A Surge Strategy for
Smokefree Aotearoa 2025
The role and regulation of vaping and other
low-risk smokefree nicotine products

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Executive summary

In New Zealand, smoking is the leading cause of premature mortality for cancer, cardiovascular and respiratory disease. Smoking is also a leading contributor to ethnic and socioeconomic inequities in health and welfare, while imposing financial burdens on the poorest people. Progress in meeting the ambitious Smokefree Aotearoa 2025 goal to reduce adult smoking prevalence to below five percent by 2025 is now significantly off-track.

To get back on track, we advocate a surge strategy based on driving down smoking by facilitating smokers to switch to smokefree alternatives such as vaping products, heated tobacco and smokeless tobacco products. These smokefree alternatives present much lower health risks compared to cigarettes and with the right tax structure can ease financial pressures on smoking households, mitigating both health and economic inequities.

The concept of a public health surge is drawn from management of disasters and emergencies where a rapid increase in capability is essential to meet immediate demands. We argue that the concept can be applied to long-running chronic emergencies where a rapid change relative to business-as-usual is necessary – in this case to meet a target that will otherwise be missed.

We outline the proposed surge strategy in more detail below and expand in the body of this report.

- Smoking remains a major public health challenge that causes 5000 deaths every year. In New Zealand, around one in seven adults (13.1%) or about 512,000 persons continue to smoke daily despite sustained tobacco control efforts over several decades. For Māori adults, the daily smoking prevalence is one in three (31.2%), and for Pacific adults, one in five (20.0%).

- Smoking is a significant cause of health inequity between ethnic groups and by socio-economic status. The health inequities are compounded by the financial burdens of purchasing tax-paid cigarettes, which attract one of the highest tax rates in the world and fall disproportionately on the poorest groups.

- The Smokefree 2025 goal can be achieved by accelerating the trend towards switching from high-risk smoked products such as cigarettes to low-risk smokefree products such as e-cigarettes, heated tobacco products, and smokeless tobacco.

- This approach is known as tobacco harm reduction, and is based on the idea that people smoke for the nicotine but die from the tar. It works because almost all of the disease risk attributable to smoking arises from the smoke: the particles of tar and toxic gases that are inhaled from burning
tobacco. Nicotine creates dependence, which keeps people smoking. The smoke contains thousands of toxic agents, many of which are formed in reactions during combustion. If smokers can find satisfactory alternatives to cigarettes that do not involve combustion but do provide nicotine, then they would avoid almost all of the disease risk.

- This harm reduction concept is endorsed in Article 1 of the World Health Organization Framework Convention on Tobacco Control (FCTC) and is supported by many scientists and policy experts world-wide. It is a complement, not an alternative to established tobacco control approaches and works by giving smokers additional and more appealing options to quit smoking.

- E-cigarette use or vaping has emerged as a popular new technology and phenomenon. The devices deliver nicotine via an aerosol (liquid mist) with added flavours. They are popular with many former smokers because they replace many aspects of smoking, not just nicotine. This includes hand-to-mouth habits and behavioural rituals, while also providing a pleasurable sensory experience and flavours that aid in switching. They are largely marketed as consumer alternatives to smoking and are intended to be pleasurable. That is an important contrast with nicotine replacement therapy or smoking cessation medicines. This consumer appeal may be the reason why vaping attracts smokers in greater numbers and faster than established smoking cessation approaches.

- There is also a new generation of tobacco products that heat rather than burn tobacco. These smokefree products also create a flavoured vapour aerosol but do not create products of combustion. In three years following introduction of heated tobacco products in Japan, cigarettes sales volumes fell by 33 percent, an unprecedented decline.

- There has been renewed interest in smokeless tobacco as the experience of snus, a form of smokeless tobacco, in Scandinavia has become more widely recognised. For example, in Sweden where snus use has been displacing smoking, adult daily smoking prevalence has already fallen to five percent – compared to a European Union average of 26 percent.

- Like many new and disruptive innovations, there are also potential risks. Concerns have been raised about abuse, youth uptake and unknown long-term health effects. However, there is much existing evidence to provide reassurance. Regulators therefore must try to exploit the opportunities but also to mitigate the risks of adverse effects through effective regulation.
• Effective regulation involves striking a balance between measures that are so weak they do not have the intended effect and measures that are so excessive that they cause unintended harm. For example, by obstructing smokers switching from smoking by making smokefree alternatives more expensive, less appealing, or more difficult to access. The way to strike this balance is to adopt risk-proportionate regulation. This imposes regulatory burdens and controls in proportion to the risk posed by the product, but also taking account of the opportunities it offers.

• The New Zealand government is currently revisiting the regulatory framework for consumer nicotine products. It has the opportunity to introduce world best-practice by developing a framework for risk-proportionate regulation for smokefree alternative nicotine products. Key features of such a framework would include the following:

  – **Differentiation between smoked and smokefree products.** A comprehensive framework would cover all forms of consumer nicotine product. The key differentiator for policy purposes is whether the product is for smoking. Combustion is far more important than the distinction between tobacco and non-tobacco products. Smokefree tobacco and nicotine products can displace smoking and greatly reduce health burdens. It follows that they should be treated differently to smoked products – reflecting opportunity as well as risk.

  – **A nuanced approach to youth use of smokefree products.** Measures introduced to protect youth should focus primarily on responsible marketing and not on modifying or limiting the appeal of the product itself to adults. Youth use may be beneficial for some young people who are smokers or would-be smokers – it is important, therefore, to recognise that some young people could be potentially harmed by measures aimed to protect youth.

  – **Recognising that flavours play an important role.** Flavours are integral to the appeal of smokefree alternatives and an essential part of the proposition to smokers to try switching and remain smokefree. They also raise concerns about attracting non-smoking youth. We recommend focusing controls on marketing, branding, and flavour descriptors rather than on banning particular flavour chemicals or categories (except where there are safety concerns).

  – **Controls on advertising, not an outright ban.** Advertising allows new smokefree products and innovation to reach smokers and encourage switching. It is, in essence, anti-smoking advertising. Controls on themes, placement, timing and media are appropriate, but not a ban. It is important to recognise that a ban on advertising
of smokefree alternatives has the effect of protecting the dominant cigarette trade and discouraging smoking cessation.

- **The policy for use of smokefree products in public spaces should be a matter for owners or managers.** In the absence of evidence of a plausible material risk to bystanders arising from vaping or heated tobacco products, the government should not mandate wide-ranging bans; nor should it treat smokefree vapour products as though they are smoked products. The same reasoning applies to limitations by local authorities on vaping in outdoor places, e.g., central business districts, beaches, and parks. The government’s role should be to provide information to assist decision-making by owners and managers of properties.

- **Warning and packaging labels should convey accurate information including messages that explain relative risk.** Warnings should not be misused to scare users out of trying products that could be life-saving for them. They should be focussed on helping smokers make better-informed decisions by communicating relevant risk information, including risks relative to smoking, ideally using a range of statements authorised by health officials.

- **Smokefree products should have access to the market via a notification regime.** There should be no requirement for pre-market authorisation, but post-market surveillance and a system for product stewardship that allows improvements and innovations to assist in mitigating safety risks or emerging problems.

- **Products should meet specific safety standards for devices, liquids and ingredients.** Such standards for chemical, thermal, mechanical and electrical safety are emerging internationally, and New Zealand is well placed to take advantage of these. For heated tobacco, standards should provide assurance that there is no combustion. There are established and recommended standards for smokeless tobacco to draw on.

- **Plain-packaging should be mandatory for smoked products only.** The rationale for standardised plain packaging does not apply to smokefree alternatives, which both impose low risks and offer substantial benefits to smokers who switch. Different packaging would also help convey to consumers the different risk profile of these products in a clear and intuitive manner.

- **The fiscal regime should create a strong incentive to switch from smoking to smokefree products.** Most smokefree products should attract only standard sales taxes and zero excise duties. If excise duty is applied, it should leave the highest-taxed smokefree product with
a much lower tax burden than the lowest-taxed smoked product to support switching.

– Public health agencies should provide well-crafted communications to help smokers make informed choices. Public health communicators should engage all relevant stakeholders in communicating risk and the case to switch from smoking to smokefree products.
1 Introduction

1.1 New impetus needed to meet New Zealand’s 2025 smoking targets

In 2011, the government of New Zealand set the ambitious Smokefree Aotearoa 2025 goal to reduce adult smoking prevalence to ‘minimal levels’. This has been defined as daily smoking rates falling below five percent for all New Zealanders.\(^1\) Data from the New Zealand Health Surveys show achievement falling far short of ambition.\(^2\) Should the trend since 2011 persist, the target will be missed by a substantial margin as shown in figure 1 and confirmed in independent assessments.\(^3\)

![Figure 1: Daily adult smoking and linear trend New Zealand 2011-17](image)

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\(^1\) Ministry of Health, Smokefree Aotearoa 2025, initiated in March 2011 https://bit.ly/2n8lMaD and Health Promotion Agency (New Zealand) Smokefree Aotearoa 2025 web site https://bit.ly/2PNdrp6. The targets are not precisely specified in official sources. For example, it is not always clear whether the targets refer to daily or current smoking; which datasets and years will be used to assess progress; and whether the targets apply to the whole population or to each major population group.


### Table 1: Smokefree Aotearoa interim targets versus shortfall

<table>
<thead>
<tr>
<th>Daily smoking %</th>
<th>All adults</th>
<th>Māori</th>
<th>Pacific</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline 2011-12</td>
<td>16.3</td>
<td>37.7</td>
<td>22.6</td>
</tr>
<tr>
<td>2018 interim target</td>
<td>10.0</td>
<td>18.9</td>
<td>11.3</td>
</tr>
<tr>
<td>Shortfall 2017-18</td>
<td>13.1</td>
<td>31.2</td>
<td>20.0</td>
</tr>
<tr>
<td>2017-18 shortfall from 2018 target</td>
<td>49%</td>
<td>66%</td>
<td>77%</td>
</tr>
</tbody>
</table>

In setting the aspirational goal for 2025, the government also set specific interim targets for 2018:

- daily smoking prevalence must fall to 10 percent
- the Māori and Pacific rates should have halved from their 2011 levels.

The 2017-18 the actual smoking prevalence fell short of these 2018 targets by approximately half for the general adult population, by two-thirds for the Māori population and by three-quarters for the Pacific population.

### 1.2 Smoking as a driver of health inequity in New Zealand

Though the average daily smoking prevalence in 2017-18 Health Survey was 13.1 percent, the burden of smoking is highly inequitable, in particular for Māori and Pacific populations. Māori adults have daily smoking prevalence of 31.2 percent and Māori women 34.9 percent. As a result, the Māori population suffers significantly worse outcomes for smoking-related diseases. For example, the rates of lung cancer mortality for Māori are three times that of non-Māori. Māori also have significantly higher rates of cardiovascular and respiratory disease, and sudden unexpected deaths in infancy.4,5 Smoking accounts for a substantial share of socio-economic gradients in health and well-being in every country and has long been understood to be a critical driver of health inequity in New Zealand6. Adults living in the most socio-economically deprived areas were three times as likely to be current smokers as people living in the least-

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5Ministry of Health, Mortality 2016 Data Tables. Published December 2018 http://bit.ly/2mBGjUI
deprived areas, after adjusting for age, sex, and ethnic differences. In New Zealand, the poorest 20\% of adults have four times the daily smoking prevalence (23.2\%) as the 20\% in the highest income (5.7\%).

