

# Submission

Senate Standing Committees on Community Affairs

Therapeutic Goods and Other Legislation  
Amendment (Vaping Reforms) Bill 2024  
Parliament of Australia

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## Executive summary

- Smoking remains the leading preventable cause of death and illness in Australia
- Vaping nicotine is the most effective and most popular quitting aid for adult smokers
- Vaping could reduce Australia's smoking rates, preventing death and disease in hundreds of thousands of smokers, and is a huge public health opportunity
- Australia's current model for regulating vaping has
  - Failed to meet its objectives of providing an acceptable legal pathway for adult smokers with medical support and minimising access for youth
  - Created serious unintended consequences
- **The Bill** aims to make final changes to this model. However, these changes do not address the fatal flaws of the underlying policy and will not solve the problems it has created
- The current model is not supported by the public and has created
  - A thriving black market run by criminal gangs and escalating criminal activity
  - Widespread youth vaping from black market sales
  - Widely used unregulated products which put people at risk
  - Highly restricted access by adult smokers and vapers
  - Rejection by most general practitioners and pharmacists
  - Criminalisation of otherwise law-abiding citizens
  - Loss of government taxation and other revenue
- **Rather than make further changes, the current failed model needs to be replaced with a more effective and workable alternative**
- Current Australian policy is driven by valid but exaggerated about youth vaping
- The main driver of policy must be reducing smoking-related death and disease and the net public health impact
- Regulation should find the optimal balance between facilitating legal access for adult smokers and restricting access by youth.
- The preferred regulatory model is a risk-proportionate adult consumer model, with vapes sold from licensed retail outlets with strict age verification, like tobacco and alcohol. This would bring Australia into line with other Western countries.
- Jurisdictions such as New Zealand, the United Kingdom and United States have introduced this model and have reported accelerated declines in smoking, modest youth vaping rates and minimal or small black markets

## About me

I am an Australian medical doctor who has worked in the field of smoking cessation and tobacco control for 40 years, specialising in tobacco harm reduction for the last 10 years. I am currently involved in teaching and research and advocacy.

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

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 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 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 published extensively on smoking cessation and tobacco harm reduction and my publications are available [here](#).

Further information about me is available at [www.colinmendelsohn.com.au](http://www.colinmendelsohn.com.au).

## Disclosure

### **I have never received payments from electronic cigarette or tobacco companies**

I was an unpaid Board member of the Australian Tobacco Harm Reduction Association (ATHRA) from October 2017 - January 2021 when it accepted:

- Unconditional seed funding from the vape retail industry. Funding ceased March 2019
- A donation from KAC Communications in March 2018, sourced from a surplus arising from the Global Forum on Nicotine conference in May 2017

Invited speaker at World Vape Show Conference 2022 (Dubai). Travel expenses paid

Author of the book, *Stop Smoking Start Vaping*

## Preliminary statement

This Bill seeks to ban the importation, domestic manufacture, supply, commercial possession, and advertisement of vaping goods.

However, the underlying regulatory model is seriously flawed and it has failed to achieve its objectives. The fundamental error is that nicotine vaping products (NVPs) are treated as prescription-only medicines, rather than as adult consumer products as they are in all other Western countries.

The current model has been rejected by the vast majority of adult vapers and has become a 'de facto' ban. It is supported by very few general practitioners and pharmacists. This has led to predictable and serious unintended consequences, such as difficulties accessing legal products and very low levels of compliance. It has also created an uncontrolled black market run by criminal networks resulting in escalating violence and an accelerated youth uptake.

The current model treats vaping as a threat rather than as an opportunity for public health. It focusses on preventing any harm to youth as its primary goal. In doing so, it undermines the opportunity to prevent the substantial and immediate threat to adult smokers. Smoking is the leading preventable cause of death and disease in Australia. Two out of three long-term smokers will die from a smoking-related disease. For smokers who are otherwise unable to quit, vaping is a life-saving alternative.

Regulation should find the optimal balance between both restricting access by youth and facilitating legal access for adult smokers wishing to quit. The main driver of policy must be reducing smoking-related death and disease. [1]

It is now clear from other Western countries and peer-reviewed research that vaping can help accelerate the decline in population smoking rates. Although there are risks and harms from vaping, numerous modelling studies have demonstrated that the overall impact on public health is positive.

**There is no point in tweaking the final elements of the model addressed in the Bill until the base policy is reformed into an acceptable and workable regulatory model.**

This submission outlines the flaws in the current regulatory model for nicotine vaping products and explains why further restrictions will not help.

It outlines the details of an alternative regulatory model: a risk-proportionate, adult consumer model with NVPs sold from licensed retail outlets with strict age verification, like tobacco cigarettes and alcohol. It also outlines the evidence that underpins this model.

Finally, it provides a summary of the application of this model in other jurisdictions such as New Zealand and the United Kingdom, and the resulting benefits for public health.

## The current model has failed

Nicotine vaping products (NVPs) were confirmed as prescription-only medicines (Schedule 4) on 1 October 2021. According to the TGA [\[link\]](#), the aim of the reforms was

“to prevent children and adolescents from accessing NVPs, whilst allowing smokers to access these products for smoking cessation with a doctor’s prescription”

However, the TGA has acknowledged that the reforms have failed to meet either objective. “Children and adolescents are continuing to obtain NVPs in higher numbers. ... There is evidence that many adults are accessing NVPs without a prescription, rather than through lawful supply channels with a prescription from an Australian doctor.” [\[link\]](#)

### A ‘de facto’ ban

The current model of harsh restrictions is tantamount to prohibition, or a ‘de facto’ ban. The essence of a ban is to prevent access or to make access so difficult that it becomes impractical for the average person to follow the preferred legal pathways. [Over 90%](#) of Australia’s adult vapers purchase their products illegally.

## 1. Youth vaping is increasing

The current illegal market makes it [easier, not harder](#), for teens to access vapes because there are no restrictions on who can buy them. Nearly 80% of young people who had ever vaped in the Generation Vape study reported finding it very easy, easy or quite easy to access vapes. [2]

Youth vaping rates are escalating. According to the recent National Drug Strategy Household Survey 2022/23, 28% of 14-17-year-olds have tried vaping and 9.7% were ‘current vapers’ ie vaped once or more in the last month. [\[NDSHS 2022/23\]](#) In 2019, only 1.8% were current vapers. [NDSHS 2019]

Youth vaping is creating alarm for parents and causing disruption in schools. [3] The Health Minister Mark Butler describes it as the leading behavioural problem in Australian schools. There are concerns about potential health harms, especially nicotine addiction. However, the harms attributed to youth are exaggerated (see Best Practice Regulation).

Young people almost exclusively use three brands of illicit disposable devices sourced from the black market – IGET, HQD and Gunpod. [4] These devices contain high levels of nicotine (average concentration of 40mg/mL), are inaccurately labelled and are not regulated under Australia’s quality and safety standards (TGO 110). None of the products used by Australian youth are made by tobacco companies.

## 2. Control by criminal networks

History has repeatedly shown that banning drugs doesn’t stop people using them. Instead, prohibition leads to “driving drugs underground and creating a black market or increasing harms”. [\[link\]](#) Australia’s [de facto ban](#) has predictably handed control of the vaping market to the same criminal networks that import illicit tobacco. The illegal vape industry is highly lucrative. A disposable vape can be purchased from China for as little as \$3 and sold for \$35.

An estimated [120 million](#) unregulated, disposable vapes are imported illegally from China into Australia each year, mostly by criminal gangs. Unregulated products without quality or safety control create potential health concerns.

There is an escalating turf war with rival criminal gangs competing for share of the [black market](#), resulting in 60 firebombings of tobacco and vape shops so far, public executions, violence and extortion.

Crime groups are recruiting [young people](#) to carry out crimes, such as carjackings, often performed blatantly during daylight and putting the public at risk. Others are introduced to crime by becoming 'dealers' of illicit products for their peers.

Harsh prohibitive policies often end up doing more damage than the drug itself. According to the [Iron Law of Prohibition](#), illegal drugs become more potent and more dangerous. Under prohibition, drugs become [more costly](#) and fuel criminal networks with drug wars, further crime and corruption.

Health Minister [Mark Butler](#) says the black market for vapes is "funding the criminal activities of organised crime gangs, drug trafficking, sex trafficking and the like".

The Australian Border Force does not have the necessary resources to intercept a significant portion of the illegal vape imports. ABF Commissioner [Michael Outram](#) warned recently that the ABF was only managing to detect a quarter of illicit drugs making their way into Australia "on a good day".

Law enforcement's victories are often celebrated in the media, but are a [drop in the ocean](#) compared to the scale of the problem.

The products are openly displayed and sold from a wide network of retail outlets, such as tobacconists, convenience stores, petrol stations and vape shops. They are also widely accessible on social media. However, state Health Departments are under-resourced to police illegal sales and there are very few prosecutions with small penalties. [\[link\]](#) Many stores continue to sell illegal products even after prosecution. [\[link\]](#)

### 3. It has failed adult smokers and vapers

The current policy is not supported by doctors and pharmacists and has been rejected by people who vape.

Very few doctors are willing to prescribe nicotine liquid. The TGA reported that as of April 2023, only 1,963 general practitioners (out of 104,000 in Australia) had registered to become authorised prescribers. The lack of doctor prescribers is driving a Telehealth model, which has been criticized for suboptimal and fragmented care. [\[link\]](#)

Studies of Australian GPs have found that [5, 6]

- Most GPs are poorly informed about vaping and lack the knowledge or confidence even to discuss the issue with smokers. Many are skeptical about vaping
- Many GPs feel they are at risk when prescribing nicotine, a product that is not approved as a medicine by the TGA
- Some GPs are resentful that they are expected to prescribe nicotine at all

Most pharmacies do not stock any NVPs or only stock a very small range. Most pharmacists remain uninformed about vaping and are not generally supportive. [6] Also, see [here](#).

The medical-pharmacy pathway is onerous and costly for patients. In the 2022/23 [NDSHS](#), 87% of adult vapers reported not having a prescription. Perversely, it is much harder for adult smokers to legally access a far less harmful alternative to smoking.

### 4. A lost opportunity for public health

Vaping has "the potential to disrupt the 120-year dominance of the cigarette". [7] If appropriately regulated it could help to substantially reduce smoking rates in Australia as it is doing in other countries.

## Effectiveness

Vaping is an effective quitting aid.

The most recent Cochrane review of randomised controlled trials concluded that there was high quality evidence that vaping nicotine was 59% more effective for quitting smoking than nicotine patches and gum. [8]

Two other high-quality reviews compared studies of vaping with other quitting aids:

- A review by the UK National Institute for Health Research found that vaping was the most effective single quitting aid. [9]
- Another Cochrane review in 2023 concluded that nicotine vapes and varenicline (Champix) were the two most effective treatments for quitting smoking. [10]

These results are consistent with findings from the England stop smoking services [11], observational studies [12-14], population studies [15-17] and declines in national smoking rates [18-20]. Vaping is also the only quitting aid to assist smokers with no intention of quitting ('accidental quitters'). [21-23]

## Safety

Vaping is not risk-free, but it is beyond reasonable doubt that it is far less harmful than smoking. Smokers who switch completely to vaping are likely to have substantial health benefits.

The UK [Royal College of Physicians](#) [24] and England's [Office for Health Improvement and Disparities](#) [11] have both independently estimated that vaping is at least **95% less harmful** than smoking, based on comprehensive reviews of the science. This is not meant to be a precise figure but is to communicate the large difference in relative risk to smokers. This is based on:

<b>Toxins</b>	As there is no combustion, almost all the toxic chemicals in smoke are absent from vapour. Those that are present occur in far lower doses than in tobacco smoke.
<b>Toxins in the body</b>	There are substantial reductions in toxins in the body fluids of smokers who switch to vaping. [25-27]
<b>Health improvements</b>	Studies of smokers who completely switched to vaping have shown improvements in asthma [28], chronic obstructive pulmonary disease (COPD) [29], blood pressure [30], muco-ciliary clearance [31], respiratory infections [32], lung function [33], respiratory symptoms [34, 35], cardiovascular risk factors [36, 37] and gum disease [38].
<b>Cancer</b>	The life-time cancer risk from vaping is estimated to be < 0.5% that of smoking. [39]
<b>Mortality</b>	There are no documented deaths from vaping nicotine but 8 million people die from cigarette smoking every year. Any serious side effects of vaping are very rare.

Contrary to popular belief, nicotine is a relatively benign drug in the doses used in vaping. [40] Nicotine does not cause cancer [41] or lung disease [42] and only has a minor role in cardiovascular health. [43]

Vaping nicotine does not cause the serious lung condition EVALI [44], popcorn lung [\[link\]](#), seizures [45], or spontaneous pneumothorax, as often reported in the media.

