29 May 2023

Hon Mark Butler MP
Minister for Health and Aged Care

Dear Minister,

We are Australian and New Zealand tobacco control and addiction experts with no links to tobacco or e-cigarette companies. We are writing to ask you to reconsider your proposal to further restrict access to nicotine vaping products in Australia. In our view, this approach will have serious and harmful unintended consequences for public health.

Below is a summary of our concerns. Further details are in the Briefing that follows.

The likely outcomes of the proposed changes are

1. The black-market will continue to import and supply unregulated and potentially unsafe nicotine vaping products to adults and young people
2. People who smoke will have greater difficulty legally accessing nicotine for vaping, a far safer alternative
3. Some former smokers who currently vape will return to smoking
4. Uptake of the prescription model will continue to be low
5. Smoking rates will decline more slowly
6. Increased smoking-related death and disease will result, and
7. The model will ultimately fail.

A well-designed adult consumer regulatory model is most likely to achieve the two goals we all seek, i.e., making vaping products readily available as a quitting aid for adults who smoke and minimising access by young people.

While measures to protect non-smoking youth are essential, excessive regulation that makes vaping less accessible, less appealing, more expensive or less effective perpetuates adult smoking and increases smoking-related death and illness.

We urge you to reconsider the totality of the scientific evidence and reassess the proposed changes. We believe the proposed policy is likely to have an overall negative effect on smoking rates and thus on population health as well as Medicare and health-care costs in Australia.

We would be happy to meet with you to discuss in more detail how a risk-proportionate adult consumer model might work to achieve better public health outcomes.

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Briefing on vaping regulation in Australia

Contents

1. Evidence summary

Based on the international empirical evidence and overseas experience, it is now clear that

- Vaping nicotine is the most effective quitting aid for smokers [1-3]
- Vaping is the most popular quitting aid in Australia [4] and other western countries
- Vaping nicotine is not risk-free but is far less harmful than smoking. [5] This is based on a substantial reduction in toxicant exposure [6-8], fewer harmful toxins in the urine and blood of smokers who switch to vaping (biomarkers of harm) [9-11] and improved symptoms and clinical changes after switching [12-20]
- Rather than being a threat to tobacco control, nicotine vaping is associated with accelerated declines in national smoking rates in countries where it is easily accessible [21-23]
- Policies to reduce vaping such as flavour bans [24], increased taxation [25] and sale bans [26] are associated with increased cigarette sales
- Most vaping by never-smoking youth is experimental and short-term resulting in low levels of exposure to toxicants [27]
- There is no good evidence that vaping causes young people who would not otherwise have smoked to progress to regular smoking (‘gateway theory’). [27] The evidence suggests that vaping is displacing smoking at the population level [28-32]
- Only a small proportion of young people who vape but have not smoked become dependent on nicotine [33]
- There is no evidence that nicotine is harmful to the human adolescent brain [34]
- While the long-term risks of using e-cigarettes will not be fully known for many decades, it is highly likely to be far less harmful than smoking [5, 35-40]
- No tobacco company vaping products are currently sold on the black market in Australia

2. Unintended consequences

The current prescription-only model is not working and has had unintended negative consequences. Continuing with this regulatory model is likely to increase these problems. [41-44]

The prescription model is a significant barrier for adult smokers wishing to legally access regulated nicotine vaping products to quit smoking or to reduce smoking-related harm. Most doctors are reluctant to prescribe nicotine and this is unlikely to change significantly with the removal of the authorisation scheme. [45] Currently few pharmacists stock supplies. Eight per cent of adult vapers have a nicotine prescription and only 10% of vapers indicate they would be willing to get a prescription to vape, even if they could find a prescribing doctor. [46, 47]

Surveys suggest that around 13% of vapers will return to smoking under the proposed further restrictions. [46, 47] Given the relative risks, even a small increase in smoking could outweigh any benefits arising from reduced vaping.

