

**SUBMISSION TO THE THERAPEUTIC GOODS  
ADMINISTRATION (TGA) JOINT ADVISORY COMMITTEE  
ON MEDICINES SCHEDULING (ACMS)/ADVISORY  
COMMITTEE ON CHEMICALS SCHEDULING (AACS)**



**Australian Retail  
Vaping Industry  
Association**

Member Group of the **Australian Retailers Association**

**Proposed Amendments to the Poisons Standard  
(Medicines/Chemicals)**

**Schedule 4, 6, 7 & Appendix D, Item 5 – Amend Entry – Nicotine**

**CAS Number 54-11-5**

18 May 2020

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## Executive Summary

- The Australian Retail Vaping Industry Association (ARVIA) represents specialist vape stores and ordinary retailers that support the legalisation of smoke free products such as nicotine vapourisers and electronic cigarettes.
- ARVIA opposes the Department of Health application to amend the Poisons Standard scheduling of nicotine because it is fundamentally flawed, illogical, regressive, unnecessary and will result in millions of innocent Australians being senselessly killed.
- This application has been developed in secret without any prior consultation under the cover of COVID-19 by unelected autocrats from the Department of Health. We believe that the proposed amendment is undemocratic and seriously undermines and subverts various parliamentary processes that are still ongoing.
- The only beneficiaries of this proposal are tobacco companies who manufacture and profit from a product that kills 21,000 Australians every year, and pharmaceutical companies who manufacture products that are expensive but are otherwise ineffective in helping smokers quit.
- The scientific evidence in support of vaping continues to grow, and the available peer-reviewed research consistently demonstrates that vaping is at least 95% safer than smoking and is the most effective and popular quit smoking tool globally.
- Australian retailers believe that the best outcome for Australian smokers and their families is to make nicotine vaping and electronic cigarette products legal as consumer goods and to give smokers the choice to legally access these scientifically proven lifesaving products.
- Australia's smoking rate hasn't fallen since 2013. Not only are our efforts failing to reduce smoking, but imposing the largest tobacco taxes in the world in an apparent effort to curb smoking is actually driving unprecedented growth in the illicit tobacco trade, which deprives business and governments of revenue, and is fueling organised criminal activity.
- Australia is now considered a global laggard on tobacco harm reduction as every other civilised country in the world embraces vaping and e-cigarettes. Nicotine vaping products and e-cigarettes are legal and are saving lives in New Zealand, Canada, the United States, the United Kingdom, Ireland, Japan, Korea, France, Italy, Denmark, Norway, Finland, Netherlands, Switzerland, Sweden, Spain, Portugal, Belgium, Germany, Austria, Iceland, Poland, Hungary, Estonia, Latvia, Slovenia, Slovakia, Croatia, Serbia, Czech Republic, Romania, Bulgaria, Greece, the United Arab Emirates, Belarus, Georgia, Moldova, Macedonia, Tunisia, Morocco, South Africa, Namibia, Indonesia, Malaysia, Cambodia and Vietnam.

- Smoking of traditional cigarettes that are legally endorsed and protected by the TGA and the Department of Health kills 21,000 Australians every year or a death every 25 minutes due to a range of causes such as lung cancer, bladder cancer, pancreatic cancer, kidney cancer, breast cancer, liver cancer, bowel cancer, cervical cancer, oesophagael cancer, stomach cancer, prostate cancer, laryngeal cancer, nasopharyngeal cancer, acute myeloid leukaemia, chronic myeloid leukaemia, chronic lymphocytic leukaemia, aortic aneuysm, COPD, asthma, lip and oral cavity cancer, stroke, coronary heart disease, atrial fibrillation and flutter, gallbladder and bile duct disease, otitis media, gastroduodenal disorders, hypertensive heart disease, lower respiratory infections and other cardiovascular diseases, just to name a few.
- Given the complete lack of transparency surrounding this application, and the absence of any strong public policy justification for this illogical and frankly ridiculous proposal, it appears designed as a pre-cursor for further restrictions and crackdowns on vaping and on vapers.
- The cumulative impact of the Department of Health's efforts, including this application, is to drive vapers back to smoking lethal combustible tobacco products and to deny smokers access to lifesaving smoke free alternatives.
- If the amendment proposed by the Department of Health is adopted, it will result in the deaths of millions of innocent Australians. The TGA and the Department of Health who have an ideological and pathological opposition to vaping based on emotion rather than on science will have the blood of Australians on their hands.