The precise long-term effects of vaping have not yet been established but are likely to be far less harmful than smoking. [24] Restricting vaping while waiting for long-term outcomes allows the substantial harms of smoking to continue.



There is no evidence so far of harm from secondhand vapour due to the extremely low doses of toxicants released into the surrounding air, the lower toxicity of vapour and the quick dissipation of vapour particles. [46]

### *Popularity*

Vaping is the most popular quitting aid for Australian smokers. In the 2022/23 [NDSHS](#), 32% of smokers reported using vaping to quit or cut down smoking, compared to 17% who used nicotine replacement therapy. The use of other medications was far less common.

### *Modelling studies*

In the absence of long-term data, modelling studies are a well-accepted way of estimating the population impact of an intervention. Numerous modelling studies suggest that the overall public health benefits of vaping are considerably greater than the risks. [47-49]

The population impact of an intervention is a function of its effectiveness as well as its reach. [50]  
**Because of its proven effectiveness and wide reach, vaping is likely to have a greater population effect than any cessation therapy.**

An Australian modelling study examined the impact of relaxing nicotine vaping regulations in Australia, so vaping products were as widely and legally accessible as in the United States. [51] Assuming an excess risk of vaping of 5% of that of smoking, the study estimated that 104,200 smoking- and vaping-attributable deaths (SVADs) and 2.05 million life-years lost (LYLs) would be averted during 2017–80. Assuming a 40% excess risk, an estimated 70,000 SVADs and 1.2 million LYLs would be averted.

### *Population studies*

Population studies suggest that NVPs increase the rate of quit attempts and quitting success compared to not using an NVP.

An Australian population-based study found that vaping during a smoking cessation attempt was associated with greater success compared to not using a vape. [15] In countries where vaping is readily accessible, the decline in smoking rates has accelerated.

In a large representative sample in the United States, ‘e-cigarette use was associated with an increase in smoking cessation at the population level’. [52] In two large US population studies, current e-cigarette use was associated with increased past 12-month quit attempts and successful smoking cessation among established smokers. [53]

In England, the Smoking Toolkit Study shows a clear association between the prevalence of e-cigarette use and changes in population quitting rates. [54] Beard estimated that, in 2017, an additional 50–70,000 smokers in England stopped smoking by using a vaping product who would otherwise have continued to smoke. [55]

After vaping nicotine was legalised in New Zealand in August 2020, there was a rapid increase in adult daily vaping from 3.5 to 9.7% from 2020 to 2023, associated with an unprecedented 43% decline in adult daily smoking from 11.9 to 6.8%.

## **5. Loss of revenue and commerce**

The current regulatory model has a significant negative impact on the economy, the vape industry and on government revenue.

## ***Taxation***

A policy costing prepared by Tulipwood Economics in March 2024 estimated that regulating vapes could raise nearly \$6bn in excise revenue and over \$3bn in GST revenue over the 4-year forward estimates. [\[link\]](#)

UK consultancy [Independent Economics](#) estimated in March 2023 that legalising and regulating NVPs could generate \$510 million per year from GST, company taxes (retail and wholesale) and a 5% import tariff.

## ***Healthcare costs***

Smoking-related healthcare costs in Australia were [estimated](#) to be a staggering \$137 billion in 2015-2016. A [UK study](#) estimated that if 50% of smokers switch to vaping, assuming a conservative 70% risk reduction, there would be annual savings of £518 million (approximately AUD 1 billion) for five disease categories.

## ***Compliance costs***

The necessary efforts to target the illegal vape network will incur hundreds of millions of dollars of costs annually. This includes border control, retail enforcement and prosecuting cases through the courts.

## ***Reduced GP visits***

The cost of an annual doctor's visit for a nicotine prescription amounts to \$68 million (based on 1.7 million vapers at \$39.75 per visit). The RACGP advises 3-monthly visits, at a total annual cost of \$272 million.

## ***Reduced smoking cessation treatment costs***

Vapers tend to quit on their own, usually without additional costs to the healthcare system. More widespread adoption of vaping would also lead to reduced expenditure on PBS-subsidised smoking cessation medications, which cost [\\$36 million](#) in the 2020 financial year.

## ***Closure of the retail vape industry***

Under the medical-pharmacy model, hundreds of legal retail vape shops will close, without any compensation. Thousands of staff will become unemployed and numerous businesses will become bankrupt.

Vape shops are staffed almost exclusively by former smokers who now vape. Staff can provide expert advice to help smokers transition to vaping and have been shown to increase quit rates. [56] The closure of vape shops will result in the loss of a valuable, free smoking cessation service.

## ***Gross Value Added (GVA)***

A legal vaping industry could contribute \$601 million annually to the Australian economy by stimulating the retail and wholesale sectors, according to [Independent Economics](#), including the employment of thousands of workers.

## ***Manufacturing and export potential***

Australia boasts numerous manufacturing facilities capable of producing nicotine liquids, which are currently limited to nicotine-free variants. Legalising vaping opens the door to manufacturing

nicotine liquids for local markets and significant export opportunities, including markets in Asia-Pacific, the EU, Canada, and the UK.

### *The UK example*

The United Kingdom's vaping sector serves as a compelling example of the economic potential of vaping. According to a report by the UK Centre for Economics and Business Research: [\[link\]](#)

- In 2021, the vaping industry was valued at £1,325 billion (AUD 2.55 billion), contributing significantly to the UK's economy.
- The sector employed 17,700 people and contributed £310 million (AUD 600 million) in taxation to the Exchequer.
- An estimated potential healthcare saving of £698 million (AUD 1.35 billion) in 2020 if 50% of smokers switched to vaping.

## **6. Unregulated products**

Australia has mandatory quality and safety standards for nicotine vaping products (TGO110). However, under the current regulatory model, [over 90%](#) of products are supplied by the black market and are completely unregulated, exposing users to greater risk.

One study analysing the illicit products used by school students found them to contain coolants and high levels of nicotine. [4] Prohibited chemicals were found in 3.4% of samples (acetoin, benzaldehyde, cinnamaldehyde, and ethylene glycol). The products were labelled inaccurately, with most not indicating the presence of nicotine.

Unregulated, illicit products can have fatal outcomes. In 2019-2020, an outbreak of serious lung disease (EVALI) occurred in North America which led to 2,807 hospitalisations and 68 deaths by February 2020. [44] The EVALI outbreak was caused by vaping black-market THC oils adulterated with vitamin E acetate in the criminal supply chain. Similar health tragedies have occurred with illicit drugs of other kinds and could also occur with black market nicotine vaping products in the future.

## **7. Public support**

The Australian public does not support the current prohibitionist approach.

A [Redbridge](#) Market Research Survey of 1,515 adults in March 2024 found that

- 84% of adults agree/strongly agree that “Nicotine vaping products should only be available through licensed retail outlets to adults, the same as alcohol and tobacco products”.
- Only 7% thought that “Government performance on the regulation of nicotine vaping products” was good or very good
- 74% agreed that “Treating nicotine vapes as a medicine sends the wrong signal that these products are healthy”
- 53% agreed that “If adults don’t require a medical prescription to buy cigarettes, they shouldn’t need one to buy vapes”
- 71% agreed that “Requiring doctors’ appointments to purchase nicotine vapes is not a good use of Australia’s healthcare system”

## Will further restrictions help?

The government maintains that doubling down with further policing and border enforcement will solve the problem. History suggests this approach will fail.

### Enforcement is ineffective, costly, and harmful

Once a black market is established for a product that is in high demand, it is exceedingly rare for harsh restrictions (such as large fines, intense policing, border enforcement etc.) to be successful in reducing it.

“Law enforcement and border control efforts have minimal long term impact on the supply of drugs in the community”, according to a 2023 [report](#) on vaping by Australian health consultancy group, 360Edge.

The Australian Border Force scans just [1.4 per cent](#) of the 6.3 million containers that arrive in Australia by sea every year. “It’s impossible to stop this [illicit vapes] at the border,” according to the founder of the ABF Tobacco Strike Team, [Rohan Pike](#). “We have a huge border and not enough resources.”

The necessary efforts to control the illegal vape network will cost hundreds of millions of dollars annually. This includes border enforcement, policing illegal retail sales and prosecuting cases through the courts.

Even an authoritarian country like Singapore has been unsuccessful in banning vaping. Singapore has a total ban on vaping and has some of the world’s toughest anti-vaping laws and penalties. However, a thriving black market “has driven vaping to new highs”. [\[link\]](#) India also banned vaping in 2019. Since then vaping has skyrocketed and the black market has thrived. [\[link\]](#)

**The only way to significantly reduce a black market is to replace it with a legal, regulated one with products sold by licensed legal outlets.**

### The failure of prohibition

“History has repeatedly shown that banning drugs doesn’t stop people using them. Instead, prohibition leads to “driving drugs underground and creating a black market or increasing harms”. [\[link\]](#)

For example, heroin was banned in Australia in 1953. In the 2023 [National Illicit Drug Reporting System](#), 87% of intravenous drug users reported that accessing heroin was easy or very easy..

Experts from the Australian National Advisory Council on Alcohol and Other Drugs have advised that the ban on vape sales outside pharmacies would backfire. [Professor Rebecca Lang](#) said the 2021 policy which limited nicotine vaping liquids to prescription-only had

“inadvertently but ‘entirely predictably’ led to a bigger unregulated market with more young people accessing, and that additional restrictions “will likely only make the problem worse.”

Furthermore, it is well established that drug prohibition paradoxically increases criminal violence in drug markets. [57]

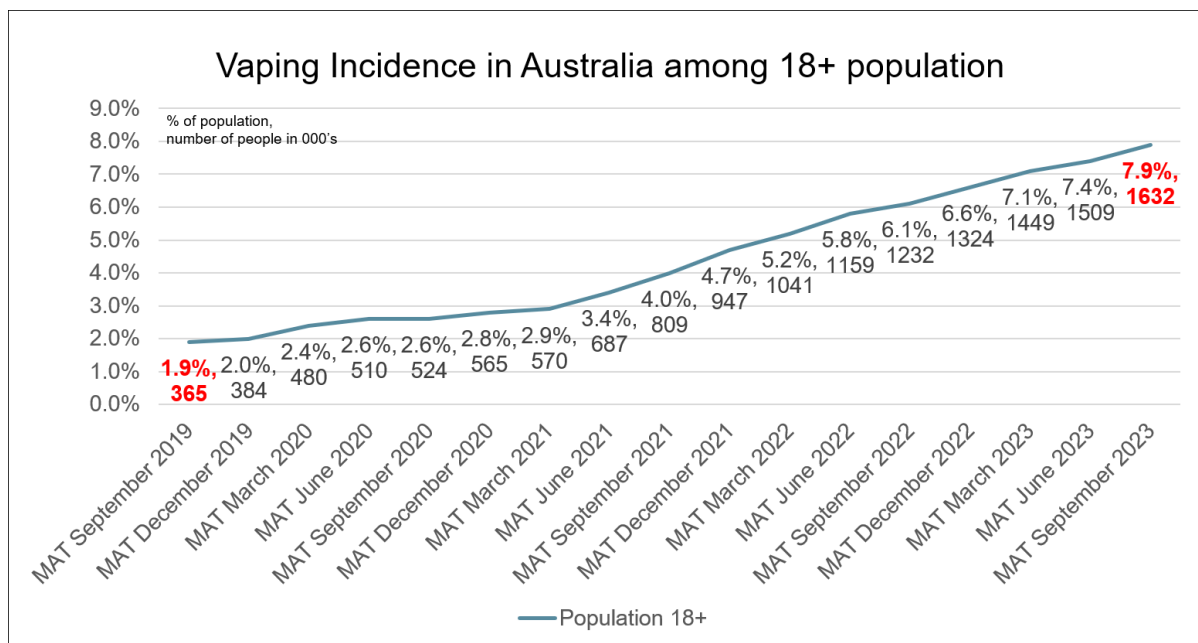
### GPs are unlikely to change

Given the almost universal reluctance of GPs to prescribe nicotine, it is unlikely that many will engage with vaping. The service is being provided by Telehealth services which have been criticized for poor standards and fragmenting medical care. [\[link\]](#)

## Vaping continues to escalate

The genie is out of the bottle. Despite the harsh restrictions on vaping in Australia, adult vaping prevalence (most of it illicit) has increased four-fold since 2019.

Almost 400,000 Australians took up vaping between December 2022 and December 2023. [\[link\]](#) It is highly unlikely that further restrictions will constrain the behaviour.