1.3 Smoking as a driver of economic inequity in New Zealand

The differential health impact and life-expectancy arising from the unequal distribution of smoking is compounded by a painful economic penalty experienced by the poorest. According to Stats New Zealand,\(^7\) cigarette prices are a driver of financial inequity:

The tax increase was implemented at the beginning of the year 2018, bringing the average price for a packet of 25 cigarettes up to NZ$35.14. Of the different household groups measured, Māori households saw the highest inflation in the March 2018 quarter (up 1.3\%), compared with 0.8\% for all households. This increase for Māori households was driven by higher prices for cigarettes and tobacco, and interest payments.

The average price of tax-paid cigarettes in New Zealand has risen by 92\% in real terms since 2011 and is now high by international standards.\(^8\) A person earning the average New Zealand wage and smoking the average of 10 cigarettes a day would need to work full time for 6 weeks in order to fund their annual tobacco use.

Tobacco taxes are strongly regressive, and the burdens fall heavily on those in poorer groups who continue to smoke. Some argue that tobacco tax increases are progressive, because they prompt more quitting in poorer groups and that there is therefore a net benefit to poorer groups as a whole\(^9\) even though they continue to bear a disproportionate share of the tax burden. We argue that under any conventional definition, tobacco tax is highly regressive with some of the harms mitigated by increased quitting in poorer groups. Whatever definition is used, it is an ethical imperative to reinforce the quitting effect by providing support for smoking cessation as an ancillary policy to tobacco taxation –

\(^7\)Stats New Zealand, Cigarettes spark inflation for most household groups, 13 May 2018 https://bit.ly/2mxNnSe


\(^9\)See, for example: Cancer Council of Victoria (Australia), Are Tobacco Taxes Regressive? https://bit.ly/2o7MbFj
an approach endorsed by the World Health Organization.\textsuperscript{10} smokefree products add to the range of pro-health options available to smokers respond to cigarette taxation.

This point was recognised by Ernst & Young\textsuperscript{11} in its review on New Zealand’s tax policy for the Ministry of Health:

When looking at daily smoking prevalence by deprivation quintile, more deprived populations appear to have much higher rates of smoking in each year of analysis (2006/07 to 2016/17) – suggesting that tobacco control interventions targeted towards deprived groups are required to achieve equitable outcomes.

Taxation on cigarettes has been increased aggressively as a key policy instrument in tobacco control. It is effective in reducing smoking and smoking initiation but has driven up consumer prices for continuing smokers.

\begin{figure}
\centering
\includegraphics[width=\textwidth]{figure2.png}
\caption{Figure 2: Real price increases since 2011 – New Zealand}
\end{figure}


\textsuperscript{11}Ernst & Young Transaction Advisory Services Limited (EY) Evaluation of Tobacco Excise Increases as a Contributor to Smokefree 2025. (under contract to Ministry of Health) 27 November 2018 http://bit.ly/2nbC7jC
<table>
<thead>
<tr>
<th>Year</th>
<th>Current adult smoking prevalence</th>
<th>Population (≥ 15 years) million</th>
<th>Smoker population million</th>
<th>Tax revenue NZ$ million</th>
<th>Average tax per smoker NZ$</th>
<th>Average tax per smoker at 2018 prices</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>18.2%</td>
<td>3.476</td>
<td>633,596</td>
<td>$1,270</td>
<td>$2,008</td>
<td>$2,179</td>
</tr>
<tr>
<td>2018</td>
<td>14.9%</td>
<td>3.899</td>
<td>580,951</td>
<td>$1,923</td>
<td>$3,310</td>
<td></td>
</tr>
</tbody>
</table>

Table 2: Smoking and tax burden New Zealand 2011 and 2018

Despite falling smoking prevalence, official data\(^{12}\) show increases in overall tax revenue over time. This higher revenue take is now concentrated on a smaller smoker population, disproportionately from the poorer groups. This means tobacco tax paid by the average smoker increased from around NZ$2,000 in 2011 to approximately NZ$3,300 in 2018, with General Sales Tax adding a further tax burden.

The average New Zealand smoker consumed 9.9 cigarette equivalents per day in 2018\(^{13}\). In early 2019, the cheapest tax-paid cigarettes were approximately NZ$25 for 20,\(^{14}\) meaning an average smoker buying the cheapest tax-paid budget cigarettes would spend NZ$4,517 per year. But these averages obscure much higher overall financial burdens for more dependent smokers. A pack-a-day budget cigarette smoker would spend in excess of NZ$9,000 per year on smoking.\(^{15}\)

Because smoking rates are much higher in the lowest socio-economic groups, approximately 60% of the total tobacco tax take in New Zealand is paid by people in the poorest 40% of the population. Māori make up 16% of the New Zealand adult population but contribute 30% of the total tax on tobacco.\(^{16}\) Tobacco tax is just one tax that falls disproportionally on Māori: the same analysis shows that the 2018 annual tax taken from Māori via consumption of tobacco,


\(^{15}\)Ernst & Young Transaction Advisory Services Limited (EY) Evaluation of Tobacco Excise Increases as a Contributor to Smokefree 2025. (under contract to Ministry of Health) 27 November 2018 http://bit.ly/2nbCJc

alcohol and gambling was $1.1 billion. To put this in perspective, two years of tax revenue at this amount is almost equal to the nominal total paid out in Treaty of Waitangi settlements over the last 25 years (i.e. $2.2 billion by mid-2018).\textsuperscript{17} Just three years of annual tax-take for tobacco, $723m in 2018, would approximate to the nominal treaty settlements to date.

**How much would a smoker switching to vaping save?** The savings depend on what sort of cigarettes they smoke and how many per day, which alternative devices they use, how much of which consumables they consume, and how it is sourced. One informal estimate suggested that for New Zealand, a switch from smoking to vaping would reduce the costs for a pack-per-day user by at least 90 percent, from over NZ$9,000 to less than NZ$900 per year.\textsuperscript{18} The tax regime for smokeless and heated tobacco products is still under development, but we argue that it should be designed to create an economic incentive to switch to complement the health and welfare incentive.

### 1.4 The concept of tobacco harm reduction

The idea of tobacco harm reduction is that non-combustible nicotine products (e-cigarettes, smokeless tobacco, heat-not-burn tobacco products, pure nicotine products) can displace combustible smoking products such as cigarettes. Because it is smoke (the tar particles and toxic gases) that causes the harm to health, not the nicotine, there is a dramatic dividend to health from switching from a smoked to a smokefree nicotine product. The key health distinction in nicotine products is whether they involve smoke (as distinct from vapour) – the products of combustion of burning tobacco – or not. This has been known since at least the 1970s:\textsuperscript{19}

> People smoke for the nicotine, but they die from the tar.

The harm reduction concept has considerable support in the expert community, both internationally and in New Zealand. In October 2018, a letter to WHO from 72 experts worldwide made the case:\textsuperscript{20}

> These are established and new technologies that deliver nicotine to the user without combustion of tobacco leaf and inhalation of tobacco smoke.

\textsuperscript{17} Fryers A. The amount allocated to Treaty of Waitangi settlements is tiny, compared with other Government spending, Stuff, August 2018 https://bit.ly/2mxPVjg citing data from the Office of Treaty Settlements.

\textsuperscript{18} NZVapor, Smoking and vaping – a cost comparison. 8 October 2018 https://bit.ly/2oHCuxI


\textsuperscript{20} Letter from 72 specialists in nicotine science, policy and practice to Director General World Health Organisation, Innovation in tobacco control: developing the FCTC to embrace tobacco harm reduction, 1 October 2018 https://bit.ly/2oHLpzd
These technologies offer the prospect of significant and rapid public health gains through ‘tobacco harm reduction’. Users who cannot or choose not to quit using nicotine have the option to switch from the highest risk products (primarily cigarettes) to products that are, beyond reasonable doubt, much lower risk than smoking products (e.g. pure nicotine products, low-toxicity smokeless tobacco products, vaping or heated tobacco products). We believe this strategy could make a substantial contribution to the Sustainable Development Goal to reduce premature deaths through non-communicable diseases (SDG Target 3.4).

Tobacco harm reduction is recognised as part of the definition of tobacco control in the WHO Framework Convention on Tobacco Control:\textsuperscript{21}

\textit{tobacco control} means a range of supply, demand and harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke.

A joint House of Representatives Māori Affairs and Health Committee inquiry noted in December 2018\textsuperscript{22} that New Zealand was off-track to meet the 2025 goal and that regularising the market for vaping products should be recognised as part of the policy response:

We recommend that legislation be enacted to recognise and regulate vaping and ecigarettes as a pathway to help smokers to quit.

The most recent data show 4.7 percent of New Zealand adults use e-cigarettes and a higher proportion, 8.1 percent, among the Māori population\textsuperscript{23}. Prevalence for the highest income third of New Zealanders is 2.5% compared to 6.2% of the lowest income third\textsuperscript{24}. This suggests those under financial stress from smoking and with the highest smoking rates are turning to these products. A 2018 exploratory survey of New Zealand vapers (n=218) found 99% of vapers were either current or former smokers and that 94% of participants reported they were smokers when they started vaping\textsuperscript{25}. The HPA Healthy Lifestyles Survey found that 47% of New Zealand vapers were ex-smokers, 50% were current smokers and only 3% were never smokers.\textsuperscript{26}

\textsuperscript{22}Māori Affairs Committee and Health Committee of the House of Representatives, joint Briefing on achieving the Smokefree 2025 goal for New Zealand, 11 December 2018 http://bit.ly/2oazXF7
\textsuperscript{26}Health Promotion Agency. Personal communication to B Youdan. June 2019.
1.5 Categorising tobacco harm reduction products

The following diagram represents the current state of the smokefree (i.e. reduced risk) consumer products. Four categories are identified: vaping products; heated tobacco products; smokeless tobacco products and oral nicotine products.

![Diagram of alternative nicotine delivery systems (ANDS)](image)

Figure 3: Categorizing alternative nicotine delivery systems (ANDS)

The key distinction for public health policy is not whether a product does or does not contain tobacco, it is whether or not it is intended to be smoked. From a health risk perspective, the key distinction is between combustible and non-combustible products. The risk profile of e-cigarettes, smokeless nicotine and tobacco, and heated tobacco products have more in common with each other than with cigarettes – they are all much less risky than smoking products.