## Introduction

The Australian Retail Vaping Industry Association (ARVIA) was established by the Australian Retailers Association (ARA) in November 2019 to represent Australian vape retailers and ordinary retailers who want nicotine vaping products to be legalised as consumer goods, just as they are in every other civilised nation in the world.

ARVIA represents vape retailers as well as ordinary retailers who would like to see electronic cigarettes (e-cigarettes) and nicotine vaping products legalised. We do not represent the makers or manufacturers of vaping or e-cigarette products nor do we represent the tobacco industry.

We strongly support the sale of non-combustible tobacco and nicotine liquid products because they are a demonstrably safer and healthier alternative to traditional cigarettes. There are strong public health grounds to make all categories of smoke free products legal in Australia, not least because doing so will save the lives of 21,000 Australians who die from smoking every year but also because it will deliver wide-ranging health, social and economic benefits to the entire Australian community.

The current available scientific literature indicates beyond doubt that HTPs and nicotine vaping are at least 95 per cent safer than traditional cigarettes. We do not claim, nor has anybody ever claimed, that nicotine vaping and e-cigarette products are entirely risk free and we accept that the long-term health implications of vaping are not clearly understood. Notwithstanding this, the available peer-reviewed evidence that we have before us as at May 2020, is that vaping and e-cigarettes deliver the nicotine that smokers crave but without the cancer-causing cocktail of chemicals and carcinogens that cause so much of the harm associated with combustible tobacco use.

It is illogical, unethical and simply unsustainable for the TGA to continue to allow harmful combustible tobacco products to be legally sold while banning or restricting access to nicotine vaping and e-cigarettes.

## ARVIA Recommendation

ARVIA opposes the Department of Health application to amend the Poisons Standard because the changes proposed do not provide Australian adults with easier access to lifesaving nicotine vaping products. Instead, the proposed amendments are designed to make vapers lives more difficult by further restricting access to nicotine and to force vapers back to smoking harmful cigarettes which will most certainly kill them.

### RECOMMENDATION

ARVIA recommends that the Therapeutic Goods Administration (TGA) and the Secretary of the Department of Health reject the Department of Health application.

In its place, we recommend that you approve a previously submitted application to amend the poisons schedule to allow for the sale of nicotine ***in tobacco prepared and packed for heating*** and to add a further amendment to allow for the sale of nicotine ***in liquid prepared and packed for vapourising***.

If the Department of Health amendment is adopted, the evidence tells us quite definitively that Australians will die. The TGA, the Department of Health together with the Secretary of the Department of Health will be collectively responsible for the deaths of at least 200,000 out of 300,000 Australian vapers who are forced to return to smoking harmful combustible tobacco, as well as the deaths of two million out of three million current smokers who will be deprived of the opportunity to access nicotine vaping to quit smoking in the future. Such brazen and wonton disregard for human life is about as barbaric and as disgraceful as anybody could possibly contemplate.

### ALTERNATIVE RECOMMENDATION (if the Department of Health application is successful)

If the TGA accepts the Department of Health application, we recommend the TGA and the Department of Health keep an official death tally of the number of Australian smokers that will be killed as a direct result of this decision, in order to substantially improve public policy formulation in the future, and to avoid such diabolical and disastrous outcomes from ever happening in Australia again.

## Feedback on the Department of Health application

ARVIA members hold a number of serious concerns about the proposed amendment to the scheduling of nicotine and the highly secretive and non-transparent manner in which the unelected Department of Health officials have gone about it.

### Process

#### Lack of consultation and transparency

We are firstly concerned that the Department of Health has prepared this application in secret and without any consultation with affected stakeholders about how these changes will impact on them and why they are needed. For example how many vapers, vape stores, smokers and other stakeholders did the department consult with prior to drafting and preparing this amendment? What is the policy rationale and the intended objective of this amendment? Has the Department of Health consulted with regulators and public health authorities in New Zealand, the EU, the US and the United Kingdom about their experience with nicotine and if not why not? What are the likely costs of further restricting access to nicotine? These are very serious questions which the Department of Health have so far refused to answer, and likely never will.

The only notification provided to ARVIA was an automated email from the Therapeutic Goods Administration (TGA) on the day that scheduling applications were closed. By this point there was no prior warning nor was there an opportunity to provide any meaningful feedback on the content of the amendment, blindsiding affected stakeholders and flying in the face of open and accountable government. A democratic government and its public agencies have a duty to be fully transparent with its citizens. We note that the tobacco company applicant that has a current scheduling amendment application pending publicly announced and released its application prior to the deadline for applications in December 2019; meaning that bizarrely a tobacco company has in fact been more open and transparent in its conduct than the Department of Health.