Source: Roy Morgan Single Source Sept2023 [\[link\]](#)

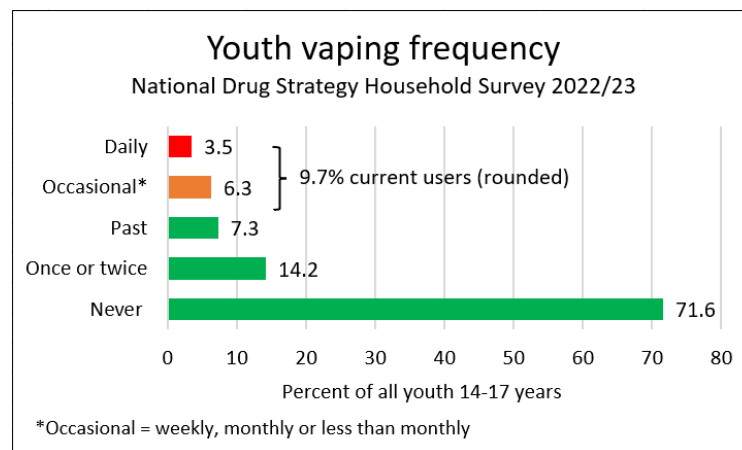
## Youth vaping

Youth should not smoke or vape and there is some risk of harm for never-smokers who vape frequently and continue long-term. However, much of the available information on youth vaping is exaggerated and misinformed. This section provides an evidence-based appraisal of youth vaping in Australia based on the evidence.

Any harm to youth should be balanced against the substantial potential benefits to Australia's 1.5 million adult vapers and 2.3 million adult smokers. [2022/23 [NDSHS](#)]

### *Frequent vaping by never-smokers is rare*

Most youth vaping is experimental and transient. **Only frequent vaping by never-smokers is of public health importance.** The 2022/23 [NDSHS](#) reported that only 3.5% of 14-17-year-olds vape daily and other research indicates that about half of these had already smoked. [2] Much use is experimental - of those who had ever vaped, **half vaped only once or twice**. Frequent vaping by never-smokers is rare and is mainly confined to smokers and former smokers.

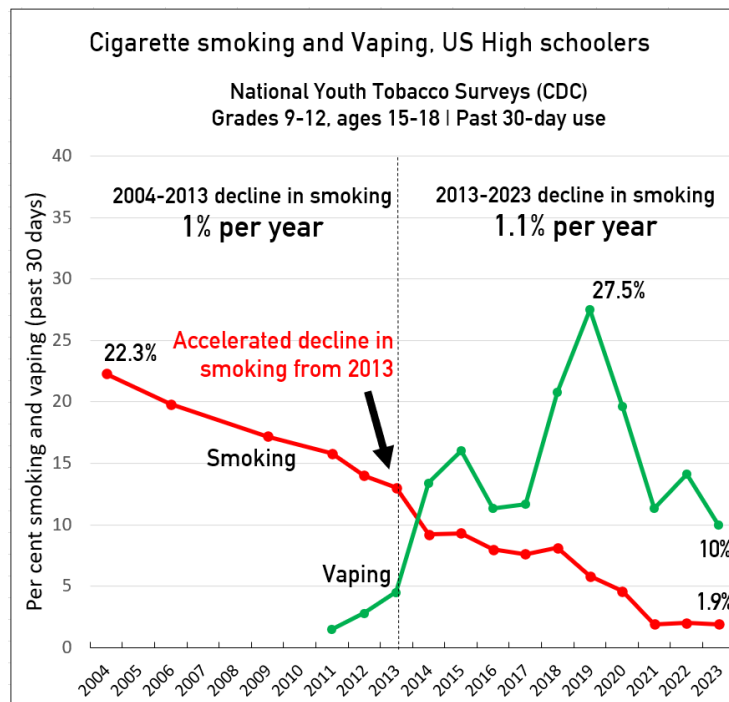


**Frequency of youth vaping in Australia (2022/23 NDSHS)**

### *Diversion from smoking*

Vaping and smoking are substitutes. Vaping is diverting some young people who would have otherwise smoked away from smoking. [58-60]

The increase in youth vaping has coincided with an accelerated decline in youth smoking in the UK [61], New Zealand [62] and the US [63, 64] (Figure below). This is the opposite of what would be expected if vaping was a significant gateway to smoking.



#### Decline in smoking in high school students (mean age 16y) in the US (NYTS)

Vaping may be a gateway to smoking for some young people, but this is outweighed by the much larger number who move from smoking to vaping. [65]

Young people who vape are three times more likely to later try smoking, but there is weak evidence that this is a causal relationship. A more plausible explanation is that young people who engage in one form of risky behaviour, such as vaping, are more likely to engage in other risky behaviours such as smoking, hazardous alcohol consumption and illicit drug use. [66]

Shared risk factors for vaping and smoking such as genetic factors [67] and environmental, psychological and social causes [68] create a 'common liability' for risk-taking. [69]

Some young smokers also switch from smoking to vaping, which is far safer.

#### Nicotine dependence

Vaping can cause nicotine dependence in some young people who have never smoked. However, this is only in a small minority of cases. [70] In the 2022/23 [NDSHS](#), only 3% of 14-17 year olds were possibly "addicted". [Based on: 9.7% of 14-17-year-olds are current users. Of these 31% were "unable to stop or cut down the use of e-cigarettes" and are probably "addicted".]

Vaping is not "creating a new generation addicted to nicotine" as is often claimed. Nicotine dependence is actually becoming less frequent. A study in the US showed that from 2010 to 2019 when vaping was at its peak, there was **no increase** in nicotine dependence overall, at least partly due to the shift from smoking to vaping (which causes less dependence). [71]

Nicotine dependence can lead to withdrawal causing short-term symptoms such as irritability, restlessness, anxiety, difficulty concentrating and depression. These symptoms are unpleasant but not serious.

Nicotine dependence is mostly concentrated in young people who are current or past smokers.

### *Health effects*

Youth vaping carries relatively minor health risks. Most young non-smokers who vape do so infrequently and transiently. Only frequent vaping over the longer-term has the potential to cause harm, and serious harmful effects to date are very rare.

Some young people have reported cough or wheeze from vaping. [72, 73] However, there is no clear evidence that vaping causes “**functionally important**” **respiratory symptoms**. [74, 75] Youth vaping is not linked with the onset of **asthma** (although smoking is). [76, 77]

Vaping nicotine does **NOT** cause seizures [45] or pneumothorax (lung collapse). There is a very rare risk of burns from lithium-battery explosions, a risk from all devices that use these batteries, such as mobile phones and laptops.

**See the Appendix for more:** Mendelsohn CP, Hall W. What are the harms of vaping in young people who have never smoked? International Journal of Drug Policy 2023



## Best practice regulation

### Finding the right balance

Regulation should find the optimal balance between facilitating legal access for adult smokers while restricting access by youth.

- Middle-age and older smokers are at immediate and substantial risk of death or of developing smoking-related disease. Two in three long-term smokers will die prematurely from smoking. Switching to vaping dramatically reduces risk and can be lifesaving.
- There are small and potential risks from vaping to a small number of young people.
- Only 7% of people who vape in Australia are underage (100,000) – the vast majority are adults 18+ (1.4 million). [2022/23 [NDSHS](#), Table 3.4]

The focus of policy should be to balance these competing risks and benefits to get the best outcome for public health. The main driver of policy must be reducing smoking-related death and disease. [1]

As the UK Royal College of Physicians states [24]

“If [a risk-averse and precautionary] 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”

### Optimal regulation

The preferred model is a [risk-proportionate adult consumer model](#), with vapes sold from licensed retail outlets with strict age verification, like tobacco and alcohol. This would bring Australia into line with other Western countries.

Vapes should be available from a wide range of outlets, so they are at least as accessible as combustible cigarettes. It makes no sense for deadly cigarettes to be more accessible than a far less harmful alternative.

Regulations should be proportionate to risk and reflect the lower harms of vaping relative to smoking, for example with respect to advertising and use in public places. [78]

This will bring the industry under government control, ensure quality products, reduce access for youth, enable legal access for adult smokers, stimulate a legal industry, reduce compliance and health costs, and generate government revenue. It is the only way to eliminate the black market.

### Consumer product classification

Low concentrations of nicotine liquid are not therapeutic goods. They are consumer products designed to replace an existing but deadly consumer product, tobacco cigarettes. They should be classified as consumer products and exempted from the Poisons Standard like cigarettes. Nicotine e-liquids should be regulated by the Australian Competition and Consumer Commission, not the TGA.

### Disposables

The Australian government introduced a ban on disposable NVPs on 1 January 2024. However, the disposables used by teens are already banned black market devices and a further ban is unlikely to have any effect on long-term supply and use. As vaping is diverting youth away from smoking, a disposable ban may also increase smoking. [58-60]

Disposable vapes are also a popular transition device for adult smokers, especially those with severe mental illness, homelessness, learning disabilities, hospital inpatients and older smokers who struggle with more complex vaping devices. A ban would remove an effective and popular quitting aid for vulnerable populations from the legal market. Restricting the sale of disposables to adult-only stores would reduce youth access without preventing access by smokers.

### **Flavours**

Flavours play an important role in the initiation of vaping for adult smokers [79] and are associated with more quit attempts and higher quit rates. [80, 81]

- Banning flavours makes vaping less attractive as a quitting aid and increases smoking in young people [82] and adults. [83]
- Flavour bans lead to increased illicit supplies and dangerous home mixing. [84]
- However, flavours with known harms [46] or with disproportionate appeal to youth should be banned.

Flavours are not the primary reason for youth experimentation with vaping. The main reasons are curiosity and peer pressure, followed by liking the flavours and for stress relief. [85-87]

### **Advertising**

A blanket advertising ban is counterproductive. Advertising can help raise public awareness about new options to replace deadly smoking and motivate smokers to switch. Advertising bans on much-safer entrant products protect the established cigarette trade from competition.

Responsible adult-orientated advertising would restrict the content, timing and placement of advertising so that it is appropriate for adult audiences and communicates the relative risk compared to smoking.

- Restrict advertising targeted at smokers who are unable or unwilling to quit with a 'switch' message.
- Ban all advertising that could appeal to young people, such as lifestyle ads associating vaping with positive imagery and adventure.
- The placement of advertising to minimise exposure to young people.

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 NVPs. [88]

### **Nicotine concentration**

The proposed nicotine limit of 20mg/mL (2%) is too low to satisfy more dependent smokers. Higher nicotine concentrations are more effective for quitting [23, 89, 90] and a nicotine concentration of at least 50 mg/ml (5%) is needed to match a cigarette. [91-93] Higher nicotine levels are in fact safer [94] – when the nicotine concentration is too low, vapers compensate by inhaling more deeply and more often and inhale more chemicals. [95, 96]

### **Taxation**

Taxation of vapes should be proportionate to risk. Higher prices reduce vaping but increase smoking in youth [97, 98], young adults [99] and adults [100, 101]. The application of GST without excise taxes would bring Australia into line with the UK and New Zealand.

### *Reducing appeal to young people*

Other measures to reduce youth access could include

- Substantially increased fines and loss of licence for underage sale
- Restricted advertising to prevent marketing to adults, but balanced against the need to attract more smokers to switch from deadly cigarettes to much safer vaping nicotine
- Licensing and training of retailers
- Third-party age verification for online orders
- Mandatory CCTV at point of sale
- Banning flavour names, images and packaging that specifically appeal to young people while recognising that attractive flavours help to increase switching adults from smoking to vaping and that flavour bans inadvertently increase smoking.

**See Appendix for more:** Mendelsohn C, Wodak A, Hall W. How should nicotine vaping be regulated in Australia? Drug and Alcohol Review 2023

## Case study: New Zealand

**The case of New Zealand is especially pertinent. Smoking rates between 2016-2023 declined much faster in New Zealand than in Australia. Both countries have very similar demographic and social characteristics and tobacco control policies and there were no significant changes in these policies during 2016-2023. The less restrictive policy for vaping in New Zealand is likely to be the main cause for the faster decline in adult smoking.**

Nicotine e-liquid has been widely available as an unregulated adult consumer product since 2015. In 2020, the New Zealand Parliament passed the Smokefree Environments and Regulated Products (Vaping) Amendment Act 2020. This Act legalised and regulated NVPs, allowing them to be legally sold from licensed retail outlets, including a wide range of specialised vape shops and general stores. Vaping is the most popular quitting aid in New Zealand.

The New Zealand Ministry of Health takes a risk-proportionate, harm reduction approach to vaping. It endorses vaping and encourages its use for adult smokers who are otherwise unable to quit. It provides online resources such as [www.vapingfacts.com.nz](http://www.vapingfacts.com.nz) and [www.quitstrong.nz](http://www.quitstrong.nz).