1.5.1 Vaping products

There remains some controversy about how much lower risk vaping is compared to smoking, but it is beyond reasonable doubt that vaping will prove to
be much less harmful than smoking\textsuperscript{27}. The Royal College of Physicians (London) uses the following formulation to communicate the relative of smoking and vaping risk:\textsuperscript{28}

Although it is not possible to precisely quantify the long-term health risks associated with e-cigarettes, the available data suggest that they are unlikely to exceed 5\% of those associated with smoked tobacco products and may well be substantially lower than this figure.

Because vapour-based products more closely resemble smoking than smoking cessation medications – providing nicotine impact, throat sensation, flavours, and behavioural ritual – it is likely they will be an alternative that works well for many smokers, especially as the products continue to evolve through innovation.

As early as 2013, a New Zealand-based randomised controlled trial (RCT) was among the first to demonstrate the potential of e-cigarettes in smoking cessation.\textsuperscript{29,30} These findings were supported by a Cochrane Review the following year.\textsuperscript{31} Five years later, with improved technologies available, a new randomised controlled trial showed that in a clinical trial setting, e-cigarettes were almost twice as effective at supporting smoking cessation as nicotine replacement therapy.\textsuperscript{32}

The 1-year abstinence rate was 18.0\% in the e-cigarette group, as compared with 9.9\% in the nicotine-replacement group.


Randomised controlled trials are informative, but do not tell the full story. In real life, most nicotine use is not in a clinical setting but by consumers purchasing from shops on their own initiative and subject to multiple behavioural influences. For example, in real life the success of such products depends on users choosing to try them. A 2014 study\textsuperscript{33} showed that e-cigarettes sold direct to consumers were substantially more effective than NRT at achieving smoking cessation.

People attempting to quit smoking without professional help are approximately 60\% more likely to report succeeding if they use e-cigarettes than if they use willpower alone or over-the-counter nicotine replacement therapies such as patches or gum.

More recently, a large scale, multi-year UK survey showed that users of e-cigarettes showed the highest odds of reporting abstinence compared to users of other forms of smoking cessation aid and those using no aids to quit.\textsuperscript{34}

1.5.2 Heated tobacco products

Heated tobacco products use an aerosol to draw flavours and nicotine from tobacco that has been electrically heated to below the temperature at which combustion begins (typically not above the range 300–350°C; combustion occurs at ~900°C).

The first heated tobacco product has recently been classified as “appropriate for the protection of public health” by the U.S. Food and Drug Administration and is likely to be much less harmful than smoking as trials confirm much lower exposures to harmful agents\textsuperscript{35}.

In some jurisdictions, heated tobacco products have made a dramatic impact. Cigarette volumes in Japan have fallen by 33 percent in three years, from 43.6 billion sticks in Jan-March 2016 to 29.1 billion sticks in Jan-March 2019\textsuperscript{36}. Analysts at Citi Group attribute the disruption of the cigarette market to heated tobacco products\textsuperscript{37}. A one third decline in cigarette sales in three years is unprecedented and shows the potential of this technology to bring on the endgame for smoking.

\textsuperscript{37}A. Spielman, The new world of tobacco, Citi Group, page 20. 18 April 2018
1.5.3 Smokeless tobacco

One comprehensive literature review puts the risks of snus use at around 1 percent of that of smoking.\textsuperscript{38} American analysis of modern smokeless tobacco showed no excess all-cause mortality risk among exclusive smokeless users.\textsuperscript{39}

There is proof-of-concept for the possible health gains from this idea: in Sweden current adult smoking had fallen to seven percent by 2017\textsuperscript{40} primarily because smoking has been displaced by use of a form of smokeless tobacco known as snus. There has been a substantial beneficial impact on cancer and other smoking-related diseases in Sweden as a consequence.\textsuperscript{41} There has not been a shift in the site of cancers from the lung to the oral cavity.

Smokers are at approximately three times the risk for oral cancers than snus users. Snus users have oral cancer risks that are not significantly different to non-users, but there are persistent misperceptions about smokeless tobaccos and oral cancer.\textsuperscript{42,43,44}

In Norway, daily smoking prevalence among 16-24-year-old women fell from 17 percent in 2008 to just one percent in 2017,\textsuperscript{45} again because of the displacement of smoking by snus.

1.5.4 Oral nicotine products

In some jurisdictions there are emerging new non-tobacco products such as gums, lozenges or film, strips designed to be sucked or chewed, or otherwise consumed orally through absorption via the mouth, gums or throat. There are,


\textsuperscript{44}Data from International Agency on Cancer (IARC) WHO cancer mortality database. http://www-dep.iarc.fr/WHOdb/WHOdb.htm

\textsuperscript{45}Statistics Norway, Tobacco Alcohol and Other Drugs, https://bit.ly/2Eb1O5y
for example, non-tobacco variants of snus now available in New Zealand\textsuperscript{46}. Some forms of nicotine replacement therapy may also be placed in this category. These products are likely to have similar risk profiles to NRT but may be packaged and marketed as consumer products designed as alternatives to smoking rather than as medicines.

In summary, there is now a substantial body of literature\textsuperscript{47} that, taken as a whole, indicates that low-risk non-combustible nicotine technologies can successfully displace smoking and provide a significant dividend for public health. Further background on tobacco harm reduction is available in Appendix 3.

\textsuperscript{46}For example, New Zealand Smokefree Tomorrow launched ‘White Fox’ non-tobacco nicotine pouches in May 2019 with a stated aim of contributing to smoking cessation and the 2025 target. Scoop NZ, Will New Zealand Smokers Quit Scandinavian Style? 8 May 2019 http://bit.ly/2o3uLtL

1.6 The precautionary principle – misunderstood and misused

Much policy discourse has focussed on applying the precautioning principle to recognise residual uncertainties in the ultimate health risks of smokefree and the obvious limitation that it is impossible to have multi-decadal epidemiology when products are relatively new. However, the precautionary principle requires disciplined application. For example, the European Union’s interpretation stresses the need for a rounded assessment, taking account of: 48

• Proportionality between the measures taken and the chosen level of protection.
• Non-discrimination in application of the measures.
• Consistency of the measures with similar measures already taken in similar situations or using similar approaches.
• Examination of the benefits and costs of action or lack of action.
• Review of the measures in the light of scientific developments.

Of particular relevance in this list, is the requirement to assess consequences of both action and inaction – in other words, to take account of plausible harms that would arise from restricting what are likely to be far less harmful products in a market dominated by cigarettes. There is no avoiding a risk assessment based on what is known, looking not only at the risks of the product, but also risks that might arise from policies justified on supposedly precautionary grounds.

Because the risks of smoking are so great and the ease with which poorly-designed regulation of smokefree products can increase smoking, there should be a high bar to restricting safer alternatives on the grounds of uncertainty about future risks that are unknown, implausible or likely to be far lower than for smoking. Recommendation 3 below and Appendix 2 includes further discussion on the role of unintended consequences in policy-making in this area.

The precautionary principle has greatest relevance where risks are systemic, irreversible, accumulative or severe, and this is why the principle initially gained prominence in environmental decision-making. These conditions do not apply to smokefree products, which pose individual risks which can be addressed through changing user behaviour or retrospective regulation.

Uncritical recourse to the precautionary principle is not helpful in forming nicotine policy and that the concept has not been applied rigorously by those arguing for precautionary restrictions. 49

2 Policy development and legislative proposals

Until March 2018, the default position of New Zealand legislation was that import-for-sale, sale or distribution of vaping products containing nicotine, smokeless tobacco, and heated tobacco products were prohibited under the smokefree Environments Act, unless licensed as a medicine with a therapeutic claim under the Medicines Act, 1981. New Zealand users were, however, able to source products online and via some shops that sold products without nicotine.

However, from 2016 an emerging new approach began. A consultation on policy towards e-cigarettes in 2016 provided new impetus to tobacco harm reduction. In 2017, in response to a request from the Cabinet, the Ministry of Health released new policy papers with a view to providing a proper legal foundation for use of e-cigarettes to help achieve the Smokefree 2025 goal.

In March 2018, the Ministry of Health took legal action against Phillip Morris International to enforce a prohibition on the sale of the company's heated tobacco product, IQOS, by applying Section 29 of the Smokefree Environments Act. The court rejected the government's arguments and found in favour of PMI. In May 2018, the government announced it would move to risk-proportionate regulation of all tobacco/nicotine products, and amend the legislation as needed.

In November 2018, the Ministry of Health published new policy papers: a Cabinet paper and a Regulatory Impact Statement outlining proposed amendments to the smokefree Environments Act to implement risk-proportionate regulatory policy. Six main proposals are introduced in the Cabinet paper:

- 8.1 clarify that all nicotine vaping liquid is covered by the SFEA and extend coverage to include nicotine-free vaping liquid, and vaping

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51 Medicines Act, 1981 (New Zealand) [http://bit.ly/2o03b0u](http://bit.ly/2o03b0u)
56 Associate Minister of Health, paper to Cabinet: Supporting smokers to switch to significantly less harmful alternatives, 21 November 2018 [http://bit.ly/2nk3SSS](http://bit.ly/2nk3SSS)
and smokeless tobacco product devices and components

- 8.2 enable the prohibition of flavours and colours that attract children and young people to vaping and smokeless tobacco products
- 8.3 prohibit vaping and the use of similar tobacco devices in legislated smokefree areas, with an exemption for specialist R18 retailers
- 8.4 enable product safety requirements to be set for vaping and smokeless tobacco products
- 8.5 implement a product notification system to support post-market action where concerns arise with a product
- 8.6 introduce adverse reactions reporting and monitoring, product recalls, and suspensions and cancellations of product notifications.

These six measures are discussed in the six sections below. Further proposals (warnings, packaging, taxation and public information) are discussed in Section 3. The full list of recommendations is set out in Appendix 1.

2.1 Widening the scope of tobacco control legislation – the general framework

The Cabinet paper states:

- 8.1 clarify that all nicotine vaping liquid is covered by the SFEA and extend coverage to include nicotine-free vaping liquid, and vaping and smokeless tobacco product devices and components

It would be far better for a government to have made an active choice about the appropriate policy for all the emerging products rather than let policy follow a default from legislation designed primarily to regulate smoked products. This should be based on a calculation of public interest and appropriate management of risks and benefits.

A reliance on regulation developed before new products existed, and often for a different purpose, is rarely likely to lead to the best outcome. It can exclude public deliberation or close down opportunities before they can be assessed. This is an unfortunate feature of the Australian system, which perversely favours the most harmful products. In Australia, regulation designed to schedule nicotine as a poison has the effect of banning consumer nicotine products other than those approved as a human or animal medicine or “tobacco prepared and packed for smoking”.58 A rational regulatory system should not, by default, confer a monopoly to the most dangerous form of a consumer

58Federal Government of Australia, Poisons Standard 2019, Schedule 7 entry for nicotine
Recommendation 1. Introduce a comprehensive and flexible framework that rigorously differentiates between combustible and non-combustible products.

We recommend the chosen framework be comprehensive and flexible enough to permit innovation in the recreational nicotine market. This would widen the scope of recommendation 8.1 to embrace all existing smokefree products, and allow for innovation in this field.