The prescription model has led to a lucrative, thriving black market run by criminal gangs, selling unregulated, mislabelled, high nicotine content disposable vapes to children. Past experience has consistently demonstrated that prohibitive drug policies do not produce sustained reductions in availability but do create predictable and serious unintended consequences. [48-50] Furthermore, illicit suppliers expose young people to other illicit drugs, and some may become involved in the retail end of criminal supply, not just as consumers.

Effective border detection of illegal imports is almost impossible and will require substantial funding. [51] Eighty seven per cent of people who use other drugs report that accessing heroin was easy or very easy in the 2022 Illicit Drug Reporting System survey. [52]

In the unlikely event that the proposed new policy is successful in reducing or eliminating the existing black-market for vapes, this would likely to result in an increase in smoking among adults and young people. Some people who vape will relapse to smoking. Others who are inclined to try nicotine products in the future will smoke instead of vaping.

In our view, severe restrictions on safer nicotine vaping products are not justified when harmful cigarettes are readily available.

3. Optimal regulatory model

A well-designed adult consumer regulatory model is more likely to achieve the two goals we all seek, i.e., making vaping products available as a quitting aid for adult smokers and minimising use by young people.

The ideal model is a tightly regulated market with regulated nicotine vaping products sold by licensed retail outlets wherever regulated tobacco products are sold. [53] Strict age controls should be mandatory (penalties and loss of licence for underage sales, photo ID, age verification software, staff training, signage, restricted visibility in-store etc). [54]

Developing this model requires

1. The exemption of low concentrations of nicotine liquid from the Poisons Standard when used for vaping

2. A risk-proportionate regulatory framework addressing product standards; containers and labelling; health warnings; pre-market notification; restrictions on youth-friendly flavour descriptors; public vaping laws; public messaging; advertising; post market surveillance; and taxation [53]
3. Regulation by the Australian Competition and Consumer Commission (ACCC) instead of the Therapeutic Goods Administration, with specific responsibilities for State and territory governments and the Commonwealth. [53]

Under this model, the black-market would become less profitable and illicit sales would likely diminish over time, being largely replaced over time by a legal, regulated market.

Regulations should be proportionate to risk and reflect the lower harms of vaping relative to smoking. [55] A risk-proportionate adult consumer model would bring Australia into line with other western countries such as New Zealand, the United Kingdom and Canada. Seventy five per cent of Australian adults support this model and 79% said they would purchase vapes legally if they were available from general retail outlets, according to a recent Roy Morgan survey. [46]

Measures to protect non-smoking youth are essential, **but excessive regulation that makes vaping less accessible, less appealing, more expensive, less consumer-friendly or less effective perpetuates adult smoking and increases smoking-related death and illness.** [35]

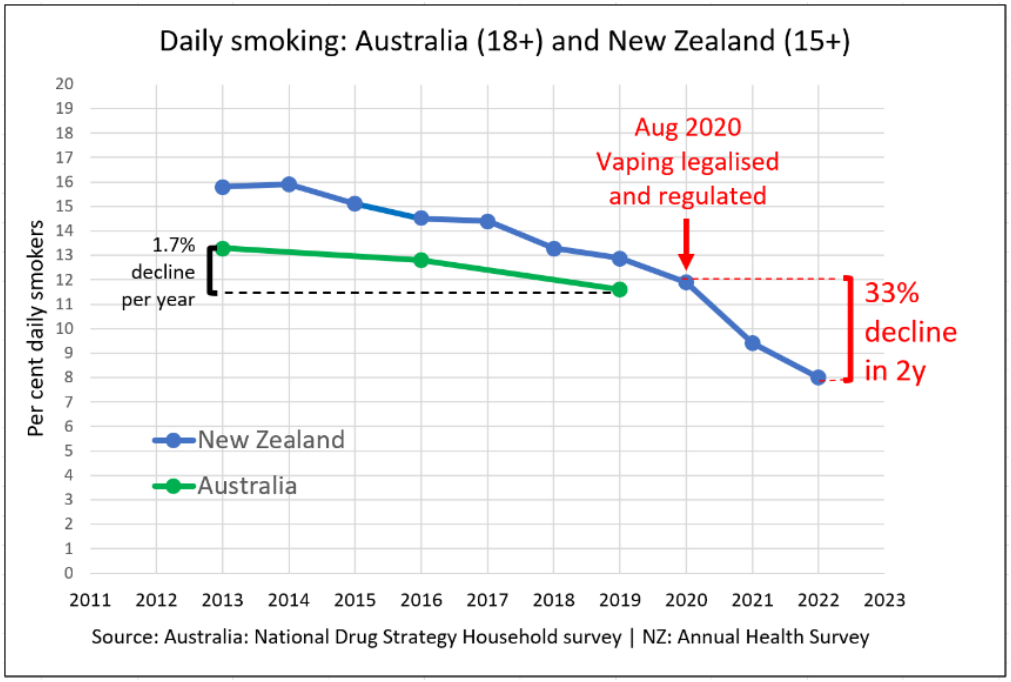
We believe there is also a minor role for a therapeutic prescription pathway as well, in addition to the consumer pathway.

