



Submission to the Legislative Assembly of the Northern Territory

Select Committee on Electronic Cigarettes and Personal Vaporisers (Vaping)

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18 April 2023

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Executive summary

- There is an urgent need to reduce smoking rates in the Northern Territory which has the highest smoking prevalence of any State and Territory in Australia
- Smoking rates are especially high in Indigenous communities and contributes to 20% of the Indigenous/non-Indigenous health gap and shortened life expectancy
- Vaping could play a major role in helping smokers who are unable to quit with conventional methods
- Vaping nicotine is an adult quitting aid and is the most effective and most popular quitting aid currently available
- Vaping nicotine is estimated to be at least 95% less harmful than smoking
- The precise long-term risk will not be fully known for decades but is highly likely to be substantially less harmful than smoking
- Young people should not smoke or vape but risk taking is a normal part of adolescence
- Most vaping by never-smoking adolescents is occasional and transient and transition to regular vaping is uncommon
- Frequent adolescent vaping is mostly confined to smokers and former smokers
- Rather than being a gateway to smoking, vaping is diverting young people from sustained smoking
- Despite media reports to the contrary, vaping nicotine does not cause EVALI, serious lung damage, seizures or harm to the adolescent brain
- Nicotine dependence is rare in never-smokers who vape
- Youth education should be honest and proportionate and include risk relative to smoking. There is no place for exaggeration or scare campaigns
- A balanced, risk-proportionate approach to regulation is needed to restrict vaping by young people while allowing easier access for adult smokers to help them quit
- Vaping products should be sold by licensed retail outlets with strict age verification, harsh penalties for breaches and potential loss of licence
- Regulation should follow the models used in New Zealand and United Kingdom

About me

I am an Australian medical doctor who has worked in the field of smoking cessation, tobacco control and tobacco harm reduction for 40 years. I am currently involved in teaching and research.

I am a member of the Expert Advisory Group that develops the [RACGP Australian national smoking cessation guidelines](#).

I was the Founding Chairman of the [Australian Tobacco Harm Reduction Association \(ATHRA\)](#), a registered health promotion charity dedicated to raising awareness of low-risk nicotine products as a substitute for smokers who can't quit. I stepped down from the Board in January 2020.

I was a Conjoint Associate Professor in the School of Public Health and Community Medicine at the University of New South Wales from 2016-20.

I am a past Vice President of the Australian Association of Smoking Cessation Professionals, Australia's peak body for experts in the field of smoking cessation.

I have served on the NSW Health Advisory Committee on Electronic Cigarettes, and on the Vaping Cessation Expert Panel for the Canadian [Centre for Addiction and Mental Health \(CAMH\)](#), commissioned by Ontario's Ministry of Health. I am also on the Expert Advisory Group for the [Coalition of Asia Pacific Tobacco Harm Reduction Association \(CAPHRA\)](#).

I am currently an investigator on an NHMRC-funded clinical trial on vaping at the National Drug and Alcohol Centre, University of New South Wales, Sydney: [Adding an electronic-cigarette to standard behavioural treatment for low-socioeconomic status smokers: A randomised trial](#) [link]

I have published extensively on smoking cessation and vaping and my publications are available [here](#).

For information about me is available at www.colinmendelsohn.com.au.

Disclosure

I have no financial or commercial relationship with any electronic cigarette or tobacco company. I have recently published a book on vaping called [Stop Smoking Start Vaping](#).

ATHRA accepted unconditional, publicly declared donations from the retail vape sector for the initial legal and website costs of establishing the charity. These donations ceased in March 2019. ATHRA has never accepted donations from tobacco companies or their subsidiaries.

Introductory comments

There is an urgent need to reduce the smoking rate in the Northern Territory which has the highest smoking prevalence in Australia. In 2019, 14.9% of Territorians aged 14+ smoked daily, compared to the national average of 11%. [1]

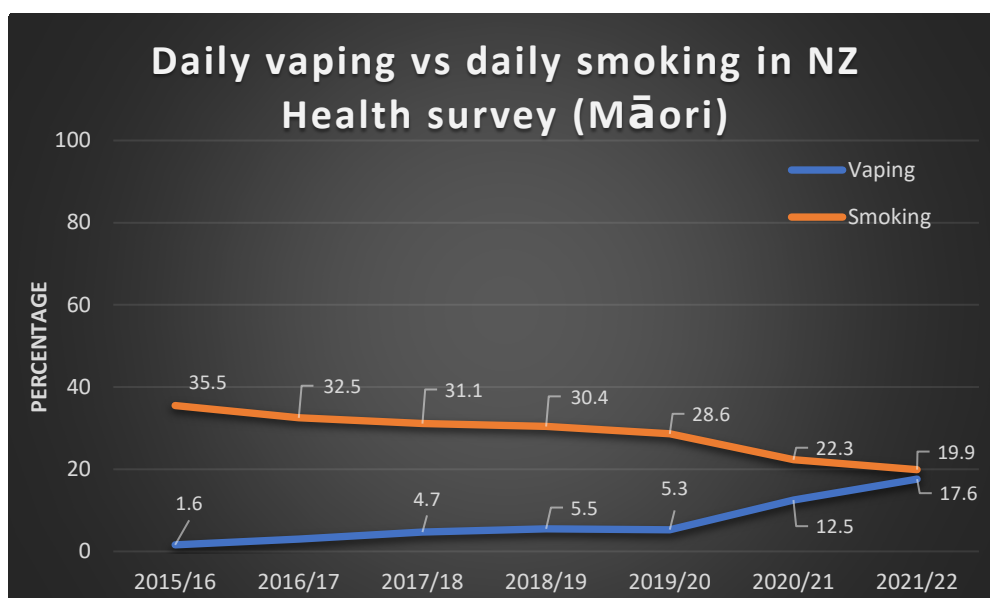
People living in the Northern Territory are more than twice as likely to suffer from a tobacco-related disease than people living anywhere else in Australia. [2] They also have the lowest life expectancy. [2]

Indigenous smoking

Tobacco smoking is especially deadly for Indigenous Territorians of whom 50% (18 years and over) smoke daily. [3] There has been no change to the gap in smoking prevalence between Indigenous/non-Indigenous adults from 1994 to 2018–19. In 2017, 49% of Northern Territory Aboriginal mothers smoked in the first 20 weeks of their pregnancy. [4]

Smoking is the leading cause of the burden of disease for Indigenous people and is responsible for 20% of the Indigenous/non-Indigenous health gap. [5] Indigenous people in the Northern Territory have a life expectancy 15 years less than the general population, with the gap unlikely to be eliminated for a further 60 years. [6] Indigenous people smoke more heavily, belong to networks where smoking is normalised and have greater difficulty quitting.

Since vaping was legalised and regulated in New Zealand in August 2020, daily smoking in Māori people declined by an unprecedented 30% (28.6% in 2020 to 19.9% in 2022), largely due to vaping. [7] Similar results could be expected if vaping was available to Indigenous Territorians.