These non-combustible nicotine products share two key characteristics: (1) they are much less risky than cigarettes, and (2) they offer smokers an alternative to cigarettes than will greatly reduce individual risk. For policy purposes, therefore, it is better to group all smokefree alternatives together, rather than to treat non-combustible tobacco products in the same way as combustibles. We emphasise that the key distinction for public health is combustion versus non-combustion, not tobacco versus non-tobacco.

Cigarettes have remained relatively unchanged since the first commercial manufacture, but the smokefree technologies are not static and there has been dramatic innovation over the past five years. Many are highly customisable by the user, and the technology continues to evolve. This innovation includes improvements to user experience, safety, ease-of-use and product constituents. From a regulatory perspective, the framework should allow or require products to be modified subject to evolving evidence about constituents and risk. From a user perspective, there will always be a reason for a smoker to try, and if not successful, to try again later.

Recommendation 2. Embrace New Zealand’s established principles of good regulatory practice.

The New Zealand Treasury has set out expectations for good regulatory practice and these principles form a good basis for making new law in this area. For example:

the regulatory system should be proportionate, fair and equitable in the way it treats regulated parties

It is an understatement to say that this proportionality principle has not been universally applied elsewhere. In June 2018, the FCTC secretariat reported that thirty, mainly authoritarian, states have banned e-cigarettes, even though they all allow cigarettes to be readily available on sale.  

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60 WHO FCTC Convention Secretariat, Progress report on regulatory and market developments on electronic nicotine delivery systems (ENDS) and electronic non-nicotine delivery systems (ENNDS) FCTC/COP/8/10, 27 June 2018 http://bit.ly/2mxK1i4
The regulatory framework developed since 2016 by the US Food and Drug Administration (FDA)\textsuperscript{61} under the Tobacco Control Act (2009) will not be proportionate, fair, or equitable. It imposes very severe, strenuous, and expensive pre-market approval burdens on vaping products to secure access to the market from 2022. However, cigarettes manufacturers were provided a simple “grandfathering” option and almost any cigarette product on the US market before 22 March 2011 has access to the market without pre-market approval.\textsuperscript{62}

The European Union Tobacco Products Directive is less disproportionate than the US Tobacco Control Act, but is still burdened with arbitrary and pointless restrictions and burdens. For example, the inexplicable ban of snus outside Sweden – even though snus is the reason why Sweden has the lowest smoking prevalence, and lowest lung cancer mortality in the EU by some distance.

New Zealand has the opportunity to learn from the errors of jurisdictions that legislated in haste or applied ill-fitting existing regulation. New Zealand can develop the world’s first truly rational and risk-proportionate framework for tobacco harm reduction as mainstream tobacco policy.

**Recommendation 3. Assess and protect against unintended consequences of regulation that may have the effect of increasing smoking and causing harm.**

Because smokefree products are intended to displace smoking, there are many ways in which excessive regulation or taxation could cause more smoking and more harm to public health. In overview, the Royal College of Physicians (RCP) set out the challenge and danger of excessive regulation:\textsuperscript{63}

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. (Section 12.10 page 187)

One important consideration in striking the balance as set out by the RCP is that smoking is far more harmful than vaping. It follows that regulators should be averse to interventions that may have the unintended effect of perpetuating

\textsuperscript{61}FDA Deeming rule for e-cigarettes, Federal Register 81 FR 28973, effective 8 August 2016 http://bit.ly/2mvRgaj


\textsuperscript{63}Tobacco Advisory Group of the Royal College of Physicians (London), Nicotine without smoke: tobacco harm reduction. 28 April 2016 http://bit.ly/2mvRG0n
It means that the precautionary principle, if applicable at all, should be applied rigorously to risks arising from regulatory interventions, not just risks arising from use of the product.

In Appendix 2 of this document, we set out a range of possible harmful unintended consequences arising from excessive regulation of smokefree products. There have been very few examples to date of regulators or legislators actively considering unintended consequences in regulatory impact assessments, yet the potential to do harm through poor regulation is far greater than the risks that regulation of smokefree products is designed to mitigate.

The Regulatory Impact Statement that accompanied the Cabinet paper is one of the first to raise possible risks from unintended consequences by listing both pros and cons of regulatory proposals, recognising that excessive regulation could have the effect of increasing smoking.

It is essential that final proposals take unintended consequences fully into account in striking a balance between costs and benefits of proposed measures.

**Recommendation 4. Avoid coding excessively prescriptive measures in primary legislation – use regulations to respond to changes in the market or new evidence.**

The policy framework should not create overly specific measures in primary legislation but create powers and due process that would allow the government to respond to new technology, improving evidence (whether reassuring or alarming), and the emergence of any unintended responses to regulation.

The European Union provides a useful example of what not to do: the EU Tobacco Products Directive specifies, for example, a maximum concentration limit for nicotine liquids of 20mg/ml and specifies maximum tank sizes of 2ml and maximum refill container volumes of 10ml (Article 20.3). These serve no purpose at all, but make vaping more difficult or less acceptable. Indeed the strength limit may cause serious harm by making it harder for smokers to get through the early stages of switching, encouraging dual-use with smoking, rendering the products too weak for more dependent smokers, and by constraining innovation.

Well before the impact of e-cigarette advertising could be assessed (recognising the possibility it could function as anti-smoking advertising), the EU implemented a widely-defined ban on cross-border advertising (Article 20.5). The European Union has locked itself into highly specific legislation for which no supporting evidence exists and which could plausibly be harmful. The al-
ternative is to take powers to define regulations, together with a process to justify proposed measures and to update them with evolving knowledge.

2.2 Protecting young people and controlling flavours

The Cabinet paper states:

8.2 enable the prohibition of flavours and colours that attract children and young people to vaping and smokeless tobacco products

The Cabinet paper also states an intention apply to some existing tobacco control measure to e-cigarettes and smokeless tobacco:

36. To protect children and young people from addiction and any other risks to their health, I propose to retain the prohibitions on sales to under-18s, promotion, sponsorship and advertising, and the requirement that sale via vending machines must be supervised by the salesperson.

There are three main challenges in designing regulation to protect youth from smokefree product use:

1. **Effect on adults.** Measures to reduce adolescent use of smokefree products may have the harmful effect of making smokefree products less attractive as an alternative to smoking for adults.

2. **Effect on adolescent smokers.** Some smokefree products may be attracting some adolescents away from smoking and measures designed to prevent youth uptake may result in more youth smoking.

3. **The connection between the welfare of adults and adolescents.** The interests of adolescents cannot be neatly isolated from the interests of adults, for example through family relationships.

2.2.1 Effect on adults

The first of these issues is recognised in the Regulatory Impact Statement:

Overall, the proposal seeks to strike a balance between the objectives of supporting smokers to switch to significantly less harmful products and protecting children and young people from any risks associated with an increased availability of vaping and smokeless tobacco products. On balance, the proposals are on the precautionary side, reflecting concerns about uptake by young people.
It is unclear how or why this balance has been struck in this way. The risks are very substantial and immediate to adult smokers. The risks to young people are relatively minor and distant.

Surveys show that adult smokers are using flavoured products to try to quit. Flavours are central, not incidental, to the smokefree proposition offered to smokers, and they are important in preventing relapse back to smoking as users make a transition away from smoking over time.

If a consequence of this notionally cautionary approach was that fewer adults switched from smoking to vaping, that would mean more smoking-related death and disease in the short-to-medium term among adults. So there are severe and rapid consequences. In contrast, an increase in youth vaping poses little risk unless it leads to decades of smoking and for some young smokers, vaping may function as a diversion from smoking and be beneficial.

Even if some people who would never have become smokers take up vaping and remain as vapers, the long-term harm is likely to be very low compared to smoking or other youth risk behaviours. Any seriously harmful consequences arising from uptake of vaping by young people would only arise if they became smokers when they otherwise would not have smoked, and remained as smokers for several decades, without subsequently returning to vaping to quit smoking. There is little to suggest that this could happen at any material scale, so long as regulation discourages smoking and supports vaping.

The perceived risk of vaping acting as a gateway to smoking for young people must also be considered in the context of New Zealand’s wider tobacco

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control policy, and goal to reduce smoking rates to under 5 percent by 2025. Smoking will continue to be substantially more expensive than vaping, the locations where people can smoke are increasingly restricted, and marketing and branding is banned (unlike vaping products). Any pathway from smokefree to smoking is increasingly difficult and unattractive, as a matter of policy, whereas the opposite path would be encouraged under a risk-proportionate regulatory framework.

### 2.2.2 Effect on adolescent smokers

Secondly, the issues with controlling youth vaping are complicated by likelihood that youth vaping will suppress and ultimately displace youth smoking. US data suggest that regular or daily youth vaping is largely confined to smokers, ex-smokers or would-be smokers. In the US, almost all the regular use is among adolescents who have already smoked. A similar pattern appears to have developed in Canada.

Data for Year 10 students (14–15 year olds) in New Zealand also show that regular vaping is concentrated among those already smoking, and to a lesser extent, those likely to smoke. For these users, vaping may be beneficial – ultimately providing an early diversion from smoking or a pathway away from smoking as they emerge as adult smokers. The balance of possible benefits to adolescent smokers and possible detriments to adolescent never-smokers cannot be assumed to be negative.

Some care is needed to target policy to avoid harmful unintended consequences of measures that seek to protect youth but may cause more harm. For example:

- Which flavours are attractive to adolescents? It cannot be assumed that adolescents seek out flavours with childish branding or wish to reinforce a

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76 Rodu B. The 2018 American Teen Vaping Epidemic, Recalculated. Tobacco Truth blog. 16 May 2019 http://bit.ly/2mtlpa5. “In summary, the oft-cited teen vaping epidemic involves not three million youths, but rather 95,000 underage teens who vaped frequently but never used other tobacco products – or 0.6% of the nation’s 14.8 million high school students”


Figure 5: 14–15-year olds’ frequency of e-cigarette use by smoking status, New Zealand 2017
childish image. American campaigners initially drew attention to flavour like ‘Gummy Bear’ or ‘Cotton Candy’, but then had to shift ground when use of the Juul product increased and its leading flavours were Mango and Crème – products not normally seen as inherently childish or designed to appeal to children.

- Do the targeted flavours exert such appeal that they change behaviour (e.g. from not using to using) or is the choice of flavour simply a preference and the decision to try the product has some other cause – such as peer influencing? One study found that non-smoking adolescents expressed little interest in flavours (scoring 0.4 on a scale from 0–10) but to the extent they expressed a preference it was slightly greater for ‘traditional tobacco’ and ‘single malt scotch’ flavours.

- If the flavours do change behaviour, is that change beneficial? For example do flavours shift nicotine-using behaviour from smoking to smoke-free?

- What would the behavioural response to a ban on certain flavours be? Abstinence, switching to other flavours, switching to smoking, or adopting other risky behaviours?

- Finally, what would the effect on adults be? What weight would be given respectively to one more young person experimenting with vaping and one less adult quitting smoking by switching? How would trade-offs be made?