If the government remains committed to a therapeutic access route only, one option is rescheduling nicotine vaping products to Schedule 3, so that nicotine vapes are dispensed by a pharmacist without a prescription. This would greatly enhance access for adult smokers while minimising access for children and adolescents. This greater accessibility of regulated products would also potentially reduce the size of the illicit market.

4. New Zealand

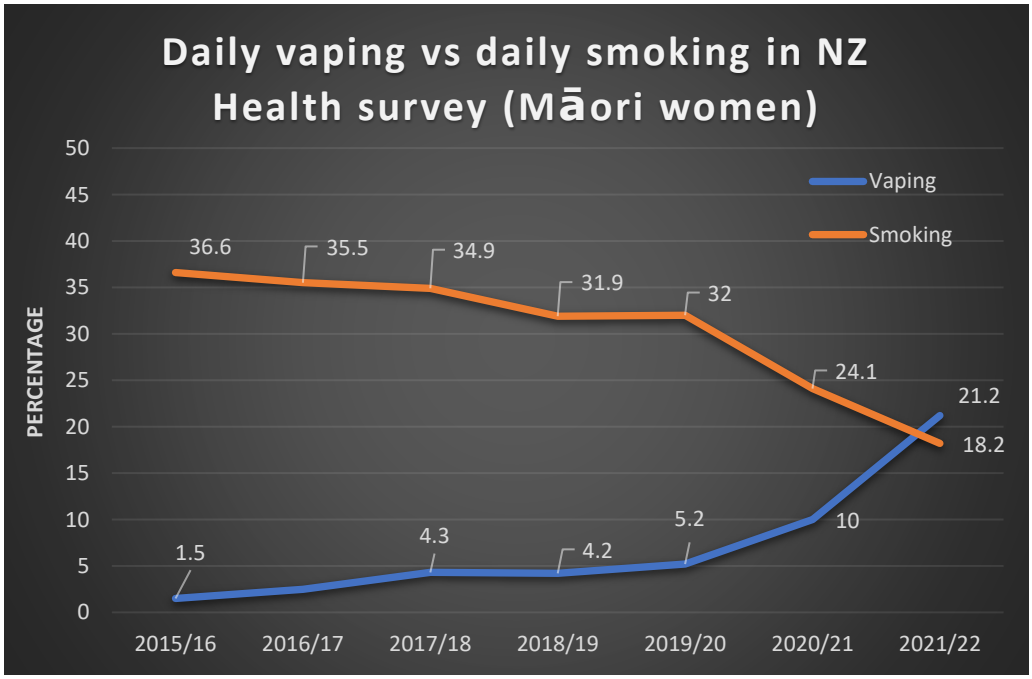
We refer to the success of the New Zealand regulatory model which most closely emulates the optimal approach in our view.