It is essential that all options to help smokers quit are on the table. Vaping nicotine is an effective quitting aid for smokers who are unable to quit with conventional treatments and will help to reduce Northern Territory's shameful smoking rate more quickly, especially for Indigenous people. Vaping is also substantially cheaper than smoking and helps to reduce financial inequalities.

1. The current scale and trends of e-cigarette and personal vaporiser use in the Northern Territory, including amongst children and young people

There are no reliable estimates of the prevalence of youth vaping in the Northern Territory at present, although there are anecdotal reports of widespread use. However, data is available from other jurisdictions.

A recent Australian study of 1,006 15-30 year olds found that current vaping by young people who have never smoked is rare. [8] Less than 1% (n= 8) of non-smokers had vaped once or more in the last month. 56 were past smokers and 65 were current smokers. Of the current or past smokers, 57% vaped to cut down or reduce smoking.

The key measure of potential harm is **frequent vaping by never-smoking youth**. Occasional use and experimentation involves little exposure to toxicants and is unlikely to have a significant public health effect.

Studies in other western countries have found **most vaping by never-smoking adolescents is occasional and transient**. Frequent vaping by never-smokers is rare and is mostly <2%. (Table 1) Vaping rates are substantially higher in current or former smokers.

Country	Vaping frequency	Year	Never smokers	Current smokers	Age	Ref
England	≥ once weekly	2021	1%	61% of regular smokers were regular vapers	11-15	[9]
	> once weekly	2022	0.5%	55.4% of current smokers were current vapers	11-17	[10]
	≥ 15 days in the last 30	2018	0.1%	13.4% of current smokers vaped frequently	16-19	[11]
United States	≥ 20 days in the last 30	2018	0.4%	88.9% of frequent vapers were current or past smokers	9-19	[12]
		2019	2.1%	48.8% of frequent vapers had smoked >100 cigarettes	14-18	[13]
	≥ 15 days in the last 30	2018	1.5%	23.4% of current smokers vaped frequently	16-19	[11]
Canada	≥ 15 days in the last 30	2018	0.6%	18% of current smokers vaped frequently	16-19	[11]
New Zealand	Daily	2022	4.3%	86.6% of daily smokers vaped daily	15	[14]

Table 1. Frequent or daily vaping by never-smoking youth

The most detailed data are available from England and demonstrate a strong association between vaping and smoking. [1] (Table 2) In 2021, only 1% of 11-15-year-old never-smokers in England were regular vapers, whereas 61% of regular smokers were regular vapers.

		E-cigarette use				
		Never used	Only tried	Former vaping	Occasional vaping	*Regular vaping
Smoking	*Regular smoker	8%	5%	14%	12%	61%
	Occasional smoker	4%	11%	7%	25%	53%
	Ex-smoker	12%	10%	22%	25%	30%
	Tried smoking	21%	35%	9%	19%	15%
	Never-smoker	87%	9%	1%	2%	1%

Table 2. Nicotine vaping product use by smoking status, ages 11-15 years, England 2021 [9]

Illegal unregulated nicotine vapes are sold by retail outlets and on social media. NT Health is responsible for policing and enforcing illicit sales but intervention has been minimal.

2. The health impacts of the use of e-cigarettes and personal vaporisers

It is well established that vaping is substantially less harmful than smoking. According to comprehensive, independent reviews by the UK Royal College of Physicians and Public Health England, vaping is estimated to be around 95% less harmful than smoking. [15, 16]

Most of the toxicants in smoke are absent from vapour and those that are present are in most cases below the threshold known to cause harm. [17-19] Levels of biomarkers (harmful chemicals in the urine, blood or saliva) are significantly lower in former smokers who vape or dual use (vape and smoke). [20] Most harms from smoking are proportionate to the level of toxin exposure. [21]

Exposure to carcinogens is substantially reduced after smokers switch to vaping. [15] The lifetime cancer risk from vaping has been estimated as less than 0.5% of the risk from smoking. [22]

Clinical trials and surveys of smokers who completely switched to e-cigarettes have shown short-medium term improvements in asthma [23], COPD [24], blood pressure [25, 26], muco-ciliary clearance [27], respiratory infections [28], lung function [29], respiratory symptoms [30, 31], cardiovascular markers [32, 33] and gum disease. [34]

The most commonly reported adverse effects are throat and mouth irritation, headache, cough and nausea which tend to dissipate with continued use. [35]

The precise long-term risk of vaping nicotine will not be fully known for decades, but it is highly likely that it will be substantially less harmful than smoking. [15, 16, 36-38] Ongoing monitoring is essential to detect any problems that may arise in the future.

Health effects specifically in young people

Vaping by young never-smokers exposes them to some of the harmful chemicals in smoke, but at low levels. [15] There are also low levels of other chemicals in vapour that are not found in tobacco smoke, such as flavouring chemicals, but so far there is “no clear evidence that specific flavourings pose health risks”. [36] Most use by never-smokers is infrequent and short-term and is therefore associated with lower exposure and risk than regular or sustained vaping.

Vaping has been associated with respiratory symptoms in young people in cross-sectional studies, but many vapers have smoked tobacco. [39-41]. Other studies have found no functionally-important respiratory symptoms in young people who vape after taking account of past cigarette smoking. [42, 43] A meta-analysis of ten studies found an association between vaping and asthma in young people but a causal link could not be demonstrated. [44] A recent large, longitudinal study found that exclusive e-cigarette use was not associated with the onset of youth asthma. [45]

Adverse effects on the adolescent brain have been found in animal studies but extrapolation to humans is speculative. [46] Studies of young people who smoked have not found any difference in IQ [47], educational achievement [48] or cognitive abilities [49] in adulthood compared to non-smokers.

Vaping nicotine has been found to improve attention, memory [50] and cognitive function [51] and to relieve anxiety [52] and improve mood. [53]

Nicotine “represents minimal risk of serious harm” in the doses used in vaping. [15, 36] Nicotine does not cause cancer [54] or lung disease [21] and it has only a minor role in cardiovascular disease. [55] A recent meta-analysis found with ‘moderate certainty’ evidence there are no significant associations between the use of nicotine and the risk of clinically diagnosed adverse cardiovascular events—specifically, arrhythmia, nonfatal myocardial infarction, nonfatal stroke, and cardiovascular death. [56]

To date, there have been no identified health risks of passive vaping to bystanders. [16, 36]

There is no evidence that vaping nicotine causes the serious lung disease E-cigarette or Vaping Associated Lung Injury (EVALI) [57] or seizures. [58] There is a rare risk of burns and injuries from explosions, but none have been reported from disposables, the most popular type of device used by young people.

Does vaping increase the risk of becoming a smoker?

The main public health concern about youth vaping is that it may cause young never-smokers to take up regular smoking if they would not otherwise have done so (the gateway hypothesis). However, we now know it is having the opposite effect.