This complex behavioural system is discussed in more detail in a letter from the Attorney General of Iowa to the United States FDA Commissioner. Attorney General Miller summarises the challenge:

To summarize, the chain of reasoning required to justify rule-making to prohibit particular flavors, flavor categories or flavor descriptors in non-combustible products is extremely challenging, with the real possibility that FDA intervention could cause harm both to adults and young people if it makes misjudgments about: (1) the effects of vaping on health, and

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(2) the effect of flavors on vaping. FDA would need to show that vaping itself is a source of net harm (this is unlikely) and show that particular flavors or descriptors were increasing uptake and contributing to harm (this is difficult). Finally, it would need to show its proposed intervention would be proportionate and effective, and not prone to excessive unintended consequences (for this there is no credible evidence). The FDA does not have a reliable case at any point in this chain of reasoning.

2.2.3 The connection between the welfare of adults and adolescents

Thirdly, it is not possible to isolate the interests of adolescents from adults in the way proposed, for at least four reasons:

- Adolescents grow into adults and measures taken to protect them as youth may do more harm to them as adults – for example if it obstructs an effective way out of smoking. What matters is risk behaviour through the whole course of life.

- Youth initiation and risk behaviours are heavily influenced by adult norms, especially parents and older siblings.82

- When adults are harmed from smoking, the whole family is harmed: through lost economic activity, increased caring burdens, or through grief and distress. High smoking rates for Māori and low-income New Zealanders, and earlier onset of smoking-related disease means this is has a particular impact on health equity.

- Young people in a smoking household are exposed to second-hand smoke in the home.

To conclude, there are many ways in which measures designed to protect youth from reduced-risk products – such as banning flavours or banning e-cigarette advertising – can be unintentionally detrimental to the health of both adults and adolescents. Navigating this landscape is a significant policy challenge. Continued surveillance is useful in monitoring youth nicotine and tobacco use and responses to observed changes is likely to be a more effective strategy than trying to guess effects in advance.

Recommendation 5. Ensure that policy driven by youth concerns takes account of interactions between youth smoking and youth vaping.

The Ministry of Health and Government should formulate policy based on a conceptual model that includes the interactions between use of smokefree

products and adolescent smoking, and takes account of the life course and tolerability of youth risk behaviours. This means recognising that for some young users smokefree products may be an alternative to smoking; that occasional vaping poses little risk; that smokefree products use only become a serious risk if it causes a progression to smoking, and that this is not subsequently reversed. The primary aim for youth policy should be the prevention of escalation of any nicotine use to smoking, with a secondary goal of prevention of nicotine use per se.83

**Recommendation 6. Take powers to control ingredients, flavours, and product descriptors but use these with caution and based on evidence – focus primarily on marketing practices.**

There are three main reasons to seek control over flavours and other ingredients.

1. Toxicology – to create a black list of flavour agents or other ingredients that are harmful or potentially harmful at relevant exposures

2. Youth appeal – the flavour descriptor is designed to appeal to young people

3. Youth appeal – the flavour formulation itself is attractive to young people

The first of these should be addressed as part of a product standard regime, as envisaged in the Cabinet paper paragraph 8.4.

As discussed above, there are multiple challenges with implementing flavour restrictions without having a negative effect on public health. These include:

- Establishing which flavours appeal to youth
- The extent to which it is the flavour sensation or flavour descriptor that is attractive
- Which flavours appeal so much that they are not just preferences but actually change behaviour (e.g. from not vaping to vaping
- Identifying flavours that do not change behaviour in a beneficial way among adolescents, for example, from smoking to vaping.

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• Determining how to specify a flavour ban. For example, should it be all fruit, a specific flavour chemical that resembles banana flavour, or a descriptor like ‘Bananarama’?  

• Whether the intervention of banning or restricting the chosen flavours or descriptors would work (e.g. would young people just choose another flavour)  

• Finally, if a successful intervention could be designed for youth vaping, then it would be necessary to check for harmful effects on both adults and adolescent smokers.

We raise this not to create evidential obstacles, but to suggest that there are many ways in which this sort of intervention, while well-meaning, could cause harm by sustaining both adult and adolescent smoking. Our recommendation is to focus on marketing (including branding).

**Recommendation 7. Control rather than prohibit advertising of low-risk alternatives to smoking such as e-cigarettes.**

We recommend that the approach adopted is not a complete ban on advertising of e-cigarettes but restrictions on the content, timing and placement of advertising so that it is appropriate for adult audiences and communicates the relative risk compared to smoking.

While there is justification for banning advertising on combustible tobacco products, the harm reduction potential of non-combustibles means the case for a ban on advertising smokefree products is much weaker. Advertisements for e-cigarettes, for example, function as advertisements against smoking. Furthermore, it would be disproportionate and discriminatory to treat the advertising of the much safer product in the same way as the much more harmful incumbent, cigarettes. Advertising bans on much-safer entrant products would protect the cigarette trade from competition while denying smokers a source of motivation to switch.

The attempt to strike a pragmatic balance between promoting products that provide significant benefits to adults while controlling the effect on adolescents has been addressed in the UK Code of Advertising Practice that applies to UK domestic advertising for e-cigarettes. This approach controls content and messaging and restricts placement of advertising. The aim is to permit responsible adult-orientated advertising that does not use media, times or locations that disproportionately reach adolescents. This approach would be risk-
proportionate and also recognise the opportunities for health of both adolescent and adult smokers.

2.3 Use of smokefree products in legislated smokefree areas

The Cabinet paper states:

8.3 prohibit vaping and the use of similar tobacco devices in legislated smokefree areas, with an exemption for specialist R18 retailers

The Cabinet paper elaborates as follows:

I propose that the Committee agree to also prohibit vaping and the use of similar devices (eg, heated tobacco products) in legislated smokefree areas. This is a precautionary measure: there is no robust evidence of harm from second-hand vapour, however, increasingly visible vaping in public has the potential to normalise it. I believe it is important to signal that vaping should be viewed only as an alternative product for smokers

We agree there is no robust evidence of harm from second hand vapour. However, it is not just an absence of evidence: the evidence that is available suggests the possibility of material harm from second-hand vapour would be minimal – whereas second hand cigarette smoke, especially the smoke generated when a user is holding a lit cigarette, has been associated with cancer and heart disease in bystanders. For example, one study estimated the excess life time cancer risk (ELCR) from passive vaping compared to passive smoking.\footnote{Avino P, Scungio M, Stabile L, Cortellessa G, Buonanno G, Manigrasso M. Second-hand aerosol from tobacco and electronic cigarettes: Evaluation of the smoker emission rates and doses and lung cancer risk of passive smokers and vapers. Sci Total Environ. 2018 Nov 15;642:137–47. http://bit.ly/2oQfT2d} The risk from passive smoking was 10,000 times higher, i.e., the risk from passive vaping was negligible:

The ELCR for second-hand smokers was five orders of magnitude larger than for second-hand vapers.

Even if there are traces of hazardous agents in e-cigarette vapour, they are present at such low concentrations in exhaled vapour that they pose no meaningful risk to bystanders.\footnote{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;14:18. http://bit.ly/2n8OW9B} The primary issue is one of nuisance, rather than a material health threat. We do not agree that very different risks should be treated the same way. The
reasoning provided in the Cabinet paper for banning vaping in the same way as smoking is “to signal that vaping should be viewed only as an alternative product for smokers.” This is not convincing – if it is an alternative product and intended as an exit route from smoking, why would policy-makers force vapers into designated smoking areas?

This is also a potential source of unintended consequences: if smokers are trying to switch from smoking to vaping, it would raise the chance of distraction or relapse. Having people who vape use smoking areas is unethical as it knowingly exposes them to secondhand smoke, something New Zealand put laws in place to protect people against 15 years ago.

In the absence of material risk to the health of bystanders, there is a very weak justification for a mandated regulatory approach in which a general prohibition would override the preferred approaches of property owners and managers. Consider the following approaches to vaping:

1. A bar wants to have a vape night every Thursday
2. A bar wants to dedicate one room where vaping is permitted
3. A corrections facility that is smokefree wants to support inmates to manage nicotine withdrawal and related tensions by allowing them to vape
4. In a town with three bars, one decides it will cater for vapers, two decide they will not allow vaping
5. A bar manager decides on balance that his/her vaping customers prefer it and his/her other clientele are not that bothered – he’d do better by allowing it
6. A hotel wants to allow vaping in a few rooms and in its bar, but not in its restaurant
7. 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
8. A care home wants to allow an indoor vaping area to encourage its smoking elderly residents to switch during the coming winter
9. A vape shop is trying to help people switch from smoking and wants to demo products in the shop
10. Vaping might be permitted in railway stations or airport terminals, but not on trains and aircraft
11. Many shops, public buildings and places catering for children decide not to allow vaping at all
We submit there is no good rationale to override these reasonable decisions with a blanket prohibition when there is no plausible material risk to bystanders. The absence of a legislated ban does not create a right to vape but it makes the vaping policy in any space a matter for the owner or manager rather than for government or legislature. The New Zealand government’s guidance on regulatory practice88 stresses the value of regulation that respects autonomy and property rights to the extent possible:

The government believes that durable outcomes of real value to New Zealanders are more likely when a regulatory system: [...] seeks to achieve those objectives in a least cost way, and with the least adverse impact on market competition, property rights, and individual autonomy and responsibility

We believe that allowing property owners and managers to determine vaping policy is a more coherent approach than applying a measure designed to address a different problem, and that this would be more consistent with New Zealand’s regulatory philosophy.

**Recommendation 8. Allow owners and managers of premises to determine policy on use of non-combustible tobacco and nicotine products.**

The government should not legislate to treat vapour products in the same way as smoked products. Owners and managers should be responsible for deciding vaping policy, unless and until there is evidence that vaping imposes material risks on bystanders. This does not mean vapour product use is uncontrolled, it means it is under the control of property owners and those managing relevant outdoor spaces.

**Recommendation 9. The government retains powers to impose environmental vaping policies in certain places or if scientific evidence evolves.**

There are some places where the government might choose to define a policy on vapour products, whether heated tobacco or e-cigarettes – possibly to avoid ambiguity or to provide reassurance that there is no vaping in environments that cater specifically for children, such as schools, though we would expect schools to ban vaping in the absence of a government mandate.