The reasons for the amendment that are listed on the TGA website are vague and do not provide any clarity as to the reasoning and the purpose of the proposed amendment, and moreover the Department of Health has not made any copies of the application available for public viewing, nor provided any further evidence or explanatory material as to the justification for amending the Poisons Standard.

The Department is operating without any care or regard for the Australian public or for the lives and circumstances of Australian vapers who have successfully quit smoking using vaping.

#### Using the cover of COVID-19

It is extremely concerning that the department has deliberately used the COVID-19 crisis in a clandestine attempt to push its anti-vaping agenda through in secret with as little public and media scrutiny as possible.

More concerning is that while Australians have been following the various pieces of confusing, contradictory and conflicting health advice being issued by the Department of Health, it's now clear that the department was actually more focused on secretly waging a war on Australian vapers rather than saving Australian lives during the pandemic. Australians are entitled to ask how many of the 99 COVID-19 deaths and 7,056 COVID-19 infections (as at 18 May 2020) could have been avoided had the health department been more focused on the coronavirus pandemic rather than in undermining the rights of vapers to save their own lives.

Disturbingly, while the Department of Health has exploited the COVID-19 pandemic to further crackdown on vapers, it is simultaneously hiding behind the pandemic to avoid fulfilling its legislated transparency obligations. ARVIA has become aware that on the 15<sup>th</sup> of May, a Freedom of Information request regarding the Department's misleading statements on vaping was refused on the basis that there were too many documents to handover, and that departmental officers who would need to process them "are working on priority work in response to the COVID-19 pandemic". The brazen hypocrisy of the department is simply breathtaking, but it is unsurprising in light of the Health Department's and its unelected autocrats long running support for smoking and opposition to vaping.

#### The Department of Health is acting undemocratically

We are extremely concerned that the Department of Health is acting independently and against the will of the elected Government. There are a number of important parliamentary and other political decision-making processes that this proposed amendment pre-empts, and will by default, overrule.

It is implausible and without precedent for a Minister of the crown to so blatantly and deliberately undermine their own government as this application does, so it appears that unelected Department of Health autocrats have seized control of the tobacco policy agenda in order to continue their pro-tobacco efforts, likely while the minister and his office is pre-occupied with the COVID-19 pandemic.

For example, a parliamentary inquiry report into vaping by the House of Representatives Standing Committee on Health, Aged Care and Sport was completed and tabled in the House of Representatives on 28 March 2018, well over two years ago.<sup>1</sup> Yet to date the Department of Health has failed to provide the official government response to this inquiry. The report made five fairly straightforward but critical recommendations, some of which are painfully overdue. In the time since the report was tabled, more than 45,000 Australians have died due to smoking.

It is unclear if the Department's failure to respond to the Inquiry report is due to incompetence or whether it is deliberate. Nonetheless, it is totally unacceptable that while the Department disrespects a current and ongoing parliamentary process, it has proposed

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<sup>1</sup>[https://www.aph.gov.au/Parliamentary\\_Business/Committees/House/Health\\_Aged\\_Care\\_and\\_Sport/Electronic\\_Cigarettes/Report](https://www.aph.gov.au/Parliamentary_Business/Committees/House/Health_Aged_Care_and_Sport/Electronic_Cigarettes/Report)



changes to the scheduling of nicotine which undermines the very parliamentary committee report and recommendations it is refusing to respond to.

In addition to refusing to respond to the House of Representatives Vaping Inquiry, in September 2018 the Health Minister commissioned the Australian National University (ANU) to examine all of the available evidence about the health benefits of vaping, of which there is plenty. The referral to the ANU was intended to inform the Government's further consideration on the issue of vaping, and whether Australia would join every other civilised nation in the world and embrace vaping, or continue to hold the line with the Communist Chinese controlled World Health Organisation (WHO) in denying the international scientific consensus on vaping. This application negates the need for the ANU study and completely neuters the government's traditional policy formulation and decision-making processes.

While this application by the Department of Health may be technically within the law, these instances of apparatchik overreach appear more in line with the actions of a Russian or Chinese totalitarian dictatorship rather than adhering to the democratic Westminster principles Australian citizens are entitled to expect.

The fact that unelected autocratic ideologues in positions of power within the Department of Health have taken it upon themselves to actively undermine and subvert the political and Cabinet processes of Government, sets a very dangerous precedent in Australian democracy.