It is well established that young people who try vaping are more likely to later try smoking. [59] However, there is weak evidence that this association is causal. [60, 61] A more plausible explanation is that shared risk factors for vaping and smoking, such as genetics [62] and environmental, psychological and social causes [63] create a ‘common liability’ for risk taking. [64] After rigorous adjustment for common risk factors (confounders), most of the association between vaping and subsequent smoking disappears. [61, 65]

In fact, the overall evidence suggests that vaping is **diverting young people away from smoking.**

Population and modelling studies suggest that vaping and smoking are substitutes and that vaping is displacing smoking at a population level. [66-69] Increases in youth vaping have been accompanied by an accelerated decline in smoking in western countries, suggesting a diversion effect. [66, 67, 69] This is the opposite of what would be expected from a gateway effect.

Studies of the effects of tax increases on vaping products and bans or restrictions on the sale of vapes to teens indicate that vaping and smoking are economic substitutes. Higher taxes on vapes are associated with increased youth cigarette smoking. [70-73] Bans or purchasing restrictions on the sale of vapes to teens are also associated with increased adolescent smoking. [74-76]

Approximately 25-50% of adolescents who experiment with vaping are non-smokers at the time. [77-80] There is growing evidence that those who vape first (before smoking) are less likely to later be smokers, compared to those who smoke first. [78-82]

Importantly, it does not appear that youth vaping leads to increases in sustained cigarette use, which is the major public health concern. [61, 66, 69, 83-86]

Dependence on nicotine

Vaping likely causes nicotine dependence in some young never-smokers. The evidence suggests, however, that this affects a small minority of vapers and it is not creating a “new generation addicted to nicotine”. [87]

An analysis of the 2018 US National Youth Tobacco Survey found that <4% of never-smokers who had vaped in the past 30 days had signs of nicotine dependence. [13] This low incidence is consistent with the dominant pattern of occasional and short-term use.

Nicotine dependence is concentrated in young people who are current or previous smokers. [11, 88, 89]

In the US, there was a 50% decline in youth vaping from 2019-2021, suggesting that significant nicotine dependence was unlikely to be an issue for many vapers. [90] This decline also raises the possibility that vaping may have been a passing adolescent fad.

Not all young people who vape use nicotine. Thirty to fifty percent report not using nicotine, or not knowing if they had used it or not. [77, 91, 92]

What about young smokers who take up vaping?

The vast majority of young people who experiment with both vaping and smoking were smokers before they tried vaping. [13, 93-95] Many teen smokers vape to quit smoking or as a safer alternative. In Australia in 2019, 44% of 14-17-year-old smokers reported using vapes to quit smoking, 32% to cut down, 23% to avoid relapse to smoking and 27% to reduce harm. [1] As vaping is substantially less harmful than smoking, young smokers who switch to vaping are likely to see health benefits. [15]

3. The efficacy of e-cigarettes and personal vaporisers in helping people to quit smoking

Vaping nicotine is the most effective quitting aid currently available.

The 2022 Cochrane Review concluded that “there is high-certainty evidence that ECs with nicotine increase quit rates compared to NRT” (RR 1.63) and that “in absolute terms, this might translate to an additional four quitters per 100”. [35] Other meta-analyses report that electronic cigarettes are superior to NRT. [96-99]

A network meta-analysis by the UK National Institute for Health Research of 171 RCTs of all smoking cessation medications concluded that vaping was the most effective single therapy, followed by varenicline and NRT. [100]

The effectiveness of vaping is also supported by evidence from UK stop smoking services [15], observational studies [101-103], population studies [104, 105] and declines in national smoking rates. [106, 107] While these studies cannot prove causality, their results are consistent with those of RCTs. The ‘triangulation’ of evidence from different study types adds strength to causal inferences since their results point to the same conclusion. [108, 109]

In other studies, smokers who did not intend to quit smoking did so after trying vaping. [110, 111] These ‘accidental quitters’ are not included in conventional RCTs.

4. The approaches being taken to discourage uptake and the use of e-cigarettes and personal vaporisers, including but not limited to, in Northern Territory Schools

Most of the information on vaping in the media and disseminated by Australian health organisations is alarmist and misleading, and often plain wrong, including campaigns by Queensland Health [112], NSW Health [113], the Alcohol and Drug Foundation [114] and South Australia Health [115].

Telling teens not to vape will only lead to more vaping, especially if the information provided is exaggerated and patently untrue.

False and alarmist misinformation will undermine trust in health authorities. It will also mislead adult smokers and discourage them from switching to the safer alternative.

Appropriate messaging to youth should be honest and proportionate. There is no place for exaggeration or scare campaigns. Youth will see through this.

One risk of exaggerating the harms from nicotine is that it may discourage youth from switching from smoking to vaping or NRT. [116]

Awareness of the harmful effects of e-cigarette use

Studies in Australia, the UK, US Canada, New Zealand and Poland have found that most adolescents **correctly** believe that vaping is **far less harmful** than smoking, [117-119] including a systematic review of 27 studies. [120] However, **less than half report that they were harmful to health.** [121]

Most youth understand that nicotine is the main chemical causing addiction. [121] A majority incorrectly perceive e-cigarettes to be **more addictive** than smoking. [122] However some studies have reported that more than half perceived e-cigarettes to be “not at all addictive. [121, 123] Like adults, youth remain misinformed about nicotine with many incorrectly believing it causes cancer. [118]

Graphic photos do not appear to reduce use as youth do not see that they are relevant for them. [117]

Appropriate risk messages for youth

- Vaping is an adult quitting aid
- Young people should not smoke or vape
- Vaping can have harmful health effects especially with long-term use but vaping is far less harmful than smoking
- Vaping nicotine can cause dependence but it is less habit-forming than smoking
- If you are already a smoker, vaping can help you quit

Programs to prevent uptake and continuing use of e-cigarettes

There have been very few evaluated youth education programs on vaping. One study of school-based substance use prevention programs in the US found that overall “There were no statistically significant associations observed for any method of PHE and e-cigarette and cigarette use.” [124]

Few Australian schools have e-cigarette policies. [125] However, the evidence concerning the effectiveness of school policies in preventing youth tobacco use is weak and inconclusive. [126] Policies are most effective when they feature prevention education and are not punitive. [125]

Sensible, accurate risk-proportionate advice at schools for young people is available from the following organisations and will require staff education:

*** [Dovetail. Queensland-based youth AOD training organisation](#)

Dovetail is a Queensland-based training organisation which provides training across Queensland including in rural and remote locations. Dovetail has a specific focus on young people who use alcohol and other drugs.

Their advice is

- Vaping is not for young people who are non-smokers
- Evidence-informed prevention work is important
- Poorly designed interventions can increase harm
- The best thing for health is to be smoke and vape free
- Vaping is not harmless but current evidence suggests it is likely less harmful than smoking
- Evidence suggests vaping can help some people quit smoking

[Sheffield City Council](#)

- Two posters for display in school toilets, classrooms, and noticeboards
- [A short, animated film](#)
- Classroom presentation for use by teachers alongside the animated film
- Teachers Toolkit to back up the classroom presentation
- Vaping: The Facts. Leaflet for parents and carers

[Talk to Frank](#)

[Action on Smoking and Health, UK](#)

ASH brief for local authorities on youth vaping

5. Best practice national and international regulatory responses to e-cigarettes and personal vaporisers

The preferred regulatory approach for vaping is a pragmatic adult consumer model, regulated tightly and proportionate to risk. **Vaping products should be sold by licensed retail outlets with strict age verification with harsh penalties for underage sales and potential loss of licence.** The only way to eliminate a black-market is to replace it with a legal, regulated one. The black-market would diminish and access to vaping products for young people would reduce.