It is important to note that there is **no significant black market for NVPs in New Zealand**.

New Zealand has the following regulatory model (see the Appendix for more details). Timeline [here](#)

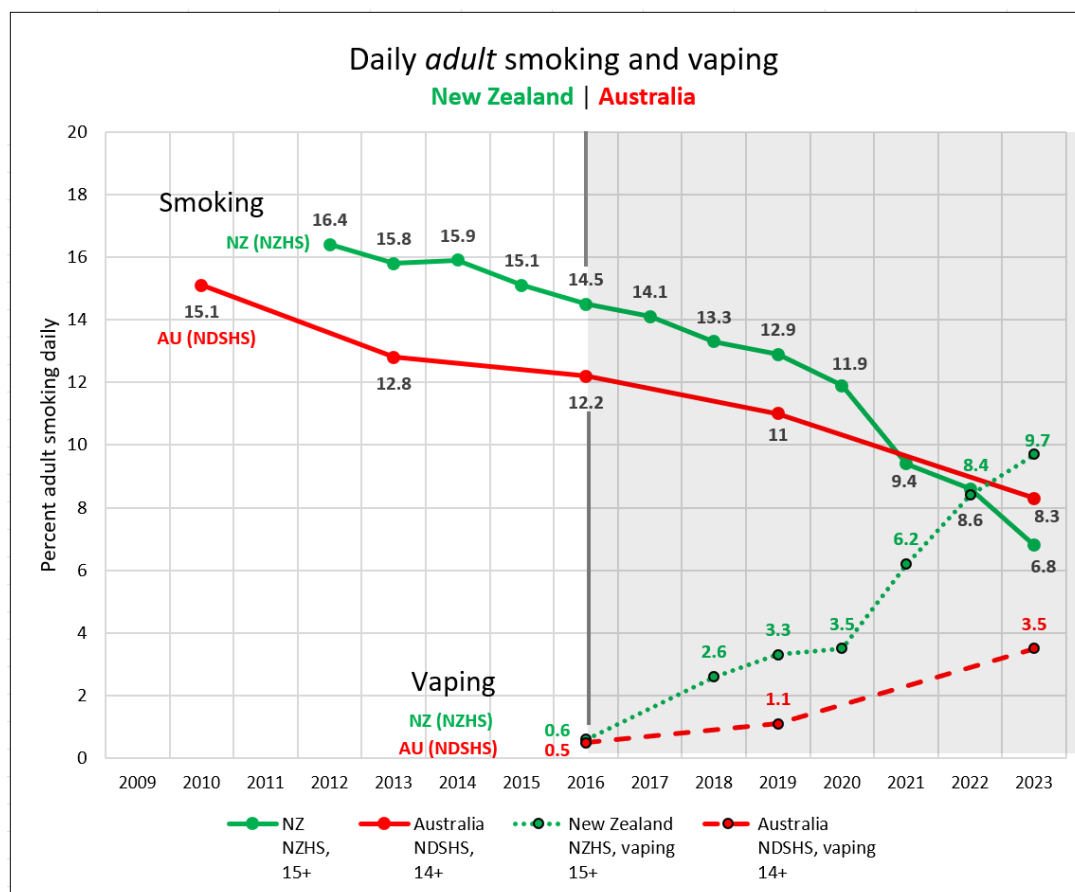
- NVPs are adult consumer products sold from licensed retail stores and online. Specialist retailers are licensed and can sell a wide variety of flavours. General retailers can only sell tobacco, mint or menthol
- Minimum age of purchase is 18 years
- Products must comply with detailed requirements for labelling, product quality, nicotine concentration, container characteristics prior to marketing.
- Taxation. 15% GST, no excise
- Nicotine concentration limited to 28.5mg/mL
- In March 2024, bans were announced for disposables. Prescribed flavour descriptors announced and no toys or cartoon images on products

### Adult smoking

**During the last 7 years daily adult smoking declined significantly faster in New Zealand than in Australia.**

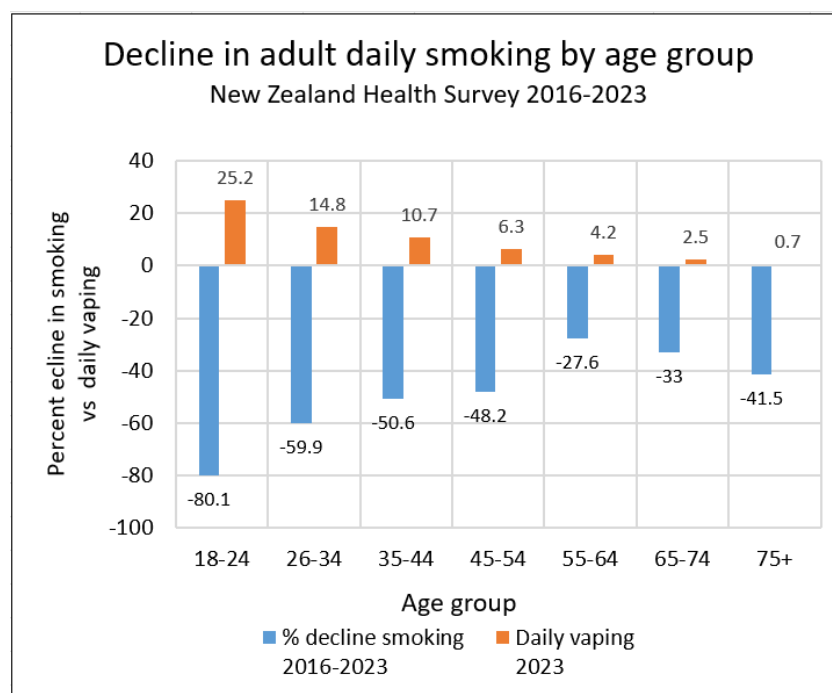
From 2016-2023, daily smoking declined 53.1% from 14.5% in 2016 to 6.8% in 2023. [[New Zealand Health Survey](#)]. In Australia, during the same period, daily smoking declined 32% from 12.2% in 2016 to 8.3% in 2023. [[NDSHS](#)]. Some of this decline is likely to be due to the uptake of illicit NVPs.

In New Zealand, there was an unprecedented 59% decline in daily smoking in the most disadvantaged populations (quintile 5) from 26.2% in 2016 to 10.7% in 2023. Notably, there was also a 52% decline in Māori daily smoking from 35.5% in 2016 to 17.1% in 2023.



**Adult daily smoking and vaping, Australia and New Zealand**

The decline in daily smoking from 2016 – 2023 was greatest in the age-groups with the highest vaping rates in 2023 (18-44 years).



**Decline in smoking by age-group and vaping rate, New Zealand**

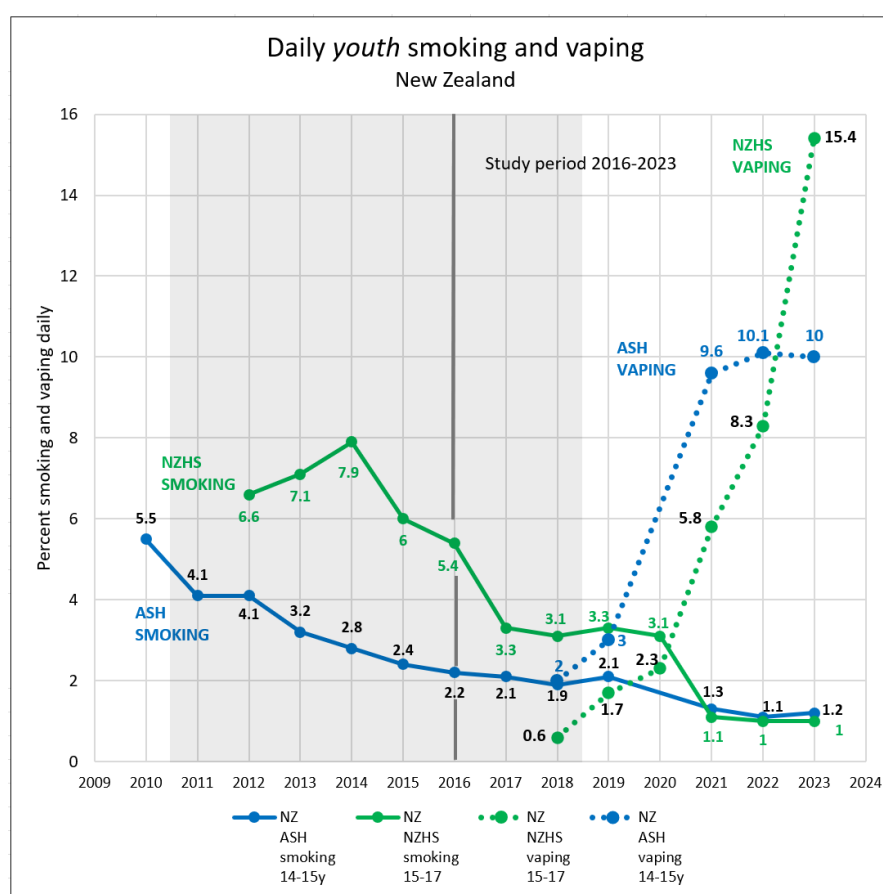
The decline in smoking also accelerated as vaping rates increased. [Table below] These findings support the claim that vaping is accelerating the rate of smoking decline.

New Zealand time periods (NZHS)			
	2012-2016	2016-2020	2020-2023
Smoking rates	16.4-14.5%	14.5-11.9%	11.9-6.8%
Vaping	Nil	0.6-3.5%	3.5-9.7%

### Dose-response effect of vaping rate on smoking decline

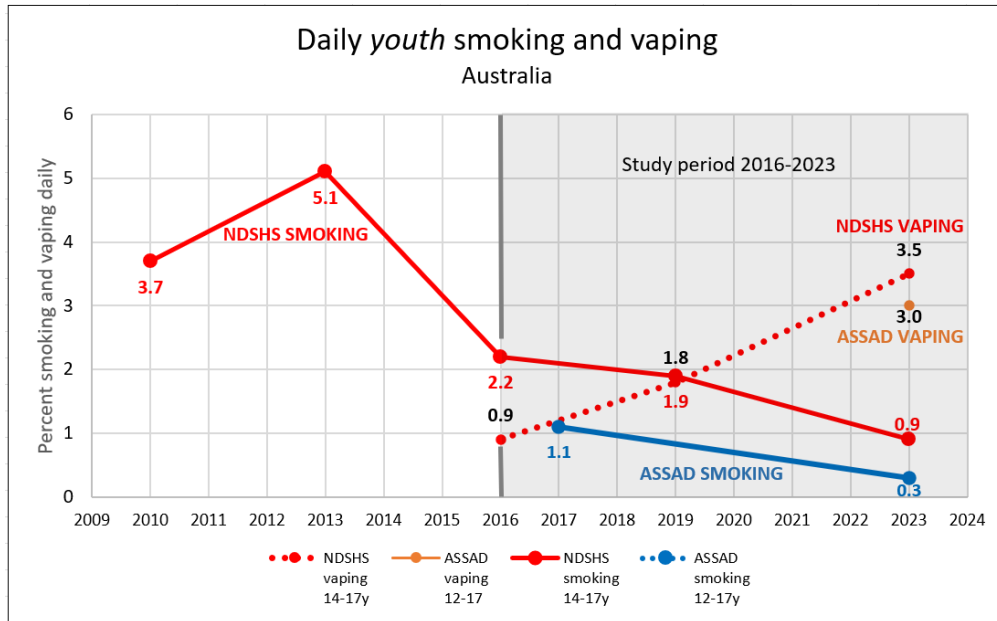
## Youth smoking

Daily youth smoking has declined to minimal levels in both Australia and New Zealand, approximately 1% or less in both countries.



### Youth daily smoking and vaping in New Zealand

Note: Higher smoking levels and a faster decline was observed in the New Zealand NZHS than in the ASH survey [[Action on Smoking and Health, 2023](#)]. The results from the NZHS are less robust due to the small sample size.



### Youth daily smoking and vaping in Australia

Youth vaping rates in New Zealand are considerably higher than in Australia. However, the New Zealand ASH survey found that most of the rise in vaping prevalence occurred **before** the legalisation and regulation of vaping were introduced in 2020. After that, the increase began to level out, as seen in the 2022 and 2023 data (Figure on previous page).