The reality is that while overpaid taxpayer funded health autocrats clink their champagne flutes in Woden and high-five each other in celebration of a 'win' in their pathological, unscientific and ideological war against vaping, innocent Australians will die. Such devastating overreach by unelected health autocrats driven purely by ideology rather than science only serves to erode trust in our democratic institutions over time, undermines public confidence in the decision-making process and shakes the very foundations of our democratic system of government.

The TGA is not impartial in this process (and the case of the mysteriously deleted tweet)

As a very obvious and high-profile member of the anti-vaping movement in Australia, it is clear that the TGA is not an impartial decision-maker or regulator in this process, and we do not have any confidence that the TGA will objectively consider the clear and compelling evidence or the merits of giving legal access to vaping products to those that need them.

It is alarming to most fair-minded observers that a health regulator would permit and endorse traditional cigarettes and combustible tobacco to be sold knowing full well that these products kill two thirds of long-term users, and currently kill 21,000 Australians every year. It is even more disturbing that the same health regulator can continue to justify dismissing and denying the growing weight of scientific evidence in support of nicotine vaping.

We note that on 11 December 2019, the TGA published a tweet and a Facebook post about how Australians wishing to quit smoking using vaping can access electronic nicotine products via the PIS. The tweet was technically, legally and factually correct, and provided Australians

with accurate information on the legal pathway to access nicotine in order to quit smoking – a rare but possibly accidental acknowledgement of the international evidence that nicotine-containing e-cigarette products do indeed help smokers quit smoking.



**TGA Australia** @TGAgovau · 2d

Provided you have a valid [#prescription](#) from an Australian doctor, you may be able to [#import](#) a nicotine-containing [#e-cigarette](#) product to help you quit smoking.

Find out more about electronic cigarettes on our website:

[tga.gov.au/community-qa/e...](https://www.tga.gov.au/community-qa/e...)



**TGA Australia @TGAgovau Tweet on Wednesday 11 December 2019:**

Provided you have a valid [#prescription](#) from an Australian doctor, you may be able to [#import](#) a nicotine-containing [#e-cigarette](#) products to help you quit smoking.

Find out more about electronic cigarettes on our website:

<https://www.tga.gov.au/community-qa/electronic-cigarettes>

Yet some hours later the social posts were deleted under very mysterious circumstances and without any explanation. To date the TGA has failed to publicly explain or account for why the tweet was deleted, given that content of the tweet was entirely factual and correct.

Since the Twitter and Facebook posts were deleted, the TGA has failed to publish any fresh advice on their social media channels about how smokers wishing to quit smoking can legally access nicotine. The only reasonable conclusion that can be drawn is that the TGA is self-censoring in an attempt to continue denying that vaping is an effective smoking cessation method.

This blatant example of self-censorship by the national medicines and chemicals regulator demonstrates its flagrant bias against nicotine vaping products and their effectiveness. The TGA has a responsibility to serve all Australians, without judgment and without prejudice, yet when it comes to offering factual information to smokers about how to legally access nicotine under the restrictive PIS regime, it proactively chooses not to as a matter of policy. This is unacceptable.

If there is a legitimate concern held either by the TGA or the Department of Health about compliance with the existing rules and regulations regarding nicotine imports or the safety of imported products, it is surely one of the primary roles and responsibilities of the regulator to ensure Australians are as informed as possible. Indeed, the [TGA website](#) itself provides that:

**It has been shown that a government regulator such as the TGA can achieve high levels of voluntary compliance through effective engagement and supply of information to those that it seeks to regulate (the regulated entities). Some of the key principles that underpin this 'responsive regulation' approach are:**

- **'Benefit of the doubt' principle**
  - The assumption is that the majority of regulated entities intend to comply with the regulatory schemes.
- **Targeting likely areas of non-compliance**
  - It is important to identify individuals or sectors of the regulated community at risk of non-compliance by assessing risks and analysing data, and to take appropriate preventive action (e.g. communication, training, inspections and audits).
- **More communication and training = higher levels of voluntary compliance.**

We believe that if the TGA and the unelected Health autocrats simply did the jobs they were already paid to do there would be no need to amend the Poisons Standard in the manner being proposed. If the TGA communicated accurate and up to date information to relevant stakeholders – as per the deleted tweet cited above – then whatever concerns about compliance or product safety that may be held could be better managed, no matter how non-existent or distorted from reality such concerns are. Indeed if the Health politburo's application is approved, the TGA will be obligated to accurately communicate and raise awareness about how Australian smokers can access nicotine under the updated access arrangements, though based on their recent past performance, it appears it has no desire or willingness to do so.