In its 2016 report on tobacco harm reduction, the Royal College of Physicians summarised the possible risks of unintended consequences arising from excessive regulation.[16]

“A risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm, e.g. 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)”

Four important principles should be considered in the regulation of NVPs.

1. The paramount objective must be reducing smoking-related death and disease.
2. Regulation of vaping should be proportionate to risk and reflect its lower harms compared to smoking. [127] As vaping is substantially less harmful than smoking, a lighter touch regulatory approach is required.
3. Policymakers should also consider the harmful unintended consequences of regulation.
4. Regulatory measures should be informed by evidence rather than by values, ideology, politics and opinion. [128]

Policymakers need to find a balance between allowing ready access to vapes for adult smokers while restricting access to youth. Harsh restrictions and bans are ineffective and often counterproductive. There is no justification for making far safer nicotine vaping products harder to access than deadly cigarettes.

Harmful unintended consequences

Well-intentioned flavour bans to reduce vaping by young people have often been counterproductive. 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. [129] Among adults, vaping was reduced and smoking increased. [130]

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. [131] The main impact on youth vapers was a shift to disposable products. Vaping and smoking behaviours remained unchanged. [132, 133]

Increased taxation of NVPs has led to increased smoking by youth [70, 72], young adults [134] and adults [135]. This suggests that NVPs and cigarettes are economic substitutes.

Attempts to reduce youth vaping by restricting the age of legal sale have also perversely led to an increase in youth smoking. [74-76]

Alarmist public health campaigns to deter youth from vaping can be harmful. In an experimental setting, a youth-targeted health warning was found to discourage adult smokers from using vaping to quit. [136]

Proposals to reduce the nicotine content in NVPs risk detrimental effects. Higher concentrations of nicotine are needed for compact pod devices and disposables that are very popular transition

devices for adult smokers. Higher nicotine levels are safer because they generate smaller aerosol volume and fewer toxicants. [137-140] Excessively low doses of nicotine may make NVPs less satisfying, especially for more dependent smokers, and lead to lower rates of switching. [141] Smokers often need higher doses of nicotine in the early stages of switching while learning to vape.

A blanket advertising ban on vaping inadvertently protects established cigarette brands. However, carefully targeted, responsible marketing to adult smokers can raise awareness of vaping, reduce the demand for traditional cigarettes, and increase switching to vaping as a lower-risk alternative. [142, 143]

Exaggerated and misleading warning statements to discourage youth experimentation, even if technically correct, could deter adult smokers from switching to the safer product. [144]

Prohibition and harsh regulation push drugs underground and often cause increased harm. [145] Prohibition of vaping in a variety of jurisdictions has led to continued use [146], increased cigarette sales [147] and a shift to illegal markets and more sales to youth. [148]

Proposed regulatory framework

A carefully regulated consumer model would bring Australia into line with other western countries such as New Zealand [149] and the United Kingdom. [150] See Table 3.

Table 3. Elements of the consumer regulatory model

Product standards	<ul style="list-style-type: none"> • The current TGO 110 standards are inadequate and need to be upgraded, e.g., include all blacklisted ingredients on the TPD list • Minimum standards for the manufacture and safety of vaping liquids and devices should include electrical, thermal, mechanical and chemical safety; standardized testing regimes; purity standards for ingredients; extended blacklist or dose limits on problematic ingredients; laboratory testing; and possibly emission testing • Limits to nicotine e.g., 20mg/mL for freebase nicotine; 50mg/mL for nicotine salt (as in New Zealand)
Containers and labelling	<ul style="list-style-type: none"> • Mandatory standards for labelling: ingredient list; expiry date and batch number; PV:VG ratio; nicotine concentration; safety warning • Barcodes for tracing • Child-resistant refill containers which are leak proof, unbreakable (PET plastics) and have anti-spill protection • Removal of images that appeal to youth, e.g., cartoons, appealing characters • Bottle size limits e.g., maximum 1,800mg nicotine per container (as in New Zealand)
Health warnings	<p>Health warnings comparing the risks to smoking, for example</p> <ul style="list-style-type: none"> • “This product may be addictive but is a far less harmful alternative for adult smokers” • “If you are a smoker, switching completely to vaping is a much less harmful option”
Notification system	Mandatory notification of compliance to standards prior to marketing
Flavours	<ul style="list-style-type: none"> • Simple descriptions of flavour profiles • Prohibit descriptive flavour names and images that specifically appeal to youth, and unsafe flavouring chemicals
Public vaping	<ul style="list-style-type: none"> • Some restrictions to apply, especially indoors
Public messaging	<ul style="list-style-type: none"> • Communicate the absolute and relative harms for vaping nicotine compared to smoking • Frame vaping as a less harmful alternative for adult smokers • Messaging to youth should emphasise that no nicotine-containing product is fully safe to use, all can be addictive, and youth should never start using any tobacco or nicotine product • All messaging should be accurate and avoid exaggeration of risks
Advertising	<ul style="list-style-type: none"> • Restricted advertising targeted at smokers who are unable or unwilling to quit with a ‘switch’ message • Banning all advertising that could appeal to young people, such as lifestyle ads associating vaping with positive imagery and adventure • Placement of advertising to minimise exposure to young people
Monitoring	A system for reporting adverse effects and recall of unsafe products
Taxation	<ul style="list-style-type: none"> • Proportionate to risk, similar to nicotine gum and patches • Maintain a significant differential between NVP and cigarette prices • High NVP prices lead to increased smoking as cigarettes and vaping products are economic substitutes

The first step required is to exempt low concentrations of nicotine liquid up to 20mg/mL freebase nicotine and nicotine salt 50mg/mL from the Poisons Standard, as in New Zealand [149]. This enables them to be sold as consumer products rather than medicines. **This change could be made by amending the Northern Territory Medicines, Poisons and Therapeutic Goods Act to remove nicotine from the Poisons List.**

Nicotine liquids should be available from licensed retail outlets, such as specialist vape shops, pharmacies and general retail outlets, as for cigarettes and alcohol. The sale of vaping products where tobacco is sold exposes adult smokers to the safer alternative when they purchase tobacco.

Strict age verification at the time of purchase is required with harsh penalties for breaches and potential loss of licence. Consideration could be given to mandatory CCTV recording of sales as a condition of a sales licence. Online sales could be permitted by pharmacies and specialist vape retailers, with third party age verification on purchase and delivery.

All retailers would require a licence to sell nicotine liquids from the Northern Territory Health Department. Retailers would pay an annual licence fee, make annual reports and be subject to compliance checks.

Laws would also need to be introduced to regulate product standards, containers and labelling, advertising, health warnings, public vaping, pre-market notification and post-marketing surveillance.