## Case study: United Kingdom

**Adult smoking rates have declined faster in the United Kingdom than in Australia as vaping has increased. Youth vaping is largely confined to smokers, and youth vaping rates are lower than in Australia. Only 1% of never-smoking youth vape weekly or more.**

NVPs are readily available in the UK as adult consumer products from general retail outlets and online. Vaping is endorsed by the National Health Service [\[link\]](#) and the National Centre for Smoking Cessation and Training [\[link\]](#) as a safer alternative and as a quitting aid for smokers. Vaping is offered to smokers in government smoking cessation clinics. In 2023, the government of England initiated a Swap to Stop scheme, giving away 1 million free vape starter kits to smokers. [\[link\]](#)

NVPs are regulated under the [Tobacco and Related Products Regulations](#) since 2016

- NVPs are adult consumer products sold from unlicensed retail stores and online.
- Minimum age of purchase is 18 years
- Pre-market notification: products must comply with detailed requirements for labelling, product quality, nicotine concentration, restricted ingredients, container characteristics (child and tamper-resistant) prior to marketing.
- Taxation. 20% VAT, no excise
- Nicotine concentration limited to 20mg/mL
- Volumes: devices maximum 2mL; refills 10mL maximum
- Mandatory health warnings: 30% of surface: *This product contains nicotine which is a highly addictive substance.*
- Mandatory information for consumers
- Yellow Card reporting system for adverse events [\[link\]](#)
- Restricted advertising, as set also out in the Advertising Codes, both the [Nonbroadcast CAP Code](#) and the [Broadcast BCAP Code](#). Rules are also set out in the [UK Advertising Code](#)
- In March 2024, bans were announced for disposables. In January 2024, announcement that flavours specifically marketed at youth would be restricted

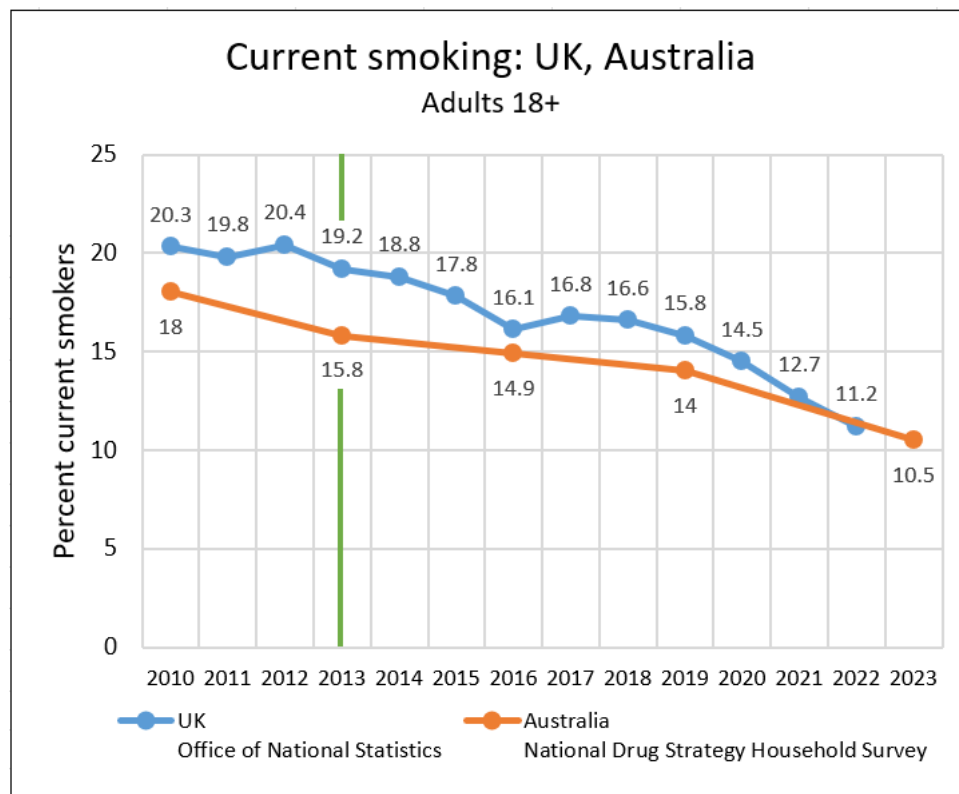
A summary of the regulations for NVPs in New Zealand, the United Kingdom and US can be found in the **Appendix**.

### **Adult smoking and vaping**

Adult smoking has declined more quickly in the UK since vaping became more widely available in 2013, and vaping is likely to be a contributing factor. [54, 55] (see following figure)

In 2022, 8.7% of adults 16+ were currently vaping (5.2% daily, 3.5% occasionally). [\[link\]](#)





**Current adult smoking in the United Kingdom and Australia 2010-2023.**  
Note the accelerated decline in the UK since 2013 when vapes became popular

### *Youth smoking and vaping*

In the UK, youth vaping is largely confined to smokers and former smokers. About half of those who try vaping vape only once or twice. Frequent vaping by never-smokers is rare, around 1%. Youth vaping rates in the UK are lower than in Australia.

Smoking continues to decline and the decline may be accelerating.

#### **1. ASH Smokefree GB Youth Survey 2023**

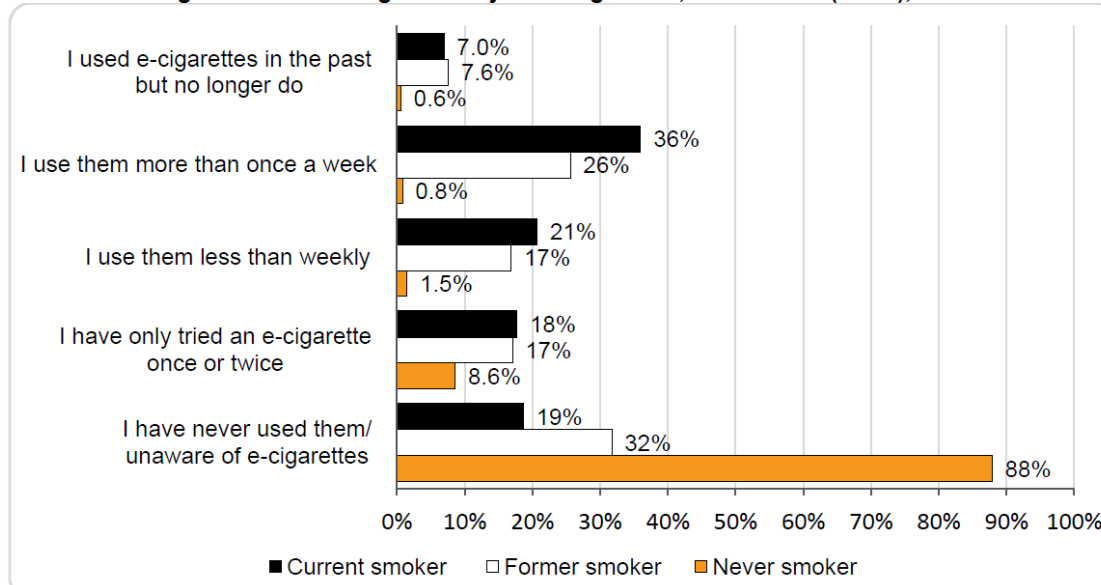
11-17-year-olds (n=2,656) [\[link\]](#)

According to ASH, “The use of e-cigarettes by youth remains largely confined to current or former smokers”.

7.6% of youth are currently vaping in 2023. 57% of smokers currently vape compared to only 2.3% of never-smokers. The majority of never-smokers (1.5%) vape less than weekly. Only 0.8% of never-smokers vape weekly or more.

Most vaping is infrequent. More than half who try vaping, vape only once or twice.

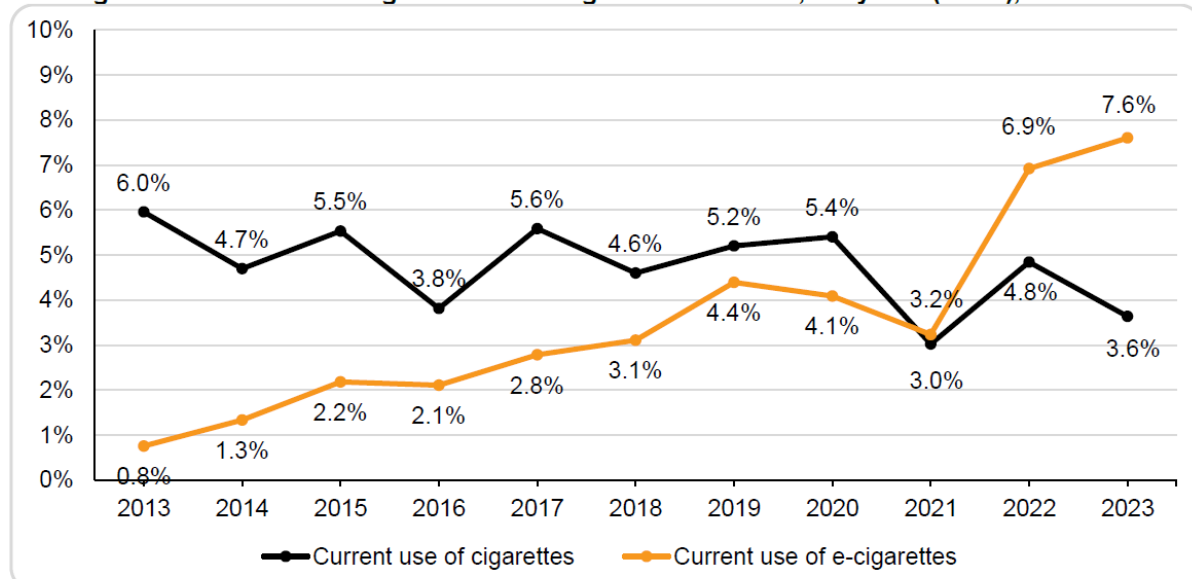
**Figure 5. Use of e-cigarettes by smoking status, GB children (11-17), 2023**



ASH Smokefree GB Youth Survey, 2023. Unweighted base: All 11-17 year olds (never smokers=1,673, former smokers =58, current smokers =88).

3.6% of youth were current smokers and the smoking rate continues to decline.

**Figure 7. Current use of cigarettes and e-cigarettes over time, GB youth (11-17), 2013-2023**

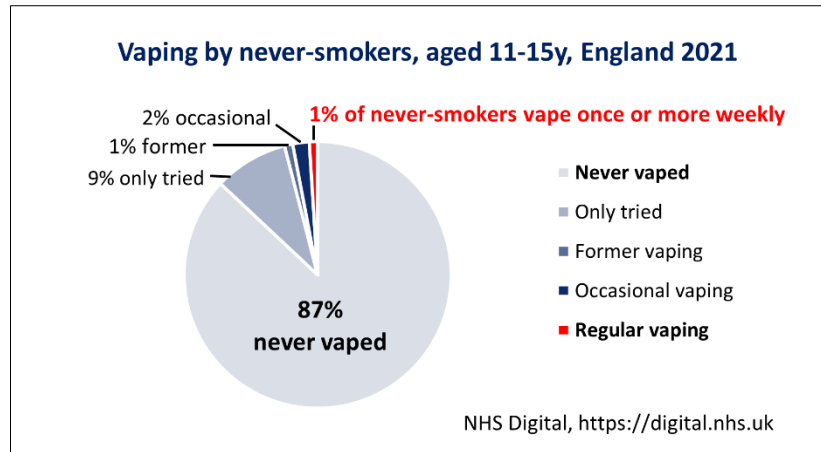


ASH Smokefree GB Youth Surveys, 2013-2023. Unweighted base: All 11-17 year olds (2013=1,895, 2014=1,817, 2015=1,834, 2016=1,735, 2017=2,151, 2018=1,807, 2019=1,982, 2020=2,029, 2021=2,109, 2022=2,111, 2023=2,028)

## 2. NHS Digital 2021

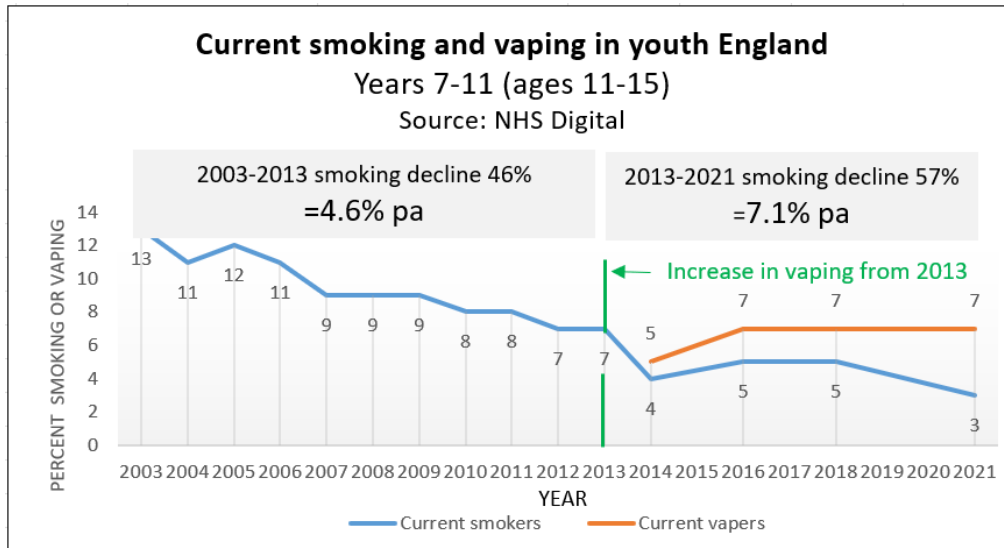
England, 11-15-year-olds [\[link\]](#)

7% of youth were currently vaping in 2021. Only 3% of never-smokers currently vape (1% at least weekly, 2% less than weekly)



**Youth vaping by smoking status in England**

3% of youth were current smokers in 2021. The decline in smoking accelerated since 2013 after vaping became widely available.