Finally, the TGA claims to be a world-class regulator that applies a risk-based approach to regulation, and even claims to work closely with international regulators.<sup>2</sup> If this was truly the case then nicotine vaping would have been made legal in Australia many years ago, as regulators in the UK, the US, Canada, the EU and New Zealand have done.

### Substance of the amendment

Beyond the many valid concerns with the secretive actions of unelected health officials and complete lack of confidence in the TGA as an impartial regulator, Australian retailers, vape stores, vapers, smokers and their families are also extremely frustrated and angered by the willful and ongoing attack on their rights that this proposal represents.

In any sensible and rational policy-setting environment, policy makers usually only propose new measures and regulations in response to a clearly identified and defined public policy issue or concern. However sadly for Australian vapers, smokers and their families, Department of Health autocrats are operating in a sensibility and rationality free zone, refusing to be guided by the science when it comes to vaping.

The reality is that these unelected health officials can point to no major problem or concern that this application is intended to address because there is simply no problem that needs solving. To date, no Australian has died or been hospitalised as a result of using electronic nicotine products. There is no public health emergency or harm associated with the current use of e-cigarettes and vaping products in Australia that is in need of a response. There is no evidence that particularly vulnerable groups, underage Australians or large cohorts of non-smokers are being exploited or are otherwise accessing and using e-cigarettes when they shouldn't.

If anything, the only motivation driving these unelected Health autocrats is the growing success, effectiveness and popularity of safer alternatives to traditional cigarettes. Globally the use and popularity of electronic nicotine products is growing exponentially. In Australia we are also witnessing record numbers of smokers making the informed choice to switch to less harmful vaping products. Tragically, it seems that the stronger the international evidence that vaping saves lives, the more that unelected Health autocrats oppose these lifesaving products.

While every other civilised nation in the world acknowledges and accepts the science that vaping is safer than smoking and saves lives, the TGA and other Australian regulators are pathologically obsessed with promoting and protecting tobacco use at all costs, despite knowing full well the pain, trauma and misery they are inflicting on thousands of Australians every year.

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<sup>2</sup> <https://www.tga.gov.au/tga-regulatory-framework>

### An illogical and senseless non-necessity

Fundamentally, this is an illogical, flawed, unnecessary and frankly stupid proposal. As already outlined, there is no clear justification nor is there a strong public policy imperative to amend the Poisons Standard as proposed by the Department of Health.

Under this proposal, nicotine liquids will continue to be a Schedule 4 and Schedule 7 substance, with liquid nicotine for vaping accessible with a prescription via the Personal Importation Scheme (PIS).

Given that Nicotine is already a Schedule 4 substance requiring a prescription, there is no sensible justification for adding Nicotine to Appendix D, Item 5, unless of course the department plans to harass and target vapers in the community on the basis of this new provision.

There is also no need to clarify any of the access arrangements for nicotine as stated in the reasons for the proposal. Australian vapers and smokers already know how difficult it is to access nicotine via the PIS. If the Department of Health does not understand how the Poisons Standard works, instead of wasting precious public resources and diverting efforts away from the COVID-19 pandemic in order to reschedule nicotine, a better approach would be to provide appropriate training and guidance to their staff about how the Poisons Standard actually works.

### Gross misuse and abuse of the TGA and Poisons Standard scheduling process

The changes proposed will not prevent Australian vapers from accessing nicotine via the Personal Importation Scheme as is currently permitted, so the amendment appears to be designed as a pre-cursor for further restrictions on accessing nicotine – both at our borders and within the community – that the Health politburo is secretly planning to implement.

The explanation provided for in the reasons for the proposal indicate that a crackdown on vapers having a valid prescription is imminent:

- The proposed amendment to include a new entry for nicotine in Appendix D, Item 5 will ensure that possession of Schedule 4 products containing nicotine must be in accordance with a legal prescription. (Emphasis added)

Because of the secretive process, lack of any meaningful stakeholder consultation, and zero transparency about the policy rationale for the entire application, the only logical explanation for this specific amendment is to compel state and federal law enforcement agencies to intercept every nicotine liquid import at the border and to harass, intimidate, persecute and prosecute vapers in Australian streets.

The unelected Health autocrats who are pushing this unscientific and ideological crackdown have a responsibility to outline what the additional regulatory costs to the Australian Border Force (ABF) and to each state and territory police force will be to enforce this wasteful and completely unnecessary crackdown.

