANDS to persons under 18 years of age.

SEAG view: There was support for the minimum age for sale of ENDs being the same as for smoked tobacco products (i.e. 18 years currently, but increased to 20/21 years if the minimum age for smoked tobacco products increased). The group noted there should be a system to ensure that minors who smoked could gain access to ENDs to help quit if they wished to use ENDS in a quit attempt – e.g. access could be administered and supervised through accredited smoking cessation providers.

Best practice for policing online sales and preventing purchases devices and consumables by minors should be investigated and implemented. For example, the feasibility of vendor registration and requirements for age verification at the point of purchase and delivery should be investigated. For retailers who fail to comply there should be stringent penalties and enforcement, including fines and substantial bans on the right to sell ENDs or tobacco products. Online sales of ENDS should require shipping with verified R18 delivery.

Product safety standards, flavours and nicotine content

1. Product safety standards

Government proposals: The Bill sets out (i) product notification requirements , (ii) establishes a pre- notification process with self-certification by importers/manufacturers that regulatory requirements are met; (iii) establishes an adverse reaction monitoring system which allows for recalls, suspensions and cancellations of product notifications; (iv) provides the Director General Health with powers that include the ability to declare a substance to be a prohibited ingredient that may not be present in notifiable products,to issue warnings, require warnings and suspend or cancel product notifications.

SEAG view: There was strong agreement that product safety standards for approval for sale or importation for devices and consumables are needed, together with an appropriate monitoring, enforcement and consumer protection mechanism. This process should be implemented through a Government led regulatory (rather than legislative) approach, to ensure the system may respond quickly to emerging evidence. It could encompass some or all of: child safety, manufacturing process, allowable levels of contaminants and harmful constituents in products or emissions, clear labelling of nicotine content, and validation of nicotine content and concentration.

A mechanism should be established to monitor the effectiveness of the safety standards, including monitoring of black market or illicit supply.

A national early warning system should be established to pick up early signs of any acute vaping-related serious adverse events, with an appropriate escalation pathway including the facility for removal from the market of products found to be hazardous. As an example, Drug Early Warning Systems have been established internationally for detection of acute events related to new psychoactive substances. Such a system is currently under

consideration in New Zealand, and could be expanded to include vaping-related events or an independent system could be established.

The regulatory framework should include requirements for sustainability (e.g. the recycling or disposal of devices and related consumables). Similar measures would be required to address the environmental impacts of tobacco products, particularly tobacco butts – for example, by introducing a tobacco industry levy or banning the use of filters.

There should be clarity in the regulations about how the standards and monitoring measures are to be enforced and resourced.

2. Flavours

Government proposals: The Bill outlines a mixed model. The Bill allows generic retailers to sell tobacco, mint and menthol flavoured vaping liquid only, whilst specialist vape retailers will be allowed to sell any flavours that have not been prohibited. These changes will come into effect six months after the date on which the Act receives Royal assent. The Bill prohibits use of colouring agents in e-liquids.Products will need to comply with any product safety requirements that are set out in regulations, for example, maximum nicotine content of vaping liquids, standards for vaping liquid containers, and standards for vaping devices. These requirements will be publicly consulted on before being finalised. They will come into effect 6 months after the date on which the Act receives Royal assent.

SEAG view: Flavours (or their marketing) were acknowledged as both potentially appealing to children/youth (and hence could potentially increase ENDs uptake by youth); and to be an important part of the appeal of vaping to smokers and ex-smokers (and so restricting flavours could reduce transitioning away from smoking or increase relapse to smoking). An additional concern of a prohibitive approach to flavours is that it may generate a black market in flavoured products and promote 'do-it-yourself' production, both of which could increase the risk of vapers using contaminated, hazardous products and suffering adverse events, such as has been seen recently in the USA with the use of contaminated, black market-sourced Tetrahydrocannabinol(THC)-based e-liquids.

SEAG members agreed that flavour-related packaging imagery or product names that appealed to children (e.g. 'gummy bear' flavour or cartoon characters on packaging) should be prohibited. We support regulations in which flavour-related marketing using evocative and appealing descriptors packaging is prohibited. Instead, flavours could be designated by numbers or colours only, with no descriptors visible on packaging. SEAG members note that the Bill allows for regulations that require regulated products to be presented in standardised packaging.

There were mixed views on limiting the range of flavours or prohibiting specific flavours. One option supported by some SEAG members is to initially allow flavours unless they have been shown to be, or are highly plausibly, associated with health risks. This approach should be accompanied by monitoring of use, particularly among children and young people, with the option of restricting specific flavours which are shown to be preferentially appealing to and used by minors. The Bill outlines powers to be conferred on the Director General Health

that enable flavour recalls. Another option supported by some SEAG members is to limit flavours to a much smaller range, with the option of liberalising these restrictions if monitoring supported such a change.