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

International practice

An outline of regulations for vaping in New Zealand, the United Kingdom and the United States can be found in the Appendix. The preferred model is the one successfully working in New Zealand and the United Kingdom.

Recommendations for regulation in Australia

Our peer-reviewed paper titled *How should nicotine vaping be regulated in Australia?* published in *Drug and Alcohol Review* in March 2023 is included in the Appendix.

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Appendix. International Regulations and recommendations for Australia

International regulations

Policies marked **yellow** are preferred options

	New Zealand	United Kingdom	USA	Australia
Classification	Dual pathway <ul style="list-style-type: none"> Consumer product, or Medical product if making claims about safety or efficacy (currently none) 	Dual pathway <ul style="list-style-type: none"> Consumer product, or Medical (therapeutic) product if <ol style="list-style-type: none"> higher nicotine concentration, or making claims of safety or efficacy. Submitted to MHRA for approval (currently none) 	Dual pathway <ul style="list-style-type: none"> Tobacco product Medicine. Submit to Centre for Drug Evaluation and Research (currently none) 	Prescription medicine <ul style="list-style-type: none"> Unapproved therapeutic products. Available to adult smokers with a prescription from a medical practitioner to purchase from a pharmacy or import from overseas Approved therapeutic products (by the TGA) if making claims about safety or efficacy. Registered on the Australian Register of Therapeutic Goods (currently none)
Nicotine concentration	<ul style="list-style-type: none"> Freebase nicotine max 20mg/mL Nicotine salt max 50mg/mL Maximum 1,800mg nicotine per container 	<ul style="list-style-type: none"> Max 20mg/mL for consumer products >20mg/mL for therapeutic products 	<ul style="list-style-type: none"> Uncapped 	<ul style="list-style-type: none"> 100 mg/mL
Minimum age	<ul style="list-style-type: none"> 18 years (smoking 18) [link] 	<ul style="list-style-type: none"> 18 years (smoking 18) 	<ul style="list-style-type: none"> 21 years (smoking 21) 	<ul style="list-style-type: none"> 18 years (smoking 18)

	New Zealand	United Kingdom	USA	Australia
	<ul style="list-style-type: none"> Individuals under 18 years not permitted entry to specialist vape shops 			<ul style="list-style-type: none"> Individuals under 18 years not permitted entry to specialist vape shops
Advertising	<ul style="list-style-type: none"> It is prohibited to encourage the use, promote the sale, or notify the availability of vaping products [link] Sponsorship of activities, events etc is prohibited [link] However a specialist vape retailer may: <ul style="list-style-type: none"> Display it's trade name outside it's premises even if it is derived from 'vape' Talk to customers about using vape products Distribute vaping products for free or reduced charge from their premises May communicate health information or warnings 	<ul style="list-style-type: none"> Prohibited except for outdoor, posters, cinema, side of bus, leaflets, direct hard copy mail, in trade press, blogs, tweets independently compiled [ASA] [TPD] 	<ul style="list-style-type: none"> Unregulated, except must include a warning that nicotine is addictive Advertising on internet, print media, TV, retail stores, social media etc FDA has the authority to restrict some marketing, but this is rarely used 	<ul style="list-style-type: none"> Prohibited Limited advertising by pharmacies re availability of vaping products, type of product, nicotine concentrations, no brands
Point of sale display	<ul style="list-style-type: none"> Allowed 	<ul style="list-style-type: none"> Allowed 	<ul style="list-style-type: none"> Permitted 	<ul style="list-style-type: none"> Pharmacies only. In-store advice that products are available
Retail and online sale	<ul style="list-style-type: none"> A two tier retail system. Specialist vape shops and general retailers Specialist vape retailers 	<ul style="list-style-type: none"> Retail stores including specialist vape shops and 'general retail' Online sales permitted 	<ul style="list-style-type: none"> Retail stores 28 states currently require a retail licence to sell nicotine [link] 	<ul style="list-style-type: none"> Only pharmacies can sell nicotine products

	New Zealand	United Kingdom	USA	Australia
	<ul style="list-style-type: none"> - are licensed, pay an annual fee [link] and are listed online. [link] - may sell all legal vape products, including tank systems and liquid refills in a variety of flavours - online sales permitted <ul style="list-style-type: none"> ▪ General retailers <ul style="list-style-type: none"> - can only sell vaping products in tobacco, mint of menthol flavours. - Are prohibited from discussions with customers that encourage, promote or notify the availability of vaping products. - No online sales ▪ No vending machines in public areas [link] 		<ul style="list-style-type: none"> ▪ Mandatory age verification ▪ No sale from vending machines ▪ Online sales permitted 	<ul style="list-style-type: none"> ▪ Non-nicotine e-liquids, devices and accessories available from any retail store ▪ Online sales from Australian websites banned ▪ Importation from international websites allowed with a doctor's prescription under the TGA Personal Importation Scheme [link]
Bans	<ul style="list-style-type: none"> ▪ n/a ▪ Disposables available 	<ul style="list-style-type: none"> ▪ n/a ▪ Disposables available 	<ul style="list-style-type: none"> ▪ Some states and cities have introduced bans on flavours, online sales and even vaping products [link] ▪ Disposables available 	<ul style="list-style-type: none"> ▪ n/a ▪ Prescription disposables available
Public vaping	<ul style="list-style-type: none"> ▪ Prohibited in smoke-free areas 	<ul style="list-style-type: none"> ▪ Vaping permitted outdoors including smoke-free areas 	<ul style="list-style-type: none"> ▪ Varies by state from unrestricted to bans in smoke-free areas 	<ul style="list-style-type: none"> ▪ Prohibited in smoke-free areas

	New Zealand	United Kingdom	USA	Australia
	<ul style="list-style-type: none"> ▪ Prohibited in workplaces, aircraft, public transport, restaurants, schools etc [link] ▪ Local authorities can make decisions on vaping in outdoor smoke-free areas ▪ Specialist vape retailers are exempt from the indoor workplace vaping ban 	<ul style="list-style-type: none"> ▪ Local proprietors or organisations can decide policy on use in their premises ▪ [PHE] [ASH] 		<ul style="list-style-type: none"> ▪ Specialist vape retailers have exemptions for vaping indoors in some jurisdictions
Labelling	<ul style="list-style-type: none"> ▪ Names and quantities of ingredients, including nicotine concentration in mg/mL ▪ Safety of use instructions ▪ Volume or weight of substances ▪ Expiry date ▪ Batch number ▪ Manufacturer name and contact details ▪ PG:VG ratio [link] ▪ Safety warnings on package: "This product contains nicotine, which is a highly addictive substance" 	<ul style="list-style-type: none"> ▪ Bottle or leaflet to display <ul style="list-style-type: none"> - List of ingredients, including nicotine content - use and storage - contraindications - possible adverse effects - addictiveness and toxicity - advice to keep out of reach of children - warnings for at-risk groups - batch number - contact details of manufacturer - no health claims ▪ Health warnings must cover 30% of label's surface area and must be placed on front and back Health warning: "This product contains 	<ul style="list-style-type: none"> ▪ Label must say it contain nicotine ▪ Ingredient list mandatory ▪ Health warning: "WARNING: This product contains nicotine. Nicotine is an addictive chemical." 	<ul style="list-style-type: none"> ▪ TGO 110 standards <ul style="list-style-type: none"> - Ingredient list - Nicotine concentration ▪ Safety Warnings <ul style="list-style-type: none"> - 'KEEP OUT OF REACH OF CHILDREN' - 'Avoid contact with eyes' and - 'Avoid contact with skin'.