If this application is accepted, state and territory police as well as ABF resources will be diverted away from their core responsibilities in order to harass and intimidate innocent Australian vapers who are simply trying to quit smoking and improve their own health.

This in our view represents a gross misuse of process and abuse of power.

It exposes the sheer arrogance and contempt for human life by these unelected and completely unaccountable Health autocrats and highlights the extreme lengths they will go to force vapers back to smoking harmful combustible tobacco and send them to a certain death.

#### [This application pre-empts a prior application to reschedule nicotine](#)

Despite claiming otherwise, it is clear that this application is also an attempt by the Health politburo to seek to pre-empt a prior application which would exempt Heated Tobacco Products (HTP) from the Poisons Standard.

On this basis we submit that should the already submitted HTP application succeed, the Department of Health application ought to be automatically rejected and nullified, because the relevant schedule that this application refers to will no longer be in force.

Given that the TGA already has a vested interest and a long history of protecting both lethal tobacco products as well as completely ineffective pharmacological treatments and has no desire to consider the most effective quitting aids, namely nicotine vaping, it is not unreasonable to conclude that the TGA will use the Department of Health application as a basis to refuse the HTP application.

#### [This application will kill innocent Australians](#)

In considering what the consequences of this application will do, it is worthwhile acknowledging the real-world impacts and consequences of the proposed amendments.

There is no other logical or plausible explanation for this amendment than to attempt to deprive the current and potential future vaping community from accessing substantially less harmful nicotine vaping products and force Australians to keep smoking lethal combustible tobacco products.

This is reckless, irresponsible and will cost the lives of millions of innocent Australians – at least 200,000 vapers and at least two million smokers. These people will die horribly painful, traumatic and entirely avoidable deaths, purely because unelected health autocrats have an irrational, unscientific, ideological and pathological vendetta against vaping.

## TGA and the Department of Health continue to endorse Big Tobacco and Big Pharma

There can be no denying that the biggest beneficiaries of this application is Big Pharma and Big Tobacco, as it forces vapers and smokers back to using their products, irrespective of how harmful or useless they are.

The TGA has many opportunities every year to remove the current exemption for tobacco prepared and packed for smoking, effectively outlawing traditional cigarettes in Australia, however it consistently chooses not to. The TGAs and the Health Department's ongoing legal protection for multinational tobacco companies and their lethal products is utterly devastating.

And for reasons best known to the TGA, it also continues to irrationally support the sale of expensive but otherwise ineffective pharmaceutical products such as Zyban, Champix, nicotine patches, nicotine sprays, nicotine gums, nicotine inhalers and nicotine lozenges. On any objective measure these TGA endorsed quit smoking methods, some of which are heavily subsidised by taxpayers through the PBS, have had very little to no success in reducing Australia's smoking rate.

In fact, if the TGA or the unelected Health autocrats can point to any other smoking cessation product that has been anywhere near as effective as nicotine vaping then Australian retailers and their customers would be interested to learn what that product is.

## The evidence in support of vaping

The overwhelming majority of peer-reviewed scientific literature clearly and unambiguously supports vaping and e-cigarettes as safer alternatives to cigarettes. The available evidence demonstrates that vaping and e-cigarettes pose no health risk to bystanders, are an effective tool to help smokers quit permanently, significantly reduce overall smoking rates as well as teen rates of smoking, and that legalising smoke-free products will deliver health system and broader economic savings.

In every other civilised nation in the world there is no longer any debate that e-cigarettes and nicotine vaping are less harmful than traditional cigarettes. While we accept that vaping may pose some potential risk, the available scientific evidence that vaping is far less harmful than traditional cigarettes is now settled and accepted. In these nations, the discussion is now appropriately focused on how to best regulate e-cigarettes and vaping products to ensure all potential harm-reduction opportunities are being maximised.

In Australia, opposition to vaping is unscientific and is based purely on ideology and emotion. To date the growing weight and strength of evidence in favour of vaping has failed to persuade anti-vaping groups that vaping is less harmful than smoking cigarettes. The current unscientific anti-vaping stance by Australian medical groups is both bizarre and tragic. The result is that the most harmful delivery method of nicotine, combustible tobacco, remains legally protected and the most widely available in Australia. While the precise motivations of Australian opponents of vaping are unclear, the reality is their inability or unwillingness to accept the settled international scientific consensus is resulting in many thousands of painful and traumatic and ultimately unnecessary deaths every year.