**Current youth smoking and vaping in England**

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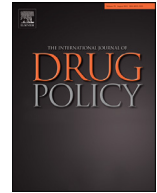
## Appendix

1. Mendelsohn CP, Hall W. What are the harms of vaping in young people who have never smoked? *International Journal of Drug Policy* 2023
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## Commentary

## What are the harms of vaping in young people who have never smoked?

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Recent increases in nicotine vaping by adolescents have understandably alarmed parents and school communities. Concerns have been greatest about the uptake of vaping by young people who have never smoked.

A reasonable fear is that vaping by people who have never smoked may cause potential new harms, such as nicotine dependence, effects on the developing brain and a transition to cigarette smoking, the most harmful way of obtaining nicotine. Vaping among young people who already smoke may be beneficial if it diverts them away completely from cigarette smoking.

Youth vaping is the key driver of media debates and vaping policy in many countries, such as Australia and the United States. An objective assessment of the risks and benefits of vaping in young people is important to understand its impact on public health and inform evidence-based policy. This requires an analysis of the prevalence of vaping by young people who have never smoked and a review of the evidence on the risks it poses to health.

## How common is frequent vaping in never-smokers?

Most vaping by never-smoking adolescents is occasional and transient (Action on Smoking and Health UK, 2022; ASH New Zealand, 2022; Glasser, Johnson, Niaura, Abrams, & Pearson, 2021; Hammond et al., 2019; Jarvis, Jackson, West, & Brown, 2020; NHS Digital, 2022). Frequent vaping by young people who have never smoked is uncommon in western countries with a prevalence mostly under 2%. (Table 1) Vaping rates are substantially higher in current or former smokers, ranging from 18–89% (Action on Smoking and Health UK, 2022; ASH New Zealand, 2022; Glasser et al., 2021; Hammond et al., 2019; Jarvis et al., 2020; NHS Digital, 2022).

The most detailed data on youth vaping are from England and demonstrate a strong association between vaping and smoking (NHS Digital, 2022) (Table 2). In 2021, only 1% of 11–15-year-olds who had never smoked cigarettes vaped regularly (once or more weekly), although a proportion of these may take up smoking later. In comparison, 61% of those who smoke regularly (at least one cigarette per week) also vaped regularly.

Measures of lifetime vaping (“even a puff”) or current vaping (at least once in the past 30-days) overestimate the prevalence of frequent vaping by those who have never-smoked because they include experimental

and infrequent vaping which is the most common pattern of use in this group (Action on Smoking and Health UK, 2022; Glasser et al., 2021; Hammond et al., 2019; Jarvis et al., 2020).

## Does vaping increase the risk of taking up smoking?

It is well established that young people who try vaping are more likely to later try smoking (Soneji et al., 2017). There is a tendency in policy discussions to assume that this association is causal (the gateway hypothesis) (Chan et al., 2021). However, it is not the only possible or the most plausible explanation. A more likely explanation is that the association is explained by shared risk factors for vaping and smoking, such as a genetic liability to develop nicotine addiction (Hall & Chan, 2021) and environmental, psychological and social causes e.g., peer group or parental smoking (Cambron & Thackeray, 2022) that create a ‘common liability’ for risk taking (Vanyukov et al., 2012). In studies that adjust for these confounders, most of the association between vaping and subsequent smoking has disappeared (Kim & Selya, 2019; Lee, Coombs, & Afolalu, 2018; Sun, Mendez, & Warner, 2022).

The gateway hypothesis also predicts that increased vaping will increase cigarette smoking among youth. However, increases in youth vaping have been accompanied by an accelerated decline in smoking since vaping became popular in the US, UK and New Zealand, suggesting either no overall gateway effect or at most, a small gateway effect that is outweighed by the much larger number moving from smoking to vaping (Centers for Disease Control and Prevention, 2021; Levy et al., 2019; Meza, Jimenez-Mendoza, & Levy, 2020; NHS Digital, 2022) (Fig. 1).

Population and modelling studies also suggest that vaping and smoking are substitutes and that vaping is displacing smoking at a population level (Foxon & Selya, 2020; Selya & Foxon, 2021; Sokol & Feldman, 2021; Walker et al., 2020). Studies of the effects of tax increases on vaping products also support a diversion effect. Higher taxes on vapes are associated with increased cigarette smoking while higher cigarette prices are associated with increased vaping (Abouk et al., 2023; Cantrell et al., 2020; Chan et al., 2022; Pesko & Warman, 2022), (Fig. 2).

Bans or purchasing restrictions on the sale of vapes to teens are also associated with increased adolescent smoking (Dave, Feng, & Pesko, 2019; Friedman, 2015; Pesko, Hughes, & Faisal, 2016). One study estimated that establishing a minimum legal sale age for e-cigarettes in

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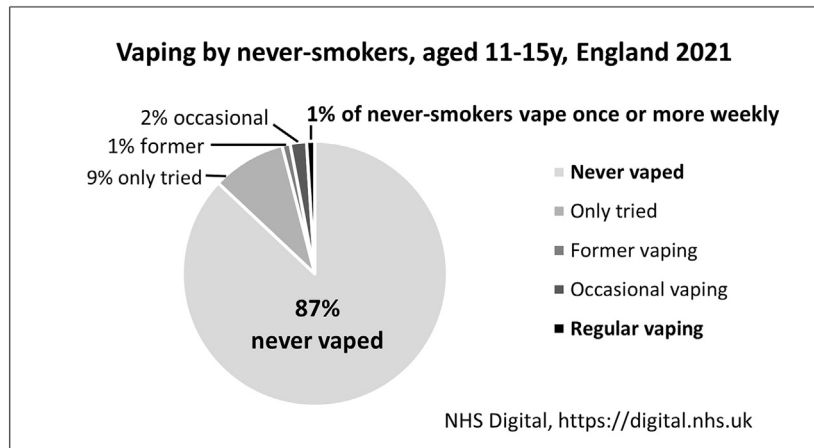
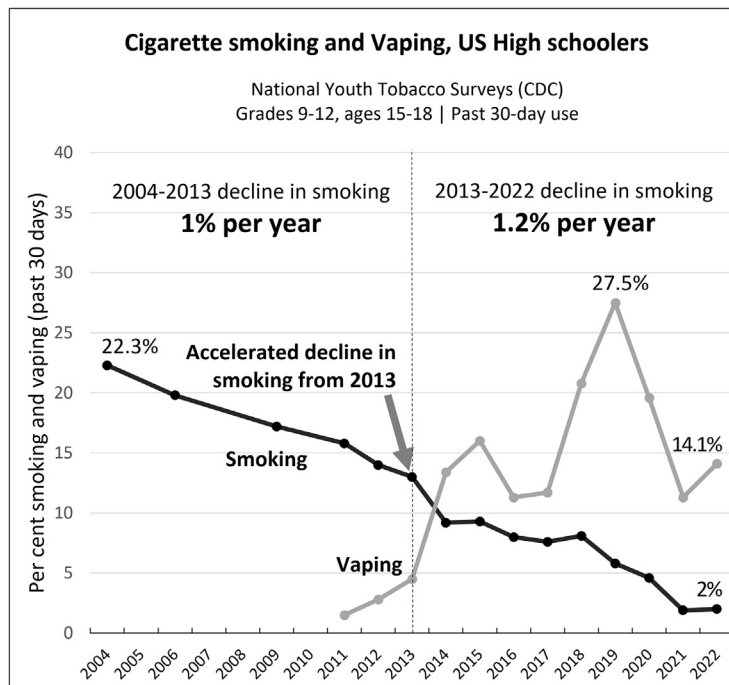
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**Table 1**  
Frequent or daily vaping by never-smoking youth.

Country	Vaping frequency	Year	Never smokers	Current smokers	Age	Ref
England	≥ once weekly	2021	1%	61% of regular smokers (at least one cigarette per week) were regular vapers	11-15	(NHS Digital, 2022)
	> once weekly	2022	0.5%	55.4% of current smokers (occasional or more frequent) were current vapers	11-17	(Action on Smoking and Health UK, 2022)
	≥ 15 days in the last 30	2018	0.1%	13.4% of current smokers (at least 100 cigarettes in lifetime and smoked in past 30 days) vaped frequently	16-19	(Hammond et al., 2019)
United States	≥ 20 days in the last 30	2018	0.4%	88.9% of frequent vapers were current (smoked in the past 30 days) or past smokers	9-19	(Glasser, Johnson, Niaura, Abrams, & Pearson, 2021)
		2019	2.1%	48.8% of frequent vapers had smoked >100 cigarettes	14-18	(Jarvis, Jackson, West, & Brown, 2020)
	≥ 15 days in the last 30	2018	1.5%	23.4% of current smokers (at least 100 cigarettes in lifetime and smoked in past 30 days) vaped frequently	16-19	(Hammond et al., 2019)
Canada	≥ 15 days in the last 30	2018	0.6%	18% of current smokers (at least 100 cigarettes in lifetime and smoked in past 30 days) vaped frequently	16-19	(Hammond et al., 2019)
New Zealand	Daily	2022	4.3%	86.6% of daily smokers vaped daily	15	(ASH New Zealand, 2022)

**Fig. 1.** Vaping by never-smokers, aged 11-15y, England 2021.**Fig. 2.** Decline in youth smoking in the US as vaping increased (Centers for Disease Control and Prevention, 2021).

the US between 2010-2016 reduced e-cigarette use but increased daily smoking by approximately 35% (Pesko, 2023).

Approximately 25-50% of adolescents who experiment with vaping are non-smokers at the time (Legleye, Aubin, Falissard, Beck, & Spilka, 2021; Mus, Monzon, Islam, Thrasher, & Barnoya, 2023; Shahab, Beard, & Brown, 2021; Watts et al., 2022). There is growing evidence that those who vape first (before smoking) are less likely to smoke later, compared to those who smoke first (Chyderiotis, Benmarhnia, Beck, Spilka, & Legleye, 2020; Legleye et al., 2021; Mus et al., 2023; Shahab et al., 2021; Sokol & Feldman, 2021; Xu et al., 2022).

Importantly, in cross-sectional (Kim & Selya, 2019; Levy et al., 2019; Shahab et al., 2021) and longitudinal studies (Sun, Méndez, & Warner, 2023) it does not appear that youth vaping leads to increases in sustained cigarette use which is the major public health concern. Studies that measure experimentation with smoking overestimate smoking uptake because only a small fraction of ever or infrequent cigarette smokers progress to become persistent lifetime users (Glasser et al., 2021).

### What are the known health effects of vaping by never-smokers?

Young people who have never smoked should not vape as this exposes them to toxic chemicals and unnecessary health risks. The precise long-term effects of vaping nicotine will not be fully known for decades. Effects from long-term vaping may include cardiovascular (Benowitz & Fraiman, 2017) and respiratory effects (Polosa, O'Leary, Tashkin, Emma, & Caruso, 2019). Ongoing monitoring and long-term studies are essential to detect any problems that may arise in the future, particularly from sustained frequent vaping.

Furthermore, most vaping by young people who have never smoked is infrequent and short-term (Action on Smoking and Health UK, 2022; Glasser et al., 2021; Hammond et al., 2019; Jarvis et al., 2020). This pattern is associated with lower levels of toxic exposure and so is likely to have fewer adverse health effects than frequent or sustained use. The most commonly reported adverse short-term effects of vaping are throat and mouth irritation, headache, cough and nausea, effects which tend to dissipate with continued use (Hartmann-Boyce et al., 2022).