**Recommendation 10. Provide guidance on setting vaping policy to owners and managers of premises and to local authorities for outdoor places.**

We recommend that the government provides guidance to assist to the owners of premises in setting policy. In England, Action on Smoking and

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Health (ASH) has produced a structured methodology to assist owners or public places\(^9\) and Public Health England has provided resources for employers to navigate the issues.\(^9\)

### 2.4 Setting product safety standards

The Cabinet paper states:

8.4 enable product safety requirements to be set for vaping and smokeless tobacco products

There is a strong case to develop such standards to cover chemical, mechanical, thermal and electrical safety and relevant testing protocols for both devices and liquids. This type of regulation, if done well, provides real benefits to users of these products. However, it is important not to over-regulate to the point where harmful unintended consequences start to emerge. The dangers include:

- Making products less attractive, less individually customisable, less user friendly
- Making the products unduly difficult or expensive to make
- Setting inappropriate regulatory goals such as metered dosing or limiting nicotine strengths (users control their nicotine exposure)
- Creating arbitrary and prescriptive design requirements that would tend to constrain innovation or efficient ways of meeting regulatory objectives

**Recommendation 11. Draw on emerging international product standards where these are credible.**

There are several standards initiatives underway. Standards bodies such as AFNOR in France\(^9\), BSI in the UK,\(^9\) and CEN at the European Union level\(^9\)

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have made significant advances in defining product safety standards for devices and liquids. The smokeless tobacco company, Swedish Match has a demanding standard for its snus products, which could form the basis for a standard on smokeless tobacco – taking account of any differences in consumer preference in New Zealand. There are many existing standards that can be drawn upon, for example for child resistant packaging, electrical safety, and quality assurance.

Modern smokeless tobacco products also present very low risk and these can be controlled by setting standards for contaminants such as tobacco-specific nitrosamines, nitrates and metals – for example the exacting Gothiatek® standard for snus applied by the company Swedish Match. The WHO TobReg advisory group has proposed proposals on smokeless tobacco product standards.

There has been early work on standards for heated tobacco products. These concentrate on ensuring there is no combustion by using limits for carbon monoxide and oxides of nitrogen as markers for combustion processes. Standards could extend to controlling for other hazardous or potentially hazardous constituents in the aerosol and aspects of design.

**Recommendation 12. Start with simple product standards but with a process for routine update.**

Progress can be made with relatively modest and uncontroversial intervention from the outset. A regulator should signal intent well in advance and tighten standards over time – a regulatory ratchet – so as to give time for adjustment and to test for unintended consequences by proceeding gradually. The purpose of regulation should be to manage risk by clearing out poor quality or

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98 This does not refer to dry powdered snuff or ‘traditional’ smokeless products that contain tobacco and other ingredients such a slaked lime, ash, betel leaf, areca nut, oils etc.
dangerous products and then improve the market performance over time. It is not proportionate or beneficial to health to radically contract the market or rule out entire sub-categories, such as open vaping systems, smokeless tobacco or heated tobacco products.

For example, for liquids, a regulation would set pharmaceutical grade standards for the major ingredient and food grade standards for flavourings. It would specify any prohibited or restricted ingredients and have a general prohibition for ingredients known to be carcinogenic, mutagenic, repro-toxic (CMR), or respiratory sensitisers. It could develop set limits for microbial activity and provide guidance on allergens. It would concentrate on the liquids and operating conditions (e.g. coil temperature) rather than attempt to measure vapour components which may vary markedly with the way the product is used.

### 2.5 A notification regime

The Cabinet paper states:

8.5 implement a product notification system to support post-market action where concerns arise with a product

The Cabinet paper elaborates:

Product safety could be supported through a product notification process; that is, a web-based system administered by the Ministry of Health whereby manufacturers and/or importers notify products prior to marketing and self-certify that regulatory requirements are met. The main advantage is that, if any post-market action is required (eg, recall of a product that is causing harm), the Ministry would know who is accountable. In addition, it gives the Ministry a mechanism to communicate with industry (eg, to notify safety concerns or changes to regulations).

We endorse this recommendation, and we believe it is essential to have a notification regime. Notification is the approach adopted in the European Union. The alternative is a pre-market authorisation regime, which is the approach adopted in the United States.

Given the pervasive presence of cigarettes, a regulator should, in effect, liberalise the entire category of non-combustible alternatives but require notification of specific products. The problem with a pre-market authorisation regime is that it would discriminate against reduced-risk products compared to cigarettes.

The incumbent products (primarily cigarettes) would require no such authorisation because it would be impossible to design meaningful pass/fail criteria for such harmful products. An authorisation regime would also be subject
to excessive loss aversion on the part of regulators and create regulatory risk that would be a barrier to entry and innovation for manufacturers of smokefree products.

Manufacturers and importers of products for sale in New Zealand should register as suppliers to the market, identify a responsible person or persons, set out procedures for recall, and provide contact information. An ideal notification regime contains data on device components and liquid ingredients and evidence that it conforms to product standards. Costs should be carried by manufacturers and importers, but user fees should be kept low by implementing a system that only requires the information that is necessary to meet policy objectives.

**Recommendation 13. Introduce a proportionate notification regime and avoid a pre-market authorisation system.**

Such a regime should collect only data for which the regulator can identify a possible use. This has not always been the practice in tobacco regulation internationally.

The European Union notification regime requires more data and paperwork than necessary for the EU to perform its regulatory functions or for any other purpose. However, there may be an efficiency case for adopting a system similar to the European Union notification regime\(^\text{102}\) or avoiding unnecessary conflicts with it, given many international suppliers will already comply with these reporting requirements. There is no equivalent notification system in the United States, and the FDA's system is unclear on what data is required for pre-market authorisation purposes.

### 2.6 A system for reporting adverse reactions and defective products

The Cabinet paper states:

8.6 introduce adverse reactions reporting and monitoring, product recalls, and suspensions and cancellations of product notifications.

**Recommendation 14. Introduce a requirement for adverse reaction and defective product reporting.**

Such systems are widely used, for example in regulation of consumer

products\textsuperscript{103} or over-the-counter medicines.\textsuperscript{104} In the UK, the reporting requirements and notification regime for e-cigarettes are managed by the medicine regulator, even though the products are not classified as medicines.\textsuperscript{105}

3 Other policy considerations

In this section, we discuss polices that do not feature in the Cabinet paper.

3.1 Labelling and consumer information

Policymakers should not simply adopt the warning philosophy that has been applied to smoked products and replicate it in some form for smokefree products. There are two reasons for this:

1. The risks to health are orders of magnitude lower than for smoking and may be qualitatively different. A risk-proportionate approach should reflect this in the content, size, intrusiveness and placement of any warning information. These design characteristics, as well as the wording itself, communicate the degree of risk.

2. For smokers, smokefree products can be highly beneficial and potentially life-saving. The challenge is therefore to warn about absolute risk, but to encourage behaviour based on relative risks.

We already know that the public in New Zealand has substantial misperceptions about relative risk. For smokers and ex-smokers:\textsuperscript{106}

- 28\% of respondents felt that e-cigarettes were as harmful, or more harmful, than tobacco cigarettes.
- 24\% did not know whether or not e-cigarettes were less harmful than tobacco cigarettes.
- Around one-half (47\%) of respondents thought e-cigarettes were less harmful than cigarettes.

\textsuperscript{103}Ministry of Business, Innovation, and Employment (NZ), Consumer protection, Common consumer issues \url{http://bit.ly/2o7Ljk0}
\textsuperscript{104}Ministry of Health (NZ), Medsafe, Safety resources \url{https://medsafe.govt.nz/safety/safety-landing.asp}
\textsuperscript{105}UK Medicines and Healthcare products Regulatory Agency (MHRA), e-cigarettes and refill containers (e-liquids): report suspected side effects and safety concerns \url{http://bit.ly/2n8AiiE}
Though nearly half correctly believe that e-cigarettes are ‘less harmful,’ it is unclear how many would correctly recognise ‘very much less harmful’ as the appropriate comparison. The misperceptions of relative risk are not unique to New Zealand. Similar misperceptions persist in the United States\textsuperscript{107} and in Britain\textsuperscript{108}.

Risk-communication and labelling gives the opportunity to correct such misperceptions, in a way that promotes healthy behaviour change (i.e. switching from smoking to reduced risk products, or quitting altogether). The British survey\textsuperscript{\textit{ibid}} showed that by far the most important reason for vaping, was to quit smoking (40%) or cut down (19%) or avoid relapse to smoking (13%). Vaping behaviour is closely linked to beneficial change in smoking behaviour. Risk communication should facilitate that through informed choice.

**Recommendation 15. Construct product warnings that place risks of non-combustible nicotine products in context with smoking.**

The following warning has been proposed for use on smokeless tobacco in the United States:\textsuperscript{109} ‘No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes’. Similar qualified warnings could be developed for all smokefree products.

**Recommendation 16. Authorise vendors to use government-approved statements about relative risk of smoking and alternative smokefree nicotine products.**

During the development of current legislation, Health Canada consulted on a series of seven statements that would help convey the proposition of switching to a low-risk product:\textsuperscript{110}

1. If you are a smoker, switching completely to vaping is a much less harmful option. While vaping products emit toxic substances, the amount is significantly lower than in tobacco smoke.

2. By switching completely to vaping products, smokers are exposed to a small fraction of the 7,000 chemicals found in tobacco smoke.

3. Switching completely from combustible tobacco cigarettes to e-cigarettes

\textsuperscript{108}Action on Smoking and Health (UK), Use of e-cigarettes (vapourisers) among adults in Great Britain, September 2018 http://bit.ly/2oLaA3T
significantly reduces users’ exposure to numerous toxic and cancer-causing substances.

4. Completely replacing your cigarette with a vaping product will significantly reduce your exposure to numerous toxic and cancer causing substances.

5. Switching completely from smoking to e-cigarettes will reduce harms to your health.

6. Completely replacing your cigarette with an e-cigarette will reduce harms to your health.

Though Health Canada has not yet taken up this approach, we believe it is a forward-looking public health concept that gives appropriate emphasis to consumers' right to true and fair information, and that it would encourage many adult smokers to quit. The problem with not having statements like this available is that smokers and the wider public form their perceptions from the flow of news and commentary. Much of that is unreliable and sensationalist – like most countries, New Zealand starts from public perceptions that are dramatically misaligned with reality, with a need for correction.

3.2 Plain packaging and point of sale display bans

The decision to make cigarette packages look unattractive, to deny branding space, and to impose graphic warnings commands considerable support. But its ultimate justification rests on the harms done by smoke and the very high risk to health. That justification does not apply to non-combustible products and does not stand up to scrutiny in a risk-proportionate regulatory system.

**Recommendation 17. Require plain packaging and display bans for combustible products, not for smokefree products.**

The key distinction in risk is not between tobacco and non-tobacco products, but between combustible and non-combustible products. The alternative smoke-free nicotine products also function as a means of attracting smokers to low-risk alternatives. Attractive packing and reassuring but realistic consumer information can assist. The default of applying plain packaging legislation to all tobacco products should be modified to impose this restriction only on combustible

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111 Ministry of Health, Tobacco Standardised Packaging 14 March 2018 http://bit.ly/2oREEUJ; Smokefree Environments Regulations 2017/123. 6 June 2017 http://bit.ly/2o3Jwwu regulations made under sections 39 and 39A of the Smokefree Environments Act 1990. Section 3 Interpretation could be amended to include a definition of tobacco products within scope of the regulations to include only ‘tobacco products intended for smoking’. Section 13 of the regulations creates a catch-all for ‘other tobacco products’ – this could be amended to refer to ‘other tobacco products intended for smoking’
tobacco products – thereby excluding smokeless and heated tobacco products. This would support the role of these products in harm reduction, avoid deterring potential switchers, and contribute to the 2025 objective.