Nicotine vaping products were legalised and regulated in August 2020 as adult consumer products**. Over the next 2 years, the adult smoking rate declined by an unprecedented 33%**, according to the New Zealand Annual Health Survey. [23] In that time there were no major ant-tobacco policy interventions, almost no mass media spend on quit campaigns, and no tobacco tax increases. The this decline in smoking is attributed largely to vaping.



In comparison, smoking prevalence declined in Australia by 1.7% per year from 2013-2019, according to National Drug Strategy Household Surveys. [4, 56]

Smoking rates fell by 43% in Māori women and 30% in Māori men in New Zealand over the same period. [23] This suggests a potential role for vaping to help reduce Australia's smoking rate.

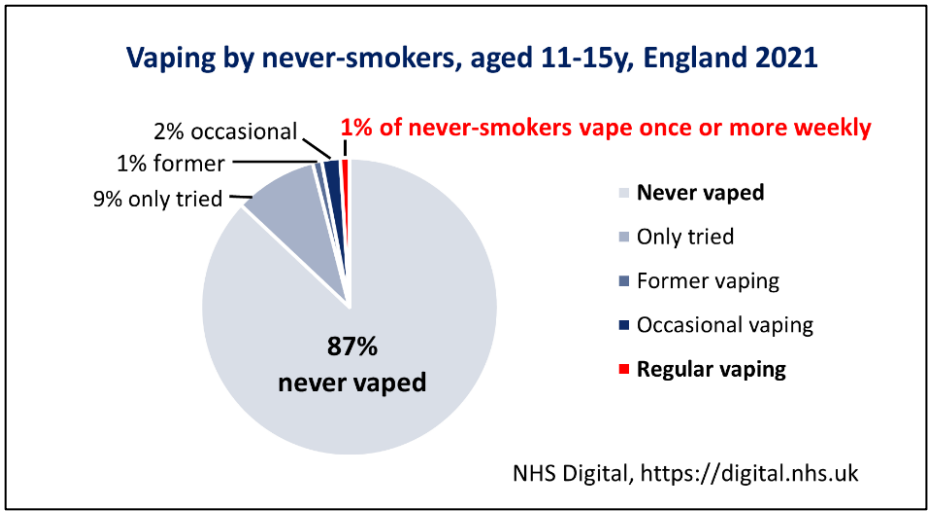


5. Vaping by young people

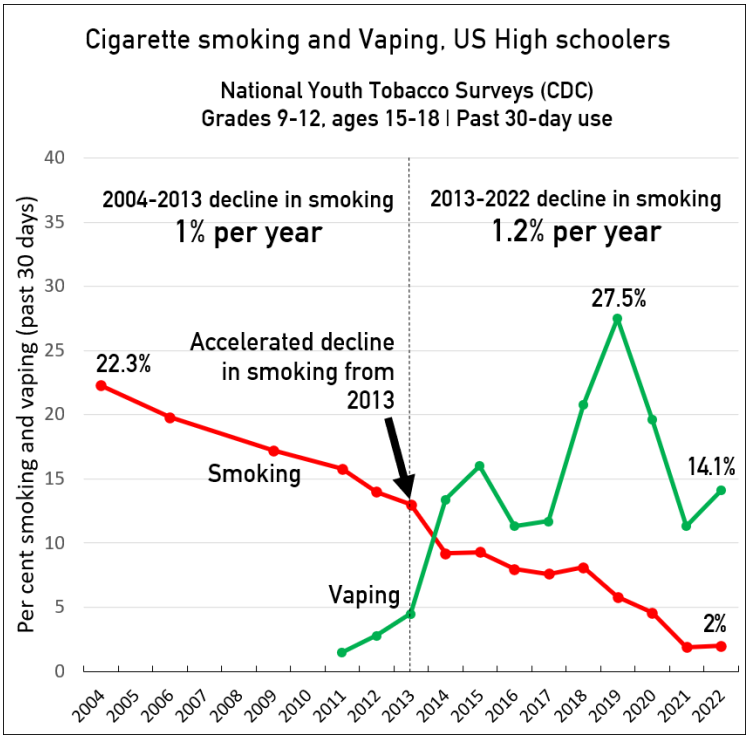
Young people should not vape or smoke and both should be discouraged. However, concerns about youth vaping are exaggerated and do not reflect the scientific evidence.