Vaping has been associated with respiratory symptoms in young people in cross-sectional studies, but many young people who vape have also smoked tobacco so the significance of these findings is uncertain (McConnell et al., 2017; Schweitzer et al., 2015; Wang, Ho, Leung, & Lam, 2016). Other studies have found no functionally-important respiratory symptoms in young people who vape after account is taken of past cigarette smoking (Stevens et al., 2022; Tanski et al., 2022). A meta-analysis of ten cross-sectional studies found an association between vaping and asthma in young people but it was unclear if the association is causal (Li et al., 2022). A large, longitudinal study found that exclusive e-cigarette use was not associated with the onset of asthma (Mattingly et al., 2023).

There is evidence from animal studies that high doses of nicotine cause harmful effects on the adolescent brain but it is uncertain if these findings can be extrapolated to adolescent humans (Balfour et al., 2021). Studies have not found large difference in IQ (Wennerstad et al., 2010), educational achievement (Treur et al., 2015) or cognitive abilities (Corley, Gow, Starr, & Deary, 2012) in adulthood between those who have smoked in the past and those who have never smoked.

There is some evidence that nicotine may in the short-term improve attention, memory (Heishman, Kleykamp, & Singleton, 2010) and cognitive function (Gil & Metherate, 2019), relieve anxiety (Morissette, Tull, Gulliver, Kamholz, & Zimering, 2007) and improve mood (Picciotto, Brunzell, & Caldarone, 2002).

Nicotine itself represents minimal risk of serious harm in the doses commonly used in vaping (McNeill, Brose, Calder, Bauld, & Robson, 2018; McNeill et al., 2022). Nicotine does not cause cancer (International Agency for Research on Cancer, 2012) or lung disease (US Department of Health and Human Services, 2014) and it has only a minor role in cardiovascular disease (Benowitz & Burbank, 2016). A

recent meta-analysis of 42 studies with a median duration of 10 weeks found with moderate certainty that there are no significant associations between the use of nicotine and the risk of clinically diagnosed adverse cardiovascular events (Kim et al., 2023).

However, nicotine withdrawal can cause short-term symptoms such as irritability, restlessness, anxiety, difficulty concentrating and depression (Benowitz, St Helen, & Liakoni, 2021).

To date, there have been no identified health risks of passive vaping to bystanders due to the low levels of toxicants emitted (McNeill et al., 2018; Royal College of Physicians, 2016).

There is no evidence that vaping nicotine causes the serious lung disease E-cigarette or Vaping Associated Lung Injury (EVALI) (Mendelsohn, Wodak, & Hall, 2023) or seizures (Benowitz, 2020). EVALI was caused by vaping illicit cannabis oils contaminated with vitamin E acetate (Krishnasamy et al., 2020). There is a rare risk of burns and injuries from lithium-battery explosions, but none have been reported from disposables, the most popular type of device used by young people (Tattan-Birch, Jackson, Kock, Dockrell, & Brown, 2022; Watts et al., 2022).

Vaping is likely to be far less harmful than smoking (Committee on Toxicity of Chemicals in Food Consumer products and the Environment (COT), 2020; McNeill et al., 2018; McNeill et al., 2022; National Academies of Sciences Engineering and Medicine, 2018; Royal College of Physicians, 2016). There are substantially fewer harmful and potentially harmful constituents (HPHC) in vapour than in tobacco smoke and those that are present occur at far lower concentrations (McNeill et al., 2022). Further research is needed to assess the potential toxicity of inhaled flavoring additives and their thermal degradation products (Committee on Toxicity of Chemicals in Food Consumer products and the Environment (COT), 2020).

### Do never-smokers who vape become dependent on nicotine?

Vaping can cause nicotine dependence in some young people who have never smoked. The evidence suggests however, that this is a minority of cases, not, as the media often claim, a "new generation addicted to nicotine" (Jackson, Brown, & Jarvis, 2021).

An analysis of the 2018 US National Youth Tobacco Survey found that <4% of young people who had vaped in the past 30 days but had never smoked had signs of nicotine dependence (Jarvis et al., 2020). This low incidence is consistent with the dominant pattern of occasional and short-term use of vapes.

Nicotine dependence is concentrated in young people who have previously or currently smoke (Hammond et al., 2019; Jackson, Kotz, West, & Brown, 2019; Liu, Wasserman, Kong, & Foulds, 2017). In the US, there was a 50% decline in youth vaping from 2019-2021 suggesting that many young people who vaped were readily able to stop. This period included the COVID pandemic, although its influence on this decline is unclear (Chen-Sankey, Bover Manderski, Young, & Delnevo, 2022) (Fig. 1).

Nicotine dependence in the US youth population has not increased overall from 2012-19 despite the rise in youth vaping (Jackson et al., 2021). This may be partly attributable to a shift away from cigarettes (on which users are most dependent) to vaping products (on which users are less dependent).

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 (Gorini et al., 2020; Miech, Johnston, O'Malley, Bachman, & Patrick, 2019; Watts et al., 2022).

As with adults, nicotine dependence is lower in young people who vape compared to those who smoke (Hammond et al., 2021; Jarvis et al., 2020). Some young people may need support to stop vaping using strategies such as counselling, a gradual reduction in nicotine concentration or abrupt cessation, switching to a nicotine replacement product and re-



lapse prevention (National Centre for Smoking Cessation and Training, 2022).

The development of nicotine dependence in adolescence is unlikely to increase the risk of later use of other drugs (Lynskey & Agrawal, 2018). However, research has not been able to discount the possibility of a causal link.

### What about the risks for young smokers who take up vaping?

The vast majority of young people who experiment with both vaping and smoking had smoked before they tried vaping (Berry et al., 2019; Chyderiotis, Spilka, & Beck, 2019; de Lacy, Fletcher, Hewitt, Murphy, & Moore, 2017; Jarvis et al., 2020). Many teens who smoke use e-cigarettes to quit smoking or as a safer alternative (Australian Institute of Health and Welfare, 2020; Camenga, Kong, Cavallo, & Krishnan-Sarin, 2017; Kong, Morean, Cavallo, Camenga, & Krishnan-Sarin, 2015). However, studies so far have not found an association between e-cigarette use and subsequent smoking cessation in this population (Lin et al., 2022; Saller, Agaku, & Filippidis, 2022; Wang, Li, Wu, Lam, & Chan, 2017).

There is also little evidence of effectiveness of nicotine replacement therapy for adolescent smoking (Myung & Park, 2019) which may be partly explained by poor compliance (Scherphof, van den Eijnden, Lugtig, Engels, & Vollebbergh, 2014).

Vaping is not harmless, but is likely to be far less harmful than smoking and those who switch from smoking to vaping are likely to see health benefits (McNeill et al., 2022). Switching to exclusive vaping is recommended for optimal benefit as dual use (vaping and smoking) is associated with greater toxicant exposure than vaping alone and greater health risk (Anic et al., 2022).

Modelling studies suggest a net benefit from vaping to population health under all plausible scenarios. These models take into account harms from vaping (uptake by never-smoking youth and adults, the potential to increase smoking, inhibit smoking cessation and promote relapse) and benefits (cessation of smoking and diversion of those who would have otherwise have taken up smoking) (Levy et al., 2021; Summers, Ait Ouakrim, Wilson, & Blakely, 2022).

### Policy measures to reduce youth vaping

Vaping policy needs to balance the substantial and more immediate benefits for adults who smoke against the smaller and delayed risks of uptake among non-smoking youth (Balfour et al., 2021). A tightly regulated, risk-proportionate consumer model with strict age verification would make regulated vaping products more available for adults who smoke, reduce illicit sales and reduce youth access (Mendelsohn, Wodak, & Hall, 2023). Nicotine liquids should be available from licensed retail outlets, such as specialist vape shops, pharmacies and general retail outlets, as for cigarettes and alcohol. Strict age verification at the time of purchase should be required with harsh penalties for breaches such as fines and loss of licence. Consideration could be given to mandatory CCTV recording of sales as a condition of a sales licence. Some leakage to youth through social sources is inevitable and controlling this would need further regulatory measures.

Strict age verification at the time of sale is essential and can be enforced under a licensing scheme for retail outlets. Breaches of age-of-sale limits should result in severe penalties and loss of licence. A third-party verification service is required for online purchases with age verification on delivery.

We need to recognize that overly restrictive policies intended to reduce youth vaping can have counterproductive results. Vaping products and cigarettes are substitutes among nicotine users. Restrictions on youth access to e-cigarettes are associated with higher adolescent cigarette smoking (Dave, Feng, et al., 2019; Friedman, 2015; Pesko et al., 2016).

Young people enjoy flavored products and longitudinal studies have found that the initial use of flavors is associated with continued vaping (Notley et al., 2022). Flavors may also contribute to the diversion of young people from smoking and as an aid to smoking cessation. There is no evidence to date that flavored e-liquid use specifically is associated with tobacco smoking uptake or cessation (Notley et al., 2022) but more research is needed to clarify the overall impact of flavors.

Flavor bans can also have unintended harmful effects. A ban on flavored tobacco and vaping products in San Francisco in 2020 was associated with a more than doubling of cigarette smoking by high school students relative to concurrent changes in other districts (Friedman, 2021). A ban on flavors in pod-based products other than tobacco and menthol in the US resulted in a shift to disposable products by adolescents. Vaping and smoking behaviours remained unchanged (Hammond et al., 2022). The effects of these policies need further evaluation. However, flavor names that specifically appeal to young people should be prohibited.

Taxation should be kept to a minimum and proportionate to risk to incentivize switching by adults who smoke (Royal College of Physicians, 2016). Increased taxation of vaping products to reduce youth vaping is associated with increased smoking by youth (Abouk et al., 2023; Pesko & Warman, 2022) and shifts the source of vapes from retail to social sources (Abouk et al., 2023).

Disposable devices are popular with young people (Tattan-Birch et al., 2022). However, a disposable ban could simply similarly shift usage from disposables to another nicotine product (Khouja & Munafò, 2022). Disposables also play an important role as a transition model for adults who smoke and a ban may have unintended consequences for adults (Russell, McKinney, & Fearon, 2023).

Advertising to adults who smoke at the point-of-sale helps raise awareness of vaping as a safer alternative and may encourage them to switch (Dave, Dench, Grossman, Kenkel, & Saffer, 2019). There is also an association between viewing advertisements and youth vaping (Dai & Hao, 2016; Padon, Lochbuehler, Maloney, & Cappella, 2018). It is not clear if this association is causal or if adolescents who are interested in vaping are more likely to notice advertisements (attentional bias) (Dai & Hao, 2016). The impact of advertising on adolescents can be minimised by enforcing socially responsible advertising and controlling the content and placement of advertisements (UK Advertising Code, 2016).

Packaging should not include images that appeal to youth. However, the one study of graphic images found that they were not effective in deterring youth vaping (Wojtecka et al., 2023). A recent study found that adolescents considered their peers would be less interested in plain, standardised green packs for vape products compared to fully branded packaging (Taylor et al., 2023). Plain packaging is appropriate for smoking products but in our view may be disproportionate to the risk involved from vaping.

Australia's current prescription-only model for vaping has primarily been justified to minimise youth uptake of vaping (Therapeutic Goods Administration, 2022). However, since the introduction of this policy in October 2021, the illicit vaping market has grown rapidly and probably contributed to a significant increase in youth vaping (Watts et al., 2022).

Strategies to reduce youth vaping are listed in (Table 2).

**Table 2**

Policy measures to reduce youth vaping.

- Legal vaping products sold only from licensed retail outlets
- Strict age verification at the time of sale
- A third-party age verification service for online purchases and on delivery
- Advertising restricted and regulated to prevent marketing to adolescents
- Substantially increased fines and loss of licences for illegal sales
- Banning flavour names, images and packaging which appeal to young people
- Education programs for young people should provide accurate information about the absolute and relative risks of vaping and smoking.

## Conclusion

Frequent vaping of nicotine by young people who have never smoked is uncommon and there is limited evidence so far that vaping has caused significant harms in this population. At a population level, the net benefits of vaping to adult and youth who smoke are likely to outweigh the feared harms of vaping to youth.

Very few nicotine-naïve young people who vape develop nicotine dependence. There is weak evidence that vaping leads to smoking. In fact, the evidence suggests that vaping is diverting more young people away from smoking. It is also likely to be beneficial to young people who smoke who switch to vaping.

A balanced, risk-proportionate approach to regulation is needed to restrict the uptake of vaping by young people who do not smoke while allowing easier access for adults who smoke, for whom it is an effective and popular quitting aid.

## Author contributions

Each author certifies that their contribution to this work meets the standards of the International Committee of Medical Journal Editors.

## Ethics approval

The authors declare that the work reported herein did not require ethics approval because it did not involve animal or human participation.