### 3.3 Taxation

There are strong reasons not to tax reduced-risk alternative smokefree nicotine products at all. This would reflect their value in supporting smoking cessation and addressing ethnic and socio-economic health inequities. In the UK, over-the-counter nicotine replacement therapy (NRT) even attracts a tax subsidy, a reduced rate of value added tax (VAT), for its perceived value in reducing smoking.\(^{112}\)

High and regressive tobacco taxation that falls disproportionately on poor or marginalised ethnic groups presents formidable ethical challenges. For users, the obvious mitigating response has been to seek out illicit untaxed supply, or to down-trade to products that attract lower duties (typically, hand-rolling tobacco or ‘budget’ brands). However, it is important to have as many lawful options as possible to mitigate the unfairness implicit in tobacco taxation – that includes facilitating low-cost pathways to switch from smoking to low risk alternatives. For that reason, we recommend a system of risk-proportionate taxation is implemented, as advocated by Chaloupka, Sweanor and Warner.\(^{113}\)

**Recommendation 18. Develop a risk-proportionate taxation regime for nicotine products with the highest taxes on cigarettes and very low or zero taxes on smokefree alternatives.**

This would recognise the health and societal benefit of a migration path for smokers to reduced risk products. In most cases this would mean no additional taxation above regular sales taxes. However, governments tend to approach taxation of such products with three objectives in mind: beneficial public health impact; raising revenue; and reducing deadweight cost of tax administration.\(^{114}\)

So, where there is a government intention to apply additional excise, additional principles are required as discussed in the following recommendation.

**Recommendation 19. Maintain a substantial difference in the tax imposed on the lowest-taxed combustible product and any smokefree alternative product.**

\(^{112}\)In the UK, NRT sold OTC is subject to a reduced 5% rate of Value Added Tax instead of the standard 20%.


We therefore urge the following consideration for the tax rates to be applied to any alternative nicotine delivery system (ANDS):

1. **The tax regime has implications for human life.** Given cigarettes and smokefree alternatives are substitute products there will be positive price cross-elasticities between smoking and smokefree products. A significant tax on smokefree products will cause a relative increase in the demand for combustibles – and will, therefore, cause more smoking. The default excise rate should be zero, proceeding with caution if higher rates are proposed.

2. **Setting the level: the highest level applied to any smokefree product should be substantially lower that the lowest rate applied to any combustible product.** Maintain a significant differential between the cost of being a smokefree product user and a smoker. This will maintain an incentive to switch, and avoid developing a black market or encouraging home-made production.

3. **Recognise cost burdens of tax administration.** Vaping is likely to have at least a 95% lower risk than smoking. If excise duties were set proportionate to risk relative to smoking to create a proportionate deterrent, then the tax yield for e-cigarettes would be so low it would not be worth the cost of collecting. The only way to make a non-zero tax viable is to tax smokefree disproportionately to risk, thereby imposing a disproportionate deterrent to users switching.

4. **Comparison with NRT – therapeutic value.** Smokefree products produce a net health benefit by reducing smoking. From an economic and tax perspective, such products should be viewed more like over-the-counter medicines. Some jurisdictions apply a reduced sales tax to nicotine replacement therapy – a tax subsidy – to reflect its public health value.

5. **Replacing lost cigarette tax revenue.** It is argued that because tax-take is falling from cigarettes as people switch or quit (though that has not so far happened in New Zealand), then excise duty should be applied to alternative products to compensate. This does not have an economic rationale, even if superficially appealing politically. Tax should be raised from the least distorting and most efficient tax base available: there is no reason why cigarette excise losses should not be recovered from taxes on, for example, carbon dioxide, fuel charges, removal of tax subsidies or by cutting spending that is less cost-effective than reducing smoking.
### 3.4 Advice to healthcare professionals and to users

There is now recognition among tobacco control professionals and public sector practitioners that e-cigarettes can be used constructively to reduce harm. For example, in Britain the National Centre for Smoking Cessation and Training and Public Health England, the government’s public health agency, has developed evidence-based guidance and training for health and smoking cessation professionals.\(^{115,116}\) It provides a clear and measured assessment of the state of science and best practice. This is a summary of the advice given to UK health professionals by the National Centre For Smoking Cessation and Training and Public Health England:

**Recommendations for practice**

1. Be open to e-cigarette use in people keen to try them; especially in those who have tried and failed to stop smoking using licensed stop smoking medicines.

2. Provide advice on e-cigarettes that includes:
   - E-cigarettes provide nicotine in a form that is much safer than smoking.
   - Some people find e-cigarettes helpful for quitting, cutting down their nicotine intake and/or managing temporary abstinence.
   - There is a wide range of e-cigarettes and people may need to try various types, flavours and nicotine dosages before they find a product that they like.
   - E-cigarette use is not like smoking and people may need to experiment and learn to use them effectively (e.g. longer ‘drags’ may be required and a number of short puffs may be needed initially to activate the vaporiser and improve nicotine delivery). They may also need to recognise when atomisers need replacing.
   - People previously using e-cigarettes while smoking (e.g. to reduce the number of cigarettes that they smoke) may need to consider changing devices and/or nicotine concentrations when making a quit attempt.
   - Although some health risks from e-cigarette use may yet emerge, these are likely, at worst, to be a small fraction of the risks of smoking. This is because e-cigarette vapour does not contain

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the products of combustion (burning) that cause lung and heart disease, and cancer.

This is a balanced and open-minded approach and reflects an emerging consensus on how to exploit the opportunities of e-cigarettes, while containing any risks.

For the public, English public agencies have provided a range of evidence-based resources to both inform and encourage consumers about e-cigarettes. This includes information from the main health care provider, well-regarded academics, and a campaign that has seen advertising on television to encourage smokers to switch to vaping.\textsuperscript{117}

\textbf{Recommendation 20. Encourage public health authorities and the Ministry of Health to provide pragmatic user-centric advice on e-cigarettes and other reduced-risk products.} Such advice should be tailored to the needs of different professional groups and different user constituencies, for example, for pregnant women, Māori adults, young people, and long-term smokers.

Appendix 1: List of recommendations

1. Introduce a comprehensive and flexible framework that rigorously differentiates between combustible and non-combustible products.

2. Embrace New Zealand’s established principles of good regulatory practice.

3. Assess and protect unintended consequences of regulation that may have the effect of increasing smoking and causing harm.

4. Avoid coding excessively prescriptive measures in primary legislation – use regulations to respond to changes in the market or new evidence.

5. Ensure that policy driven by youth concerns take account of interactions between youth smoking and youth vaping.

6. Take powers to control ingredients, flavours and product descriptors but use these with caution and based on evidence – focus primarily on marketing practices.

7. Control, rather than prohibit, advertising of low-risk alternatives to smoking such as e-cigarettes.

8. Allow owners and managers of premises to determine policy on use of non-combustible tobacco and nicotine products.

9. The government retains powers to impose vaping policies in certain places or if scientific evidence evolves.

10. Provide guidance on setting vaping policy to owners and managers of premises, and to local authorities for outdoor places.

11. Draw on emerging international product standards where these are credible.

12. Start with simple product standards but with a process for routine update.

13. Introduce a proportionate notification regime and avoid a pre-market authorisation system.

14. Introduce a requirement for adverse reaction and defective product reporting.

15. Construct product warnings that place risks of non-combustible nicotine products in context with smoking.

16. Authorise vendors to use government-approved statements about relative risk of smoking and alternative smokefree nicotine products.
17. Require plain packaging for combustible products, but not for smokefree products.

18. Develop a risk-proportionate taxation regime for nicotine products with the highest taxes on cigarettes and very low or zero taxes on smokefree alternatives.

19. Maintain a substantial difference in the tax imposed on lowest-taxed combustible products and any smokefree alternative product.

20. Encourage public health authorities and the Ministry of Health to provide pragmatic user-centric advice on e-cigarettes and other reduced-risk products.

For more details and the rationale for each recommendation, see Sections 2 and 3.
## Appendix 2: Plausible unintended consequences of excessive regulation

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<thead>
<tr>
<th>Policy</th>
<th>Plausible unintended consequence</th>
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<tr>
<td>High compliance costs or barriers to market entry</td>
<td>A loss of product diversity means consumers are unable to personalise the vaping experience or find products that they enjoy – users may find the experience less satisfactory, so continue to smoke or relapse. Alternatively, a black or grey market of possibly unregulated products develops – responsible domestic producers are destroyed and cross-border trade meets demand. Cumbersome or expensive authorisation regimes make innovation more difficult and expensive, so there will be less innovation and experimentation with consumer preferences.</td>
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<tr>
<td>Restrictions on liquid strength</td>
<td>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. Heavier or more dependent smokers may find e-cigarettes unsatisfying – so those most at risk are denied the products more likely to work. May drive users to black market and/or home mixing with high strength liquids. Barrier to successful innovation like the Juul products, which use high strength e-liquids (~5%).</td>
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<tr>
<td>Limits on container and tank size</td>
<td>The experience of vaping becomes more convenient and so less attractive. More filling operations are required and the likelihood of running out of liquid is increased – creating points for possible relapse. Poisoning risk is not normally managed by limiting container size (e.g. for medicines, alcohol).</td>
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<tr>
<td>Ban e-cigarette use in public places</td>
<td>Diminishes value proposition of e-cigarettes to users and <em>denormalises</em> 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.</td>
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<tr>
<td>Restrictions on advertising, promotion and sponsorship</td>
<td>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 products may become dull and sterile, diminishing appeal. Almost all e-cigarette advertising is a form of anti-smoking advertising provided without any call on public funds – it would be perverse to stop this and spend public money instead.</td>
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<tr>
<td>Bans on online sales</td>
<td>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 without needing thousands of shops holding very large stocks of slow-moving inventory. 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.</td>
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<tr>
<td>Policy compliance burdens and other costs – leading to black markets</td>
<td>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 as the TPD is implemented. 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 designed to mitigate.</td>
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<tr>
<td>Product design restrictions and requirements – testing and paperwork</td>
<td>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.</td>
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<th>Policy</th>
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<tr>
<td>Bans on flavours</td>
<td>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 significant risk that loss of broad flavour categories will cause relapse among e-cigarette users, fewer smokers switching, and development of DIY and black-market flavours – which may be more dangerous. Even with young people, there is the possibility that any attraction to flavours is an attraction away from cigarette smoking and may be beneficial, meaning a ban would be harmful.</td>
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<tr>
<td>Health warnings</td>
<td>Warnings should frame risk information that allows users to make informed choices. Alarmist health warnings, even if literally correct, can be misleading and misunderstood by the public. This has often been the case with smokeless tobacco (e.g. <em>This is not a safe alternative to smoking</em>) Warnings do not adequately communicate relative risk and, therefore, understate smoking risks or downplay the advantage of switching. They may obscure much more important messages about relative risk compared to smoking that is not provided in official communications. Warnings about nicotine may exacerbate misperceptions about the (minimal) role of nicotine in causing disease.</td>
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<tr>
<td>Ban sales to under-18s</td>
<td>There is near universal support for this policy. But US studies 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.</td>
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<tr>
<td>Controls on ‘addictiveness’</td>
<td>Limiting the psychoactive impact of nicotine by, for example, controlling pharmacokinetics (PK), acidity, additives etc. risks limiting the capability of e-cigarettes to replace cigarettes for some smokers – and therefore implies a trade off in favour of reducing dependence rather than reducing serious disease. The problem of <em>abuse liability</em> is why NRTs have not been that successful.</td>
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<tr>
<td>Prohibit health or relative risks claims</td>
<td>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. Those determining whether a health claim should be allowed are often loss averse – concerned about what might go wrong if they allow a claim to be made. However, they rarely pay equivalent attention to the false negative error: the lost benefit arising from rejecting a claim that is in fact valid.</td>
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<tr>
<td>Raise taxes on e-cigarettes</td>
<td>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 (which in the UK actually receives an unjustified VAT discount). Establishing a tax regime is costly for both authorities and manufacturers – those costs are passed on to consumers depressing demand and reducing the price sensitivity of users to increases in cigarette prices. If the tax is made risk-proportionate, it would likely to be too low to be worth the expense of collecting – so any tax on vaping is likely to be disproportionate be default.</td>
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Appendix 3: Five insights from the Royal College of Physicians