SEAG members agreed that restrictions on flavours should be more stringent on smoked tobacco products, and at a minimum should prohibit all characterising flavours of cigarettes and other smoked tobacco products, and a ban on capsule cigarettes.

3. Nicotine content

Government proposals: That products will need to comply with any product safety requirements that are set out in regulations, including, maximum nicotine content of vaping liquids. These requirements will be publicly consulted on before being finalised, and will come into effect six months after the date on which the Act receives Royal assent.

SEAG view: Some jurisdictions, notably the European Union have introduced a cap on the level of nicotine in e-liquids and vaping products. SEAG members noted that this is a highly complex regulatory area as there are multiple influences on nicotine uptake and bio-availability including constituents such as flavours, solvents and base e-liquid ingredients (propylene glycol, vegetable glycerin), properties of the e-liquid (e.g., pH), device characteristics (e.g., wattage, temperature, model) and user behavior (e.g., puff topography).(DeVito & Krishnan-Sarin, 2018) Hence, nicotine content may be an unreliable predictor of nicotine delivery and absorption by the user because product design and use variability is so wide.

SEAG has concluded that at this stage introducing regulations on nicotine content is not a priority, and that it should be reconsidered once it is clearer which regulatory approach will achieve the best balance between maximising appeal to smokers wishing to use ENDS to quit or as complete substitutes whilst discouraging use among never-smokers, particularly youth.

Marketing, packaging and consumer information

1. Marketing and consumer information

Government proposals: The Bill generally aligns ENDS and ANDS product devices with the current Smokefree Environments Act (SFEA), and hence the similar prohibitions on promotion, sponsorship and advertising will apply. The Bill allows all retailers to display products within stores and to display information about, for example, the relative-risks of vaping compared with smoking. The information that may be displayed within stores will be set out in regulations.

In response to a customer enquiry generic stores may do no more than identify the regulated products (including tobacco products, vaping products and smokeless tobacco

devices) available for purchase and indicate their price. A specialist vape retailer may provide advice, recommendations and demonstrations of regulated products to customers.

The government also states an intention to provide improved information on ENDS and ANDS for the public and smokers. This has been initiated with the new HPA Vaping Facts website: https://www.vapingfacts.health.nz/

SEAG view: There was support for strong controls on the marketing of ENDS, with either all marketing (including sponsorship and product placement) prohibited, or minimal marketing allowed i.e. only point of sale only advertising and displays in vape shops or pharmacies. Permissible product claims should be defined by developing a set of pre-approved statements. Consultation on a list of such statements occurred in Canada in 2018.

There was support for targeted communications to be developed and made available to:

- smokers (to promote switching), on matters such as the types of ENDS and consumables, potential benefits and harms of ENDS, education about nicotine, the effective use of ENDS devices, and how to use ENDS to support quitting, and
- non-smokers, particularly youth and young adults (to deter vaping uptake), focusing on education about nicotine and ENDS as a harm reduction tool for smokers-only.

2. Packaging and warnings/information

Government proposals: The Bill provides for tailored packaging requirements for vaping products and smokeless tobacco products which will be set in regulations. There will be public consultation before these are finalised. It is proposed that New Zealand will follow the UK model.

SEAG view: The aim of making ENDS widely available is to maximise their appeal to smokers as quitting aids or as alternatives to smoking, whilst minimising their appeal to and use among non-smokers particualry youth and young adults. Alluring or appealing packaging (particularly to minors) should not be allowed. Hence we support making ENDS products available in standardised packaging. Products (especially e-liquids) should also all be supplied in child-proof packaging.

We support a requirement to provide comprehensive and balanced information to consumers including listing ingredients, nicotine content and concentration, and providing instructions for use of devices and safety advice. Further detailed work on exploring options and evaluating current approaches to providing information to consumers is required. Packaging (on pack information panels and/or inserts) should also include information about the potential harms (e.g. possible long term health effects, addictiveness) and benefits (less harmful than smoked tobacco products) and recommended use of ENDS (i.e. by smokers to help quit smoking or as short-term complete substitutes for smoking).

Regulations for smoked tobacco products should be strengthened to ensure they are at least as stringent as those for ENDS e.g. all tobacco products must list ingredients and should provide information and tips about quitting through pack inserts.

Advice and support for ENDS for smoking cessation

Government proposals: The Bill not outline how ENDS will be promoted or supported as quitting aids or as substitutes for smoking; or if guidance/training should be given to smoking cessation staff and providers about how to support smokers quitting with ENDS.

SEAG view: Cessation service providers should be encouraged to give smokers (including smokers < 18 years) information about the full range of options available to help quitting, including ENDS. Smokers who choose to use ENDS to help them quit smoking should be provided with good quality advice and support to do so.