	New Zealand	United Kingdom	USA	Australia
	<ul style="list-style-type: none"> ▪ Safety warnings on containers - “CAUTION: Keep this substance out of reach of children or pets.”: - “Do not swallow this substance. If this substance is taken into the mouth, rinse mouth thoroughly.”: - “Contact 0800 POISON (0800 764 766) for advice if this substance is swallowed.”: <p>“Seek medical advice if you feel unwell after contact with this substance or use of this product.” [link]</p>	<p>nicotine which is a highly addictive substance”</p>		
Containers	<ul style="list-style-type: none"> ▪ Child-resistant closures and tamper-evident measures ▪ Breakage, leakage and anti-spill protection ▪ Maximum bottle size 120mL unless containing zero nicotine 	<ul style="list-style-type: none"> ▪ Nicotine-containing products or their packaging to be child-resistant, tamper evident, breakage and leak proof ▪ Refillable without leakage ▪ Limit of 2ml for tanks or pods ▪ Limit of 10ml for nicotine e-liquids 	<ul style="list-style-type: none"> ▪ Mandatory child-resistant closures 	<ul style="list-style-type: none"> ▪ Child resistant container
Product safety	<ul style="list-style-type: none"> ▪ Must not contain restricted substances [link] 	<ul style="list-style-type: none"> ▪ <u>Emissions testing</u> ▪ No vitamins, colourings or prohibited additives (including caffeine and taurine) 	<ul style="list-style-type: none"> ▪ For existing products, safety is assessed as part of the PMTA process to determine whether the product can continue to be marketed 	<ul style="list-style-type: none"> ▪ Must not contain other 'active' ingredients other than nicotine eg caffeine, THC, stimulants or vitamins

	New Zealand	United Kingdom	USA	Australia
	<ul style="list-style-type: none"> ▪ Testing of liquid by an accredited laboratory (no mandatory emission testing) ▪ USP quality for nicotine, PG, VG, alcohol, water ▪ Flavours must be water-soluble. Flavours other than tobacco extracts to meet food standards ▪ Electrical safety compliance for devices ▪ Consistent nicotine delivery ▪ No food colourings allowed 	<ul style="list-style-type: none"> ▪ Using only ingredients of high purity ▪ Must not include ingredients (except for nicotine) which pose a risk to human health ▪ Deliver a dose of nicotine at consistent levels ▪ Mechanism for ensuring re-filling without leakage 	<ul style="list-style-type: none"> ▪ Future products assessed by FDA prior to marketing 	<ul style="list-style-type: none"> ▪ Must not contain acetoin, benzaldehyde, cinnamaldehyde, diacetyl, diethylene glycol, ethylene glycol, pentane-2,3-dione, vitamin E acetate ▪ Maximum concentration of 100mg/mL ▪ Nicotine to be within 10% of concentration stated on label [TGO 110 standards]
Reporting	<ul style="list-style-type: none"> ▪ Manufacturers and importers must advise the Vaping Regulatory Authority of any adverse reaction [link] 	<ul style="list-style-type: none"> ▪ Side effects and safety concerns can be reported to MHRA through the Yellow Card reporting system 	<ul style="list-style-type: none"> ▪ Reporting of safety issues, faulty products, side effects to FDA Safety Reporting Portal [link] 	<ul style="list-style-type: none"> ▪ Importers, exporters or manufacturers to maintain records demonstrating compliance ▪ Reporting of adverse effects or faulty products to TGA
Pre-market Notification or Authorisation	<ul style="list-style-type: none"> ▪ Manufacturers and importers must notify products through the Ministry of Health's Vaping Regulatory Authority's Health Advisory and Regulatory Platform (HARP) 	<ul style="list-style-type: none"> ▪ 6 months prior to marketing, producers must supply: <ul style="list-style-type: none"> - A list of all ingredients in the product (liquid) - Emissions from the product - Toxicological data, including health and addictive effects 	<ul style="list-style-type: none"> ▪ Manufacturers apply to FDA for pre-market authorisation, PMTA (Pre-market Tobacco Product Application) [link] ▪ Only 3 manufacturers have authorised products so far (as of September 2022) [link] <ul style="list-style-type: none"> - Vuse - Logic 	<ul style="list-style-type: none"> ▪ Not applicable

	New Zealand	United Kingdom	USA	Australia
	<ul style="list-style-type: none"> All notified products are available on the HARP searchable database [link] 	<ul style="list-style-type: none"> Nicotine dose and uptake when consumed Components of the product Production process details [TPD] 	<ul style="list-style-type: none"> NJoy Only tobacco flavoured products have been approved so far 	
Flavours	<ul style="list-style-type: none"> Specialist vape shops: No flavours prohibited General retailers: Tobacco, mint and menthol only 	<ul style="list-style-type: none"> No flavours prohibited 	<ul style="list-style-type: none"> Restricted in some cities and states 	<ul style="list-style-type: none"> No flavours prohibited Certain flavouring chemicals banned for health reasons: benzaldehyde, cinnamaldehyde, diacetyl
Vaping in retail stores	<ul style="list-style-type: none"> Specialist vape shops: permitted General retailers: Prohibited 	<ul style="list-style-type: none"> Not restricted 	<ul style="list-style-type: none"> Not restricted 	<ul style="list-style-type: none"> Permitted in vape shops in most states
Taxation	<ul style="list-style-type: none"> 15% GST. No excise tax 	<ul style="list-style-type: none"> 20% VAT, no excise tax [link] Current proposal to reduce this to 5% [link] 	<ul style="list-style-type: none"> Varies by state [link] 	<ul style="list-style-type: none"> Nicotine e-liquids not taxed
Federal regulator	<ul style="list-style-type: none"> Ministry of Health's Vaping Regulatory Authority [link] 	<ul style="list-style-type: none"> Medicines and Healthcare Products Regulatory Agency (MHRA) 	<ul style="list-style-type: none"> Food and Drug Administration (FDA) 	<ul style="list-style-type: none"> Therapeutic Goods Administration (TGA)
Legislation	<p><i>Smokefree Environments and Regulated Products Regulations Act 2021 [link]</i></p>	<p><i>The Tobacco and Related Products Regulations 2016 (Parts 6, 7 and 8) [link]</i></p>		<p><i>Therapeutic Goods Regulations 1990 [link]</i></p>

	New Zealand	United Kingdom	USA	Australia
		<p><i>E-cigarettes: regulations for consumer products 2019</i> [link]</p> <p><i>Advice for retailers (MHRA)</i> [link]</p> <p><i>E-cigarettes and vaping: policy, regulation and guidance 2020</i> [link]</p> <p><i>TPD restrictions on the advertising of e-cigarettes 2016</i> [link]</p> <p><i>Advertising Standards Authority. Guidance on electronic cigarette advertising prohibition 2017</i> [link]</p> <p><i>Licensing procedure for electronic cigarettes as medicines</i> [link]</p> <p><i>Tobacco Products and Nicotine Inhaling Products (Amendment) (EU Exit) Regulations 2020</i> [link]</p> <p><i>Use of e-cigarettes in public places and workplaces. Public Health England</i> [link]</p>		<p><i>Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021</i> [link]</p> <p>Pharmacy advertising <i>Therapeutic Goods (Restricted and Prohibited Representations—Nicotine) Permission (No. 2) 2021</i></p> <p>Customs <i>Customs Tariff Act 1995</i> [link]</p>

How should nicotine vaping be regulated in Australia?