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## Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Colin Paul Mendelsohn

C.P.M. was an unpaid board member of the Australian Tobacco Harm Reduction Association (ATHRA), a registered health promotion charity, from October 2017 to January 2021. ATHRA accepted unconditional seed funding from the vape retail industry to become established. Funding ceased in March 2019. C.P.M. was a Director of ATHRA in March 2018 when it received a donation from KAC Communications.

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C.P.M. is the author of *Stop Smoking Start Vaping*, published by Aurora Press. C.P.M. has never received payments from electronic cigarette or tobacco companies.

Wayne Hall

No competing interests.

## CRedit authorship contribution statement

**Colin Paul Mendelsohn:** Conceptualization, Project administration, Writing – original draft, Writing – review & editing. **Wayne Hall:** Writing – review & editing.

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## COMMENTARY



WILEY

# 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"> <li>The current TGO 110 standards [59] are inadequate and need to be upgraded, for example, include all blacklisted ingredients on the TPD list [57].</li> <li>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.</li> <li>Limits to nicotine, for example, 20 mg/mL for freebase nicotine; 50 mg/mL for nicotine salt (as in New Zealand) [56].</li> </ul>
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"> <li>‘This product may be addictive but is a far less harmful alternative for adult smokers’.</li> <li>‘If you are a smoker, switching completely to vaping is a much less harmful option’.</li> </ul>
Notification system	Mandatory notification of compliance to standards prior to marketing
Flavours	<ul style="list-style-type: none"> <li>Simple descriptions of flavour profiles.</li> <li>Prohibit descriptive flavour names and images that specifically appeal to youth and unsafe flavouring chemicals.</li> </ul>
Public vaping	<ul style="list-style-type: none"> <li>Some restrictions to apply, especially indoors.</li> </ul>
Public messaging	<ul style="list-style-type: none"> <li>Communicate the absolute and relative harms for vaping nicotine compared to smoking.</li> <li>Frame vaping as a less harmful alternative for adult smokers.</li> <li>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.</li> <li>All messaging should be accurate and avoid exaggeration of risks.</li> </ul>
Advertising	<ul style="list-style-type: none"> <li>Restricted advertising targeted at smokers who are unable or unwilling to quit with a ‘switch’ message.</li> <li>Banning all advertising that could appeal to young people, such as lifestyle ads associating vaping with positive imagery and adventure.</li> <li>Placement of advertising to minimise exposure to young people.</li> </ul>
Monitoring	A system for reporting adverse effects and recall of unsafe products
Taxation	<ul style="list-style-type: none"> <li>Proportionate to risk, similar to nicotine gum and patches.</li> <li>Maintain a significant differential between NVP and cigarette prices.</li> <li>High NVP prices lead to increased smoking as cigarettes and vaping products are economic substitutes.</li> </ul>

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

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.

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## International regulations

Policies marked **yellow** are preferred options

	New Zealand	United Kingdom	USA	Australia
<b>Classification</b>	Dual pathway <ul style="list-style-type: none"> <li>▪ Consumer product, or</li> <li>▪ Medical product if making claims about safety or efficacy (currently none)</li> </ul>	Dual pathway <ul style="list-style-type: none"> <li>▪ Consumer product, or</li> <li>▪ Medical (therapeutic) product if               <ol style="list-style-type: none"> <li>1) higher nicotine concentration, or</li> <li>2) making claims of safety or efficacy. Submitted to MHRA for approval (currently none)</li> </ol> </li> </ul>	Dual pathway <ul style="list-style-type: none"> <li>▪ Tobacco product</li> <li>▪ Medicine. Submit to Centre for Drug Evaluation and Research (currently none)</li> </ul>	Prescription medicine <ul style="list-style-type: none"> <li>▪ Unapproved therapeutic products. Available to adult smokers with a prescription from a medical practitioner to purchase from a pharmacy or import from overseas</li> <li>▪ Approved therapeutic products (by the TGA) if making claims about safety or efficacy. Registered on the Australian Register of Therapeutic Goods (currently none)</li> </ul>
<b>Nicotine concentration</b>	<ul style="list-style-type: none"> <li>▪ Max 28.5mg/mL. From 21 March 2024 <a href="#">[link]</a></li> <li>▪ Maximum 1,800mg nicotine per container</li> </ul>	<ul style="list-style-type: none"> <li>▪ Maximum nicotine concentration 20mg/mL</li> </ul>	<ul style="list-style-type: none"> <li>▪ Uncapped</li> </ul>	<ul style="list-style-type: none"> <li>▪ 100 mg/mL</li> </ul>
<b>Minimum age</b>	<ul style="list-style-type: none"> <li>▪ 18 years (smoking 18) <a href="#">[link]</a></li> <li>▪ Individuals under 18 years not permitted entry to specialist vape shops</li> </ul>	<ul style="list-style-type: none"> <li>▪ 18 years (smoking 18)</li> </ul>	<ul style="list-style-type: none"> <li>▪ 21 years (smoking 21)</li> </ul>	<ul style="list-style-type: none"> <li>▪ 18 years (smoking 18)</li> <li>▪ Individuals under 18 years not permitted entry to specialist vape shops</li> </ul>



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

	New Zealand	United Kingdom	USA	Australia
	<ul style="list-style-type: none"> <li>- may sell all legal vape products, including tank systems and liquid refills in a variety of flavours</li> <li>- online sales permitted</li> </ul> <ul style="list-style-type: none"> <li>▪ <b>General retailers</b> <ul style="list-style-type: none"> <li>- can only sell vaping products in tobacco, mint or menthol flavours.</li> <li>- Are prohibited from discussions with customers that encourage, promote or notify the availability of vaping products.</li> <li>- No online sales</li> </ul> </li> <li>▪ No vending machines in public areas <a href="#">[link]</a></li> </ul>		<ul style="list-style-type: none"> <li>▪ Online sales permitted</li> </ul>	<ul style="list-style-type: none"> <li>▪ Importation from international websites allowed with a doctor's prescription under the TGA Personal Importation Scheme <a href="#">[link]</a></li> </ul>
<b>Bans</b>	<ul style="list-style-type: none"> <li>▪ n/a</li> <li>▪ Ban on disposable vapes, announced March 2024 <a href="#">[link]</a></li> <li>▪ Prescribed flavour descriptors announced and no toys or cartoon images on products <a href="#">[link]</a></li> </ul>	<ul style="list-style-type: none"> <li>▪ Ban on disposable vapes announced Jan 2024 <a href="#">[link]</a></li> </ul>	<ul style="list-style-type: none"> <li>▪ Some states and cities have introduced bans on flavours, online sales and even vaping products <a href="#">[link]</a></li> <li>▪ Disposables available</li> </ul>	<ul style="list-style-type: none"> <li>▪ n/a</li> <li>▪ Prescription disposables available</li> </ul>
<b>Public vaping</b>	<ul style="list-style-type: none"> <li>▪ Prohibited in smoke-free areas</li> <li>▪ Prohibited in workplaces, aircraft, public transport,</li> </ul>	<ul style="list-style-type: none"> <li>▪ Vaping permitted outdoors including smoke-free areas</li> <li>▪ Local proprietors or organisations can decide</li> </ul>	<ul style="list-style-type: none"> <li>▪ Varies by state from unrestricted to bans in smoke-free areas</li> </ul>	<ul style="list-style-type: none"> <li>▪ Prohibited in smoke-free areas</li> </ul>

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

	New Zealand	United Kingdom	USA	Australia
	<ul style="list-style-type: none"> <li>- “CAUTION: Keep this substance out of reach of children or pets.”:</li> <li>- “Do not swallow this substance. If this substance is taken into the mouth, rinse mouth thoroughly.”:</li> <li>- “Contact 0800 POISON (0800 764 766) for advice if this substance is swallowed.”:</li> </ul> <p>“Seek medical advice if you feel unwell after contact with this substance or use of this product.” <a href="#">[link]</a></p>	<ul style="list-style-type: none"> <li>▪ Plainer packaging to reduce appeal to youth eg no toy or cartoon images</li> </ul> <p>From 21 March 2024 <a href="#">[link]</a></p>		
<b>Containers</b>	<ul style="list-style-type: none"> <li>▪ Child-resistant closures and tamper-evident measures</li> <li>▪ Breakage, leakage and anti-spill protection</li> <li>▪ Maximum bottle size 120mL unless containing zero nicotine</li> </ul>	<ul style="list-style-type: none"> <li>▪ Nicotine-containing products or their packaging to be child-resistant, tamper evident, breakage and leak proof</li> <li>▪ Refillable without leakage</li> <li>▪ Limit of 2ml for tanks or pods</li> <li>▪ Limit of 10ml for nicotine e-liquids</li> </ul>	<ul style="list-style-type: none"> <li>▪ Mandatory child-resistant closures</li> </ul>	<ul style="list-style-type: none"> <li>▪ Child resistant container</li> </ul>
<b>Product safety</b>	<ul style="list-style-type: none"> <li>▪ Must not contain restricted substances <a href="#">[link]</a></li> <li>▪ Testing of liquid by an accredited laboratory (no mandatory emission testing)</li> </ul>	<ul style="list-style-type: none"> <li>▪ <u>Emissions testing</u></li> <li>▪ No vitamins, colourings or prohibited additives (including caffeine and taurine)</li> <li>▪ Using only ingredients of high purity</li> </ul>	<ul style="list-style-type: none"> <li>▪ For existing products, safety is assessed as part of the PMTA process to determine whether the product can continue to be marketed</li> <li>▪ Future products assessed by FDA prior to marketing</li> </ul>	<ul style="list-style-type: none"> <li>▪ Must not contain other 'active' ingredients other than nicotine eg caffeine, THC, stimulants or vitamins</li> <li>▪ Must not contain acetoin, benzaldehyde, diacetyl, cinnamaldehyde, diacetyl,</li> </ul>

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

	New Zealand	United Kingdom	USA	Australia
		<ul style="list-style-type: none"> <li>- Components of the product</li> <li>- Production process details</li> </ul> <ul style="list-style-type: none"> <li>▪ <a href="#">[TPD]</a></li> </ul>	<ul style="list-style-type: none"> <li>▪ Only tobacco flavoured products have been approved so far</li> </ul>	
<b>Flavours</b>	<ul style="list-style-type: none"> <li>▪ Specialist vape shops: No flavours prohibited</li> <li>▪ General retailers: Tobacco, mint and menthol only</li> </ul>	<ul style="list-style-type: none"> <li>▪ Restricted flavours that are specifically marketed at children, announced Jan 2024 <a href="#">[link]</a></li> </ul>	<ul style="list-style-type: none"> <li>▪ Restricted in some cities and states</li> </ul>	<ul style="list-style-type: none"> <li>▪ No flavours prohibited</li> <li>▪ Certain flavouring chemicals banned for health reasons: benzaldehyde, cinnamaldehyde, diacetyl</li> </ul>
<b>Vaping in retail stores</b>	<ul style="list-style-type: none"> <li>▪ Specialist vape shops: permitted</li> <li>▪ General retailers: Prohibited</li> </ul>	<ul style="list-style-type: none"> <li>▪ Not restricted</li> </ul>	<ul style="list-style-type: none"> <li>▪ Not restricted</li> </ul>	<ul style="list-style-type: none"> <li>▪ Permitted in vape shops in most states</li> </ul>
<b>Taxation</b>	<ul style="list-style-type: none"> <li>▪ 15% GST. No excise tax</li> </ul>	<ul style="list-style-type: none"> <li>▪ 20% VAT, no excise tax <a href="#">[link]</a></li> <li>▪ Current proposal to reduce this to 5% <a href="#">[link]</a></li> </ul>	<ul style="list-style-type: none"> <li>▪ Varies by state <a href="#">[link]</a></li> </ul>	<ul style="list-style-type: none"> <li>▪ Nicotine e-liquids not taxed</li> </ul>
<b>Federal regulator</b>	<ul style="list-style-type: none"> <li>▪ Ministry of Health's Vaping Regulatory Authority <a href="#">[link]</a></li> </ul>	<ul style="list-style-type: none"> <li>▪ Medicines and Healthcare Products Regulatory Agency (MHRA)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Food and Drug Administration (FDA)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Therapeutic Goods Administration (TGA)</li> </ul>
<b>Legislation</b>	<i>Smokefree Environments and Regulated Products Regulations Act 2021 <a href="#">[link]</a></i>	<i>The Tobacco and Related Products Regulations 2016 (Parts 6, 7 and 8) <a href="#">[link]</a></i> <i>E-cigarettes: regulations for consumer products 2019 <a href="#">[link]</a></i>		<i>Therapeutic Goods Regulations 1990 <a href="#">[link]</a></i> <i>Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021 <a href="#">[link]</a></i> Pharmacy advertising

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