The impact of vaping by youth should be assessed according to its frequency and the smoking status of those involved. The main concern is **frequent vaping by young people who have never smoked** (never-smokers) as this is the group at most risk. A recent Australian review of the evidence (available **HERE**) in young never-smokers who vape found that: [27]

- Most vaping by teens who have never smoked is occasional and short-term. [33, 57-61] Frequent vaping is largely confined to current or past smokers. In an Australian study of 1,006 15-30 year olds, only 8 were never-smokers had vaped once or more in the last month. [62] In England in 2021 only 1% of 11-15 year olds who had never smoked cigarettes vaped regularly (once or more weekly). [57]



- There is no strong evidence that vaping is causing young people to take up sustained smoking. [63-66] Increased youth vaping has been accompanied by an accelerated decline in youth smoking, for example in the US below. [57, 67-69]



This suggests that even if there is a small 'gateway effect', it is outweighed by the much larger number who would have smoked being diverted to vaping or moving from smoking to vaping. Population and modelling studies also suggest that vaping is displacing smoking at a population level. [28-31]

- The documented health effects of vaping are relatively small in never-smokers as most are exposed to low level exposure. There is no evidence of harm to the human adolescent brain [34] or of functionally important respiratory effects from vaping nicotine. [70-72] These small risks need to be balanced against the substantial and immediate health benefits to adult smokers who switch to vaping.
- Nicotine dependence in never-smokers is very uncommon and only occurs in a small minority of cases. [33] Nicotine dependence is mostly concentrated in young people who have previously smoked or currently smoke. [73-75]

Vaping among young people who already smoke may be beneficial if it diverts them away completely from cigarette smoking.

It should also be recognised that young people benefit when the adults in their lives quit smoking through better parents' health, improved household finances, avoiding caring burdens, and reduced loss and grief, as well as a strong role-model effect on youth behaviour.

6. Flavours

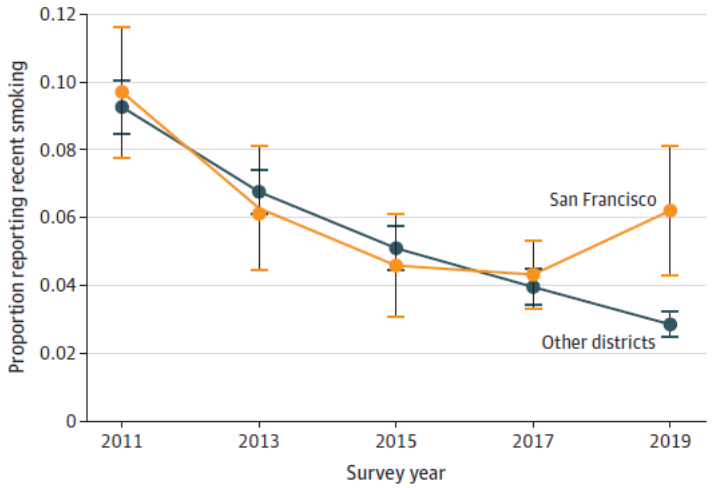
The evidence indicates that flavour bans will reduce the number of adult smokers switching to vaping, are likely to increase smoking rates and are unlikely to reduce youth vaping.