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Abstract

In Australia, nicotine vaping products are regulated as prescription-only medicines which can only be sold from a pharmacy, with the aim of preventing youth access and allowing use by adult smokers with a doctor's support. The Therapeutic Goods Administration has acknowledged that this policy has not achieved its goals. Instead, a thriving black market has developed which sells unregulated vape products to children and adults. Very few adult vapers use the legal prescription pathway. Regulation should find the optimal balance between facilitating legal access for adult smokers while restricting access by youth. The preferred approach is a tightly regulated consumer model with nicotine vaping products sold by licenced retail outlets with strict age-of-sale verification. Regulations should be proportionate to risk and reflect the lower harms of vaping relative to smoking. A consumer model would bring Australia into line with other Western countries and improve population health.

KEYWORDS

electronic cigarettes, public policy, regulation, smoking, vaping

Tobacco control has traditionally focussed on achieving complete smoking abstinence [1] but some smokers are unable or unwilling to quit on their own or using conventional treatments [2,3]. An alternative to complete quitting is to switch to one of the tobacco harm reduction options such as nicotine vaping products (NVP). Vaping is the most popular aid for quitting and reducing smoking used by Australian smokers [4].

There is now scientific agreement that vaping is more effective than nicotine replacement therapy as a quitting aid [5]. Although neither vaping nor nicotine replacement therapy are risk-free, vaping is a substantially safer alternative for adult smokers [6–9]. Switching completely to NVPs dramatically reduces toxicant exposure and biomarkers of harm and improves symptoms and clinical outcomes. The precise long-term effects of vaping have not yet been established but are likely to be far less harmful than from smoking [7].

Current Australian vaping policy is driven by alarmist and exaggerated media reports about youth vaping 'epidemics' [10]. However, most youth vaping is

experimental and transient and frequent vaping is most common among current or former smokers [11–13]. Regular vaping by never-smokers is rare. Rather than being a gateway to smoking [14], the evidence suggests that vaping diverts more young people away from smoking and is displacing smoking at the population level [15–17]. Very few young never-smokers who vape become dependent on nicotine [18, 19]. The evidence that nicotine harms the human adolescent brain is weak [20].

Four important principles should be considered in the regulation of NVPs. Firstly, the paramount objective must be reducing smoking-related death and disease.

Secondly, regulation of vaping should be proportionate to risk and reflect its lower harms compared to smoking [21]. As vaping is substantially less harmful than smoking, a lighter touch regulatory approach is required.

Thirdly, policymakers should also consider the harmful unintended consequences of regulation.

Fourthly, regulatory measures should be informed by evidence rather than by values, ideology, politics and opinion [22].

The challenge for policymakers is to find the optimal balance between facilitating access for adult smokers who are at substantial and more immediate risk from smoking, while restricting access to youth, for whom the risks of vaping are smaller and delayed [20]. Measures to protect non-smoking youth are essential, but excessive regulation which makes vaping less accessible, less appealing, more expensive, less consumer-friendly or less effective inadvertently perpetuates adult smoking and increases smoking-related death and illness [7].

1 | CURRENT AUSTRALIAN VAPING POLICY

Since 1 October 2021, nicotine liquid has been classified in Australia as an unapproved prescription-only medicine (Schedule 4) [23]. No NVPs are registered on the Australian Register of Therapeutic Goods [23].

Australians are permitted to import nicotine liquid for personal use or purchase it from an Australian pharmacy if they hold a valid doctor's prescription [24]. Possessing nicotine without a prescription is a criminal offence punishable by fines up to \$45,000 and/or 2 years jail [25].

These regulations were intended to achieve two goals: (i) firstly, to allow adult smokers access to regulated vaping products ideally through a pharmacy with a doctor's support; and (ii) to prevent youth vaping [23]. However, the Therapeutic Goods Administration has acknowledged that they have failed to achieve either objective [26].

Few doctors are prepared to prescribe unapproved nicotine products. Many are sceptical or uninformed about vaping and are discouraged from prescribing nicotine by health and medical authorities [27]. Fewer than 1% of doctors are publicly listed as nicotine prescribers [28] and over 90% of people who vape do not have a nicotine prescription [29].

Very few pharmacies stock nicotine liquids and the range of products is very limited. Only 2% of vapers are estimated to purchase nicotine from pharmacies with a prescription [29].

The de facto prohibition of NVPs has diverted users to a thriving illicit market [30]. Unregulated and incorrectly labelled products are freely sold to adults and young people and policing and enforcement are minimal. As a result, there has been a substantial increase in youth vaping, tax revenue has been lost and otherwise law-abiding citizens have been criminalised.

Proposals for more intensive enforcement of an approach already overwhelmingly rejected by consumers and health professionals will most likely boost black-market supply, intensify criminal activity and increase smoking (Data S1, Supporting information).

2 | HARMFUL UNINTENDED CONSEQUENCES

Well-intentioned flavour bans to reduce vaping by young people have often been counterproductive. 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 [31]. Among adults, vaping was reduced and smoking increased [32].

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 [33]. The main impact on youth vapers was a shift to disposable products. Vaping and smoking behaviours remained unchanged [34, 35].

Increased taxation of NVPs has led to increased smoking by youth [36, 37], young adults [38] and adults [39]. This suggests that NVPs and cigarettes are economic substitutes.

Attempts to reduce youth vaping by restricting the age of legal sale have also perversely led to an increase in youth smoking [40–42].

Alarmist public health campaigns to deter youth from vaping can be harmful. In an experimental setting, a youth-targeted health warning was found to discourage adult smokers from using vaping to quit [43].

Proposals to reduce the nicotine content in NVPs risk detrimental effects. Higher concentrations of nicotine are needed for compact pod devices and disposables that are very popular transition devices for adult smokers. Higher nicotine levels are safer because they generate smaller aerosol volume and fewer toxicants [44–47]. Excessively low doses of nicotine may make NVPs less satisfying, especially for more dependent smokers, and lead to lower rates of switching [48]. Smokers often need higher doses of nicotine in the early stages of switching while learning to vape.

A blanket advertising ban on vaping inadvertently protects established cigarette brands. However, carefully targeted, responsible marketing to adult smokers can raise awareness of vaping, reduce the demand for traditional cigarettes, and increase switching to vaping as a lower-risk alternative [49, 50].