## Smoking is the leading cause of preventable death in Australia

There are currently around 3 million smokers and we estimate over 300,000 vapers in Australia. Smoking is the single largest cause of preventable death, causing 21,000 smoking related deaths every year. This equates to 58 deaths every day or a death every 25 minutes.

Smoking was the leading cause of cancer (22%) as well as the leading cause of the preventable burden of disease (9.3%).

Smoking combustible tobacco, including second-hand or passive smoking, is responsible for a large number of causes of death including:

- lung cancer
- bladder cancer
- pancreatic cancer
- kidney cancer
- breast cancer
- liver cancer
- bowel cancer
- cervical cancer
- oesophagael cancer
- stomach cancer
- prostate cancer
- laryngeal cancer
- nasopharyngeal cancer
- acute myeloid leukaemia
- chronic myeloid leukaemia
- chronic lymphocytic leukaemia
- aortic aneurysm
- COPD



- asthma
- lip and oral cavity cancer
- stroke
- coronary heart disease
- atrial fibrillation and flutter
- gallbladder and bile duct disease
- otitis media
- gastroduodenal disorders
- hypertensive heart disease
- lower respiratory infections
- other cardiovascular diseases

The Australian Institute of Health and Welfare (AIHW) estimates that smoking related harm costs the community around \$136.9 billion a year in social and economic costs, but potentially as high as \$399.7 million per year.<sup>3</sup>

The rate of smoking cessation has also failed to decline significantly recently, with the AIHW reporting a modest 0.6% fall between 2013-2016.<sup>4</sup>

There have been no nicotine vaping or e-cigarette related deaths ever reported in Australia, or anywhere in the world.

### Vaping and e-cigarettes less harmful than combustible tobacco

Public Health England (PHE) has declared categorically and emphatically that nicotine vaping is at least 95 per cent less harmful than traditional cigarettes. PHE first published it's 95 per cent safer finding in a 2015 expert review which examined a decade worth of data:<sup>5</sup>

- Best estimates show e-cigarettes [EC] are 95% less harmful to your health than normal cigarettes.
- Acknowledging that the evidence base on overall and relative risks of EC in comparison with smoking was still developing, experts recently identified them as having around 4% of the relative harm of cigarettes overall (including social harm) and 5% of the harm to users.

In 2018, PHE published an Evidence Update<sup>6</sup> to the 2015 expert review, finding:

- The cancer potencies of e-cigarettes were largely under 0.5% of the risk of smoking
- Based on current knowledge, vaping is at least 95% less harmful than smoking remains a good way to communicate the large difference in relative risk unambiguously so that more smokers are encouraged to make the switch from smoking to vaping.

<sup>3</sup> <http://ndri.curtin.edu.au/NDRI/media/documents/publications/T273.pdf>

<sup>4</sup> <https://www.aihw.gov.au/reports/alcohol/alcohol-tobacco-other-drugs-australia/contents/interactive-data/tobacco>

<sup>5</sup> <https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update>

<sup>6</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/684963/Evidence\\_review\\_of\\_e-cigarettes\\_and\\_heated\\_tobacco\\_products\\_2018.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/684963/Evidence_review_of_e-cigarettes_and_heated_tobacco_products_2018.pdf)

And specifically in relation to the hysterical conjecture from the so-called ‘public health’ bodies that pathologically hate vaping, PHE responded as follows:<sup>7</sup>

The estimate that e-cigarette use is around 95% safer than smoking is based on the facts that:

- the constituents of cigarette smoke that harm health – including carcinogens – are either absent in e-cigarette vapour or, if present, they are mostly at levels much below 5% of smoking doses (mostly below 1% and far below safety limits for occupational exposure)
- the main chemicals present in e-cigarettes only have not been associated with any serious risk

The Royal College of Physicians (RCP) is the oldest and most respected medical college in the world. RCP was founded in 1518 and has extensively and successfully championed a range of major public health initiatives since it was formed. For example, RCP was the first to alert smokers to the dangers posed by cigarettes in 1962 and has consistently provided evidence-based advice and guidelines about smoking and other public health priorities to their members and to the wider medical community throughout their existence.<sup>8</sup>

On the issue of vaping e-cigarette use the RCP advice is clear and as recently as 25 October 2019 circulated a Position Statement firmly stating that **“vaping is still far less harmful than smoking tobacco.”**<sup>9</sup>

The RCP formally outlined its strong science-based support for vaping in its major April 2016 policy report, *Nicotine without smoke: Tobacco harm reduction*, stating:<sup>10</sup>

**“The hazard to health arising from long-term vapour inhalation from the e-cigarettes available today is unlikely to exceed 5% of the harm from smoking tobacco.”**

The Royal College of General Practitioners (RCGP) also supports e-cigarette (EC) use, with their official advice to Primary Care Clinicians (PCCs) outlined in its 2017 position statement:<sup>11</sup>

The evidence so far shows that e-cigarettes have significantly reduced levels of key toxicants compared to cigarettes, with average levels of exposure falling well below the thresholds for concern.