Adult vapers overwhelmingly prefer sweet flavours. [76] Flavours have "a central role in the appeal, adoption, and continued use of e-cigarettes for quitting" by adult vapers. [77, 78] Restricting flavours would reduce the appeal of vaping as a quitting aid, potentially leading to more smoking, relapse by current vapers to smoking and more smoking-related death and disease. [79-81]

Flavoured e-liquids also are associated with higher quit rates compared to non-flavoured or tobacco flavoured e-liquids, smoking reduction and reduced relapse. [82-85] Those who vape with flavours also have higher odds of making a quit attempt. [84]

Flavour bans to reduce vaping by young people can be counterproductive as vaping is a substitute for smoking. For example, a ban on flavoured tobacco and vaping products in San Francisco in 2020 resulted in a more than doubling of **smoking** by high school students. [24]

Figure 1. Past-30-Day Smoking Trends Among High School Students Younger Than 18 Years



In another study of adults in San Francisco, vaping was reduced and smoking increased after a flavour ban. [86]

In the United States, flavours in pod-based products (other than tobacco and menthol) were banned nationally in 2019. One study reported that 14% of adult vapers returned to smoking. [87] The main impact on youth vaping was a shift to disposable products and illicit flavoured pods. [88, 89] Vaping and smoking behaviours remained unchanged. Flavour bans also lead to increased black-market supplies and dangerous home mixing, with little effect on youth uptake. [90]

While young people like flavours, flavour is not the primary reason they give for experimenting with vaping. Flavours were the third most common reason given for trying vaping, after curiosity and use by a friend or family member, in surveys in the US and Great Britain. [91, 92] The underlying causes of smoking, vaping and nicotine use are psychosocial and genetic and run much deeper than any particular product feature such as flavour.

Reasonable recommendation for flavours are

- Allow simple descriptions of flavour profiles only e.g., ‘mint’, ‘blueberry’, ‘tobacco’, ‘vanilla tobacco’
- Prohibit descriptive flavour names that specifically appeal to youth e.g., ‘dragon vomit’, and
- Prohibit flavours found to have a material risk to health.

7. Black market disposables devices

There is understandable concern about the widespread uptake of black market disposable devices by young people in Australia as well as in the UK [93] and US. [94] However, a specific ban on disposables is highly unlikely to be effective. These products are already banned yet an estimated 100 million illegal devices are currently smuggled into Australia each year. [95]

Removing disposables from the market could have unintended consequences. Disposable vapers may switch to smoking when their preferred nicotine product is no longer available. [96] Young people may also switch to other vaping products without necessarily having an impact on youth

vaping rates overall. In the US, when flavoured pod devices were banned, young people switched to flavoured disposable devices. [79, 89]

Disposables play an important role in the transition of some adult smokers to vaping due to their simplicity of use, convenience and similarity to a cigarette. Vapers often progress to more advanced devices at a later stage. Disposables are especially useful for smokers with disabilities such as arthritis and elderly smokers. They are also suited to homeless people, prisons and hospital and residential rehabilitation facilities where battery charging is not available. Banning disposables may reduce the number of adult smokers switching to vaping.

A recycling program could be established to address the growing environmental issue arising from discarded single-use vapes. We have developed a national recycling program which could be established if vapes were made available legally. [97] Manufacturers are increasingly making disposables more recyclable and biodegradable and this will continue to improve. [98]

Action on Smoking and Health UK recommends introducing a tax specifically on disposable vapes (but still less than cigarettes) to make them less affordable for young people. [99] This would also encourage the conversion of adult users to reusable models. However, it would not reduce black market supply and may potentially increase it.

8. Rapid decline in young adult smoking rates

The claim that smoking rates are rising in the under-25-year age group is not correct. In fact, young adult smoking rates in Australia are falling **faster** than the general population. Vaping rates are highest in this age group and are likely contributing to this decline.

- In South Australia, current smoking is **declining more than twice as fast** in the 15-29 year old age group as the state average. [100] From 2020-2022, the smoking rate of 15-29 year olds fell by 55% (from 10.9% in 2020 to 4.9% in 2022). The state smoking rate (15+) declined by 24% overall (10.6% in 2020 and 8.2% in 2022). Vaping is twice as common in the 15-29 year old age group (7.8%) compared to the state average (3.2%).
- In NSW, smoking by 16-24 year olds fell by 25% in 2 years (from 17.8% in 2019 to 13.3% in 2021) as vaping rates increased. [101] This decline is faster than **the state smoking average**, which fell by 21% during the same period.