Exaggerated and misleading warning statements to discourage youth experimentation, even if technically correct, could deter adult smokers from switching to the safer product [51].

Prohibition and harsh regulation push drugs underground and often cause increased harm [52]. Prohibition of vaping in a variety of jurisdictions has led to continued use [53], increased cigarette sales [54] and a shift to illegal markets and more sales to youth [55].

TABLE 1 Elements of the consumer regulatory model [56–59].

Product standards	<ul style="list-style-type: none"> The current TGO 110 standards [59] are inadequate and need to be upgraded, for example, include all blacklisted ingredients on the TPD list [57]. Minimum standards for the manufacture and safety of vaping liquids and devices should include electrical, thermal, mechanical and chemical safety; standardised testing regimes; purity standards for ingredients; extended blacklist or dose limits on problematic ingredients; laboratory testing; and possibly emission testing. Limits to nicotine, for example, 20 mg/mL for freebase nicotine; 50 mg/mL for nicotine salt (as in New Zealand) [56].
Containers and labelling	<p>Mandatory standards for labelling: ingredient list; expiry date and batch number; PG:VG ratio; nicotine concentration; safety warning.</p> <p>Barcodes for tracing.</p> <p>Child-resistant refill containers which are leak proof, unbreakable (PET plastics) and have anti-spill protection.</p> <p>Removal of images that appeal to youth, for example, cartoons, appealing characters.</p> <p>Bottle size limits, for example, maximum 1800 mg nicotine per container (as in New Zealand) [56].</p>
Health warnings	<p>Health warnings comparing the risks to smoking, for example [58]:</p> <ul style="list-style-type: none"> 'This product may be addictive but is a far less harmful alternative for adult smokers'. 'If you are a smoker, switching completely to vaping is a much less harmful option'.
Notification system	Mandatory notification of compliance to standards prior to marketing
Flavours	<ul style="list-style-type: none"> Simple descriptions of flavour profiles. Prohibit descriptive flavour names and images that specifically appeal to youth and unsafe flavouring chemicals.
Public vaping	<ul style="list-style-type: none"> Some restrictions to apply, especially indoors.
Public messaging	<ul style="list-style-type: none"> Communicate the absolute and relative harms for vaping nicotine compared to smoking. Frame vaping as a less harmful alternative for adult smokers. Messaging to youth should emphasise that no nicotine-containing product is fully safe to use, all can be addictive, and youth should never start using any tobacco or nicotine product. All messaging should be accurate and avoid exaggeration of risks.
Advertising	<ul style="list-style-type: none"> Restricted advertising targeted at smokers who are unable or unwilling to quit with a 'switch' message. Banning all advertising that could appeal to young people, such as lifestyle ads associating vaping with positive imagery and adventure. Placement of advertising to minimise exposure to young people.
Monitoring	A system for reporting adverse effects and recall of unsafe products
Taxation	<ul style="list-style-type: none"> Proportionate to risk, similar to nicotine gum and patches. Maintain a significant differential between NVP and cigarette prices. High NVP prices lead to increased smoking as cigarettes and vaping products are economic substitutes.

Abbreviations: NVP, nicotine vaping product; PET, polyethylene terephthalate; PG, propylene glycol; TPD, tobacco products directive; VG, vegetable glycerine.

3 | PROPOSED REGULATORY FRAMEWORK

A carefully regulated consumer model would bring Australia into line with other western countries such as New Zealand [56] and the United Kingdom [57] (Table 1).

The United States approach has been less successful because of an overriding focus on protecting children rather than assisting adult smokers, restrictive pre-marketing approval requirements by the US Food and Drug Administration and unclear relative risk communication by governments in the face of widespread media advertising of vaping products [60].

The first step required is to exempt low concentrations of nicotine liquid up to 20 mg/mL freebase nicotine and nicotine salt 50 mg/mL from the Poisons Standard, as in New Zealand [56]. This enables them to be sold as

consumer products rather than medicines. This change could be made at the federal level or by State and Territory governments.

Nicotine liquids should be available from licenced retail outlets, such as specialist vape shops, pharmacies and general retail outlets, as for cigarettes and alcohol. The sale of vaping products where tobacco is sold exposes adult smokers to the safer alternative when they purchase tobacco.

Strict age verification at the time of purchase is required with harsh penalties for breaches and potential loss of licence. Consideration could be given to mandatory CCTV recording of sales as a condition of a sales licence. Online sales could be permitted by pharmacies and specialist vape retailers, with third party age verification on purchase and delivery.

All retailers would require a licence to sell nicotine liquids from state or territory health departments.

TABLE 2 Regulation and monitoring authorities.

Australian Competition and Consumer Commission
<ul style="list-style-type: none"> Standards for e-liquids, containers, labelling and health warnings Pre-market notification of nicotine liquids All notified products are recorded in a publicly available searchable database Post-market surveillance and reporting
State and territory health departments
<ul style="list-style-type: none"> Annual tobacco licences for retailers Supervision and enforcement of retailer compliance Spot checks for underage sales Advertising restrictions Public vaping restrictions Policing illicit sales by the black-market Public education about vaping Vape shop staff training and certification similar to the Responsible Service of Alcohol requirements
The Commonwealth government
<ul style="list-style-type: none"> Legislative changes Taxation Border control to intercept illicit imports Public education about vaping

Retailers would pay an annual licence fee, make annual reports and be subject to compliance checks.

A dual pathway which allows manufacturers to apply to the Therapeutic Goods Administration for medicines classification could engage additional smokers and give doctors more confidence to prescribe NVPs.

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

Further details are listed in Table 1.

4 | REGULATORY AUTHORITIES

NVPs are consumer products designed to replace deadly cigarettes [61]. They are most appropriately regulated by the Australian Competition and Consumer Commission (ACCC) under dedicated consumer legislation. The ACCC can provide consumer protection and ensure that products comply with the legal requirements of the *Competition and Consumer Act 2010*.

The ACCC would be responsible for establishing and enforcing comprehensive standards for e-liquids, containers, labelling and health warnings. It would establish a pre-market notification system for nicotine liquids and a post-market surveillance system for reporting adverse events and faulty products. State and territory governments and the Commonwealth would also have specific responsibilities (Table 2).

5 | CONCLUSION

Regulations for vaping and tobacco smoking should focus on reducing the net public health harm. Policymakers need to find a balance between allowing ready access to NVPs for adult smokers while restricting access to youth. Harsh restrictions and bans are ineffective and often counterproductive.

The preferred regulatory approach is a pragmatic consumer model, regulated tightly and proportionate to risk. An overly restrictive approach to protect young people which reduces the access, effectiveness and appeal of vaping by adult smokers is likely to perpetuate illegal vaping product sales and tobacco smoking and have an overall profoundly negative effect on population health.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Mendelsohn C, Wodak A, Hall W. How should nicotine vaping be regulated in Australia? *Drug Alcohol Rev*. 2023. <https://doi.org/10.1111/dar.13663>