A recent study showed that long-term e-cigarette users (who had been using their product for 17 months on average) had significantly lower levels of key toxicants in their urine than those that still smoked – with levels in e-cigarette users similar to exclusive Nicotine Replacement Therapy (NRT) users.

Passive vaping: There is no good evidence to suggest that passively breathing vapour from e-cigarettes is likely to be harmful.

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<sup>7</sup>[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/456704/McNeill-Hajek\\_report\\_authors\\_note\\_on\\_evidence\\_for\\_95\\_estimate.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/456704/McNeill-Hajek_report_authors_note_on_evidence_for_95_estimate.pdf)

<sup>8</sup> <https://www.rcplondon.ac.uk/projects/outputs/smoking-and-health-1962>

<sup>9</sup> <https://www.rcplondon.ac.uk/projects/outputs/rcp-advice-vaping-following-reported-cases-deaths-and-lung-disease-us>

<sup>10</sup> <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction>

<sup>11</sup> <https://www.rcgp.org.uk/-/media/Files/Policy/2017/RCGP-E-cig-position-statement-sept-2017.ashx?la=en>

PCCs recognize ECs offer a wide reaching, low-cost opportunity to reduce smoking (especially in deprived groups in society and those with poor mental health, both having elevated rates of smoking).

Cancer Research UK (CRUK) also supports nicotine vaping as a scientifically proven safer alternative to combustible cigarettes as well as an effective smoking cessation tool. Their current policy position on e-cigarettes states:<sup>12</sup>

**“While nicotine is addictive, and not entirely harmless, e-cigarettes do not contain the extensive cocktail of cancer-causing chemicals found in combustible tobacco. While the long-term health consequences of e-cigarette use are uncertain, the evidence so far suggests that e-cigarettes are far less harmful than smoking. Evidence to date indicates they are far less harmful than tobacco cigarettes given that tobacco is associated with more than one in four cancer deaths in the UK. There is also growing evidence to suggest that e-cigarettes can work successfully as an aid to cessation.”**

The British Medical Association (BMA) supports the use of e-cigarettes, and has developed a firm and unambiguous policy position to recommend e-cigarettes to patients as a safer alternative to smoking and as an effective quitting aid.<sup>13</sup>

The BMA advice to their members based on the policy position published by the BMA Board of Science states:

- There is growing consensus that using an e-cigarette is substantially safer than smoking tobacco.
- There is no situation in which it is safer to continue smoking than to use an e-cigarette.
- Unlike cigarette smoking, e-cigarette use does not expose users to the products of combustion, and most of the toxicants causing smoking-related disease are absent or significantly reduced in e-cigarette vapour.

The British Heart Foundation commissioned researchers from Dundee University to conduct a major randomized control trial to study the impact of electronic cigarettes (EC) on cardiovascular health compared to traditional cigarettes (TC).

Known as the VESUVIUS (Vascular Effects of Regular Cigarettes Versus Electronic Cigarette Use) trial, over two years researchers investigated a range of cardiovascular and other biomarker indicators of traditional cigarette smokers compared to smokers who switched to e-cigarettes (both with and without nicotine).<sup>14</sup>

The VESUVIUS findings are clinically important. Not only does the study confirm that both nicotine and non-nicotine containing e-cigarettes are a safer and less harmful alternative to traditional cigarettes, but that significant improvements in cardiovascular health were

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<sup>12</sup> [https://www.cancerresearchuk.org/sites/default/files/e-cigarette\\_briefing\\_july\\_2018\\_final.pdf?utm\\_source=t.co&utm\\_medium=referral](https://www.cancerresearchuk.org/sites/default/files/e-cigarette_briefing_july_2018_final.pdf?utm_source=t.co&utm_medium=referral)

<sup>13</sup> <https://www.bma.org.uk/collective-voice/policy-and-research/public-and-population-health/tobacco/e-cigarettes>