Cessation service providers should be supported through appropriate training and resources (e.g. guidance) in the use of ENDS, and to support quitting smoking using ENDS.

Use of ENDS in indoor and outdoor workplaces and public places

Government proposals: The Bill proposes that the same restrictions on smoking in the Smoke-free Environments Act are applied to vaping and use of smokeless tobacco products in legislated smokefree areas. An exemption is proposed for specialist vape retailers to allow for the demonstration of products in store. Local authories still have the ability to determine whether to include vaping in outdoor smokefree areas.

SEAG view: One view was that all indoor legislated smokefree areas, *including* prisons and schools, should also be vape free with the proposed exemption for R18 specialist retailers and where practicable pharmacies if they sell ENDs. Another possible exemption that could be considered is healthcare in-patient facilities, particularly in high smoking prevalence settings such as mental health facilities, where provision of a designated room for ENDs use might be appropriate. Another view was that additional exemptions should be allowed for R18 workplaces such as pubs and bars (at the discretion of the owner/management) and also prisons. Where vaping is allowed indoors it may be appropriate to introduce 'courtesy' stipulations to minimise nuisance to non-vapers e.g. prohibit 'cloud-chasing' – though the practicality and acceptability of this is uncertain, and it may become less relevant with newer devices and vaping-related behaviours.

Other smokefree areas have been introduced on a non-legislated basis at local level with enforcement through educational mechanisms (e.g. signage) only, particularly in outdoor settings such as outdoor dining, parks, playgrounds, malls and beaches. SEAG propose that the inclusion of vaping in such settings should be left to local decision-making after consultation with users, local communities and other stakeholders. This allows local flexibility but has the disadvantage that it will result in varying policies.

Where partial restrictions are introduced these are usually in the form of smokefree areas (with smoking and vaping being allowed in the non-smokefree areas by default). It might be preferable to provide separate vaping and smoking areas to minimise the risk of former smokers who are vaping being exposed to smoking and the risk of triggering relapse to smoking among vapers who are ex-smokers. However, in practice providing such facilities may rarely be feasible.

Excise duty/taxation of ENDS

Government proposals: The Bill does not discuss introducing taxes on vaping and other products, and there are no proposals to do so that we are aware of.

SEAG view: We agreed that the status quo of no specific excise tax on ENDS should be maintained but it should be kept under review.

In the event of evidence of a substantial increase in current or daily use of ENDS among youth/young people, a modest specific tax to reduce affordability may be required.

Fiscal measures to incentivise the use of ENDS (and other smoking cessation products such as NRT) by disadvantaged smokers might also be considered e.g. product subsidies, WINZ hardship grants to purchase starter kits etc. Careful monitoring of the impacts of affordability on use of ENDS is needed to inform whether tax or incentive interventions are required.

If taxes were to be imposed on ENDS, they should be set at such a level to ensure the cost of vaping is less than that of smoking tobacco products, to encourage switching by smokers.

Glossary

Smokefree Aotearoa 2025

This is the Government's goal that was adopted in 2011 in response to the 2010 Māori Affairs Select Committee report (New Zealand Parliament, 2010) into the tobacco industry and the consequences of tobacco use for Māori. The goal is expressed as follows: *"…. the Government agrees with a longer term goal of reducing smoking prevalence and tobacco availability to minimal levels, thereby making New Zealand essentially a smoke-free nation by 2025." (New Zealand Parliament, 2011)*

Tupeka Kore

Tupeka Kore arose from Te Reo Marama, the national tobacco control advocacy organisation, as a response to Māori communities korero about removing all tobacco products. A tobacco-free kaupapa in which tobacco use and availability was eliminated for Māori was also a driver for the Maori Affairs Select Committee inquiry of the tobacco industry with many recommendations reflecting Tupeka Kore aspirations.

Membership of the Smokefree Expert Advisory Group

Shayne Nahu, Manager Advocacy and Wellbeing, Cancer Society of New Zealand (convenor/chair)

Mihi Blair, General Manager, National Tobacco Control Advocacy Service, Hāpai Te Hauora

Chris Bullen, Professor of Public Health, School of Population Health, University of Auckland

Aporina Chapman, Senior Health Promotion Advisor (Team Lead), Population Health Hauora Tairawhiti

Lealeilepule Edward Cowley, Senior Advisor, Tala Pasifika

Richard Edwards, Professor of Public Health, ASPIRE 2025, University of Otago

Janet Hoek, Professor of Public Health, ASPIRE 2025, University of Otago

Julia Rout, Health Promotion Manager, Stroke Foundation of New Zealand

Andrew Waa, Senior Research Fellow, ASPIRE 2025, University of Otago

Natalie Walker, Associate Professor in Population Health, School of Population Health, University of Auckland

Ben Youdan, Strategic Policy Adviser ASH and New Zealand Heart Foundation

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