To provide background on tobacco harm reduction, we draw on five key findings of the April 2016 Royal College of Physicians (London) report: Nicotine without smoke: tobacco harm reduction. The Royal College first put the dangers of smoking on the public agenda with its ground-breaking 1962 report, Smoking and Health.

1. On the relative risks of vaping and smoking

Although it is not possible to precisely quantify the long-term health risks associated with e-cigarettes, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure. (RCP Section 5.5 page 87)

People who smoke need to know they have the option to switch to vaping, and that doing this will radically reduce their incremental risks. Likewise, professionals involved in health care and policy need a good feel for the relative risks. The RCP aimed to provide clarity and has made its own best independent estimate of relative risk based on what is known about these products.

Vaping involves fundamentally different chemical and physical processes, and the main harmful or potentially harmful agents in cigarette smoke are either not present or present at levels well below 5 percent of those found in cigarettes. Even if new harmful agents are discovered, it is much easier to remove them from e-liquids than it is to remove target chemicals from cigarette smoke. Note how carefully worded this statement is – it is steering the reader to the right ball-park, acknowledging uncertainty, and pointing out that it is a cautious estimate.

Note that the 5% figure is not a point estimate of risk – it is an expert probabilistic assessment that the risk is unlikely to exceed five percent of that of smoking, with a suggestion that this estimate is cautious.

2. On the idea that allowing e-cigarettes will somehow cause people to smoke

There are concerns that e-cigarettes will increase tobacco smoking by renormalising the act of smoking, acting as a gateway to smoking in young people, and being used for temporary, not permanent, abstinence.

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from smoking. To date, there is no evidence that any of these processes is occurring to any significant degree in the UK. Rather, the available evidence to date indicates that e-cigarettes are being used almost exclusively as safer alternatives to smoked tobacco, by confirmed smokers who are trying to reduce harm to themselves or others from smoking, or to quit smoking completely. (RCP Key recommendations)

The finding is what a rational observer would expect – that people will use much safer products to reduce the risks to their health and as a way of quitting smoking, rather than to smoke more. The rise of vaping in the UK and US has been accompanied by rapid falls in adult smoking. There are strong associations between smoking and vaping because the same personal characteristics or circumstances that cause people to smoke also cause them to use ENDS, there is no compelling evidence that vaping causes smoking.

The American experience is of rapidly declining teenage smoking coinciding with a rise in vaping, much of which is occasional. The National Academies of Science, Engineering and Medicine states “for youth and young adults, there is substantial evidence that e-cigarette use increases the risk of ever using combustible tobacco cigarettes”. However, this has not translated to increases in smoking. In fact, the opposite effect, an anomalously rapid decline in adolescent smoking, has occurred, as the National Academies point out:

Overall, the population-based data broadly show opposing trends in e-cigarette and cigarette use prevalence across time among U.S. youth in recent years and thus do not provide confirmatory evidence of the epidemiologic person-level positive associations of vaping and smoking.

Likewise, a 2017 analysis of UK survey data concluded:

In summary, surveys across the UK show a consistent pattern: most e-cigarette experimentation does not turn into regular use, and levels of regular use in young people who have never smoked remain very low.

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A comprehensive American independent review of the studies and methodologies purporting to reveal ‘gateway effects’ found multiple flaws in methodology and interpretation, concluding\textsuperscript{123}: 

Only a small proportion of studies seeking to address the effect of e-cigarettes on smoking cessation or reduction meet a set of proposed quality standards. Those that do are consistent with randomized controlled trial evidence in suggesting that e-cigarettes can help with smoking cessation or reduction.

3. On the potential for bad policies to cause additional harm

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. (RCP Section 12.10 page 187)

The Royal College draws attention to the challenge of unintended consequences, and the idea that supposedly cautious policies are not necessarily cost-free, given the risk of perpetuating smoking. Policy-makers can believe they are being ‘precautionary’ and risk-averse, while actually being reckless, by protecting the cigarette trade and discouraging smokers from quitting.

The list of potential mechanisms for harmful unintended consequences arising from poorly designed regulation is long\textsuperscript{124}. There is already evidence that superficially attractive regulation of ENDS can have the effect of perpetuating smoking.


ating smoking\textsuperscript{125,126,127}, and therefore do more harm than good. Examples of plausible unintended consequences are set out in Appendix 2.

4. On quitting smoking as a consumer behaviour

\textit{E-cigarettes are marketed as consumer products and are proving much more popular than NRT as a substitute and competitor for tobacco cigarettes. E-cigarettes appear to be effective when used by smokers as an aid to quitting smoking.} (RCP Key recommendations, original emphasis)

Vaping products are consumer products marketed as an alternative to smoking. They are not smoking cessation medications any more than diet soda is an anti-obesity drug. The overall public health impact of any given approach is a function of both uptake and impact on the person's health. Vaping works well on both of these – by being attractive as an alternative to smoking and by mirroring many of the things that people want from smoking it is an effective low-risk substitute.

In 2018, there were 3.2 million vapers in Britain, of which the majority 1.66 million were former smokers. The number of UK smokers fell by 1.25 million between 2014 and 2017 (from 8.64 to 7.39 million) – a dramatic decline. Another 1.1 million people both smoke and vape – and many may be on a journey to quitting or substantially cutting down. There is an abundance of evidence that ENDS are promoting reductions in smoking\textsuperscript{128}, including this substantial 2017 study from the United States\textsuperscript{129}:

The substantial increase in e-cigarette use among US adult smokers was associated with a statistically significant increase in the smoking cessation rate at the population level. These findings need to be weighed carefully in regulatory policy making regarding e-cigarettes and in planning tobacco control interventions.

5. On the public health interest in vaping as a harm reduction strategy

*However, in the interests of public health it is important to promote the use of e-cigarettes, NRT and other non-tobacco nicotine products as widely as possible as a substitute for smoking in the UK.* (RCP Key recommendations, original emphasis).

Professor John Britton, chair of the RCP’s Tobacco Advisory Group, said:\(^{130}\):

The growing use of electronic cigarettes as a substitute for tobacco smoking has been a topic of great controversy, with much speculation over their potential risks and benefits. This report lays to rest almost all of the concerns over these products, and concludes that, with sensible regulation, electronic cigarettes have the potential to make a major contribution towards preventing the premature death, disease and social inequalities in health that smoking currently causes in the UK.

This is a strong recommendation from the Royal College of Physicians to embrace the concept of tobacco harm reduction as a public health policy. That is not an alternative to other tobacco policies – in fact it makes the traditional tobacco control policies more effective and less ethically challenging by giving smokers a viable way to respond to incentives or pressure.

Appendix 4: About the authors

Clive D. Bates is Director of Counterfactual, a consulting and advocacy practice focussed on a pragmatic approach to sustainability and public health. He has had a diverse career in the public, private and not-for-profit sectors. From 1997-2003 he was Director of Action on Smoking and Health (UK), campaigning to reduce the harms caused by tobacco. In 2003 he joined Prime Minister Blair’s Strategy Unit as a senior civil servant and worked in senior roles in government and regulators, and for the United Nations in Sudan.

Professor Robert Beaglehole trained in medicine, cardiology, epidemiology and public health in New Zealand, England and the USA before becoming a public health physician. He was Professor of Community Health at the University of Auckland, New Zealand (1988-1999). In 2000 he joined the staff of the World Health Organization and between 2004 and 2007 he directed the Department of Chronic Disease and Health Promotion. He is now an independent global public health practitioner with a focus on the prevention and control of noncommunicable diseases (NCDs) in New Zealand, the Pacific and globally. He founded ASH in 1982 and now chairs the organisation which actively supports the Smokefree Aotearoa 2025 Goal. He is Professor Emeritus of the University of Auckland.

George Laking (Te Whakatōhea) is a Consultant Medical Oncologist in Auckland and Northland New Zealand, experienced in the treatment of lung and other smoking-related cancers. His involvement in tobacco control began with the Smokefree Environments Act in 1990 and continued in 2010 with a submission to the Māori Affairs Select Committee Inquiry into the tobacco industry in Aotearoa and the consequences of tobacco use for Māori. George is an investigator in the ASCEND-II trial of electronic cigarettes as a means for smoking cessation, and related projects from the National Institute for Health Innovation at the University of Auckland. He is the Chair of End Smoking New Zealand, an organisation that advocates for reduced harm approaches to the tobacco epidemic.

David T. Sweanor JD is Adjunct Professor of Law and Chair of the Advisory Board of the Centre for Health Law, Policy and Ethics at the University of Ottawa. He has worked on global tobacco and health issues for more than 30 years, helping set many global precedents in Canada. He has also worked globally on tobacco issues with the WHO, PAHO, World Bank and numerous other bodies and spoken and published widely on issues of tobacco and health. His interests extend to a wide range of topics, and in addition to his personal work he funds numerous initiatives. He was the recipient of the Outstanding Individual Philanthropist award for Ottawa in 2016.

Ben Youdan has worked in tobacco control and campaigning for nearly 20 years in the UK and New Zealand. He was the Director of the UK’s No Smoking Day campaign that supported over 1 million annual quit attempts and worked
with the UK defence force on setting up dedicated smoking cessation services for the UK Army and Navy. He moved to New Zealand in 2007 when he was appointed Director of ASH (NZ) until 2013. Since then he has worked as the National Campaign Director for the Green Party of Aotearoa, a campaigns and policy consultant, and is currently the Strategic Policy Lead for the New Zealand Heart Foundation.

The authors do not have conflicts of interest with respect to tobacco, e-cigarette or pharmaceutical industries, and confirm no issues arise with respect to Article 5.3 of the WHO FCTC.