No recent data are available from others states, but similar results are seen in New Zealand. [23] Between 2019-22 there were very substantial declines in smoking in 15-24-year-olds, coinciding with a rapid increase in vaping. The highest vaping rate in New Zealand is among 18-24 year olds.

In the years before vaping products became readily available, Australia was remarkably successful in reducing smoking among adolescents, but less so among young adults. At least some of the more recent declines in smoking among young adults are likely due to them vaping instead. We are concerned that the proposed policy may reverse these trends.

9. The Tobacco Industry

Some have incorrectly framed vaping as a ploy by the Tobacco Industry to “addict a new generation of youth to nicotine”.

The black market disposable vapes being used by Australian youth are exclusively Chinese-manufactured imports. **No tobacco company vaping products including disposables are sold illegally in Australia**. A small number of tobacco company pod vapes are available on prescription for adult smokers through pharmacies.

The tobacco industry did not invent vaping and currently controls only 12% of the vaping market globally by value, according to e-cigarette research company, ECigIntelligence. [102]

		Estimated share of tobacco companies			
Global market value 2023	**$28bn**	**12%**			
By product category:					
Open system (hardware+e-liquid)	*$10bn*	*3%*			
Prefilled pod products	*$8bn*	*35%*			
Disposable vape products	*$10bn*	*4%*			

Vaping is a huge disruptive threat to the sale of cigarettes and tobacco. From a public health point of view, it is a good thing that tobacco companies are transitioning from manufacturing deadly combustibles to reduced risk nicotine products such as vapes.

10. Flawed Australian reports on nicotine vaping

We draw your attention to two government-commissioned reports which underpin Australian policy, the 2022 National Health and Medical Research Council CEO Statement on E-cigarettes and the 2022 report by the National Centre for Epidemiology and Public Health at the Australian National University. Both these reports have been analysed in peer-reviewed papers and found to contain serious scientific errors, misinformation and bias.

Both critiques are available **HERE**. [103, 104]

The critique of the NHMRC Statement was co-authored by Australian experts and seven leading international tobacco addiction specialists:

- Professor Ann McNeill, Lead author on Public Health England reports on e-cigarettes; National Addiction Centre, Institute of Psychiatry, Psychology and Neuroscience, King's College London, UK
- Emeritus Professor John Britton, former Chair of the Tobacco Advisory Group, UK Royal College of Physicians; University of Nottingham, Nottinghamshire, UK
- Professor Neal Benowitz, Department of Medicine, University of California San Francisco, California, USA
- Professor Nancy Rigotti, Harvard Medical School, Director, Tobacco Research and Treatment Center, Massachusetts General Hospital, Massachusetts, Boston, USA
- Professor Chris Bullen, University of Auckland, Auckland, New Zealand
- Emeritus Professor Robert Beaglehole, School of Population Health, The University of Auckland, Auckland, New Zealand
- Professor Jean-Francois Etter, Institute of Global Health, Faculty of Medicine, University of Geneva, Geneva, Switzerland

The findings of these reports are contrary to those of leading organisations overseas, including the UK Royal College of Physicians [35], Public Health England (now OHID) [5], the UK National Institute for Clinical Excellence [105], the New Zealand Ministry of Health [106] and Health Canada. [40]

Further information

Four further peer-reviewed papers supporting our recommendations are available **HERE**.

- A paper on how to regulate vaping in Australia [53]
- An Australian review of the harms from vaping to young people who have never smoked (in press) [27]
- A modelling study predicting substantial net population health benefits from legalising and regulating nicotine for vaping in Australia as a consumer product [107], and
- A modelling study estimating that Australia will not reach its 2030 goal of 5% or less adult daily smoking until 2066 on the current trajectory. [108] Overseas experience has shown that vaping can accelerate the decline in smoking rates.

In conclusion, we recommend that the proposed plan be delayed and reviewed by a diverse range of experts to develop a more workable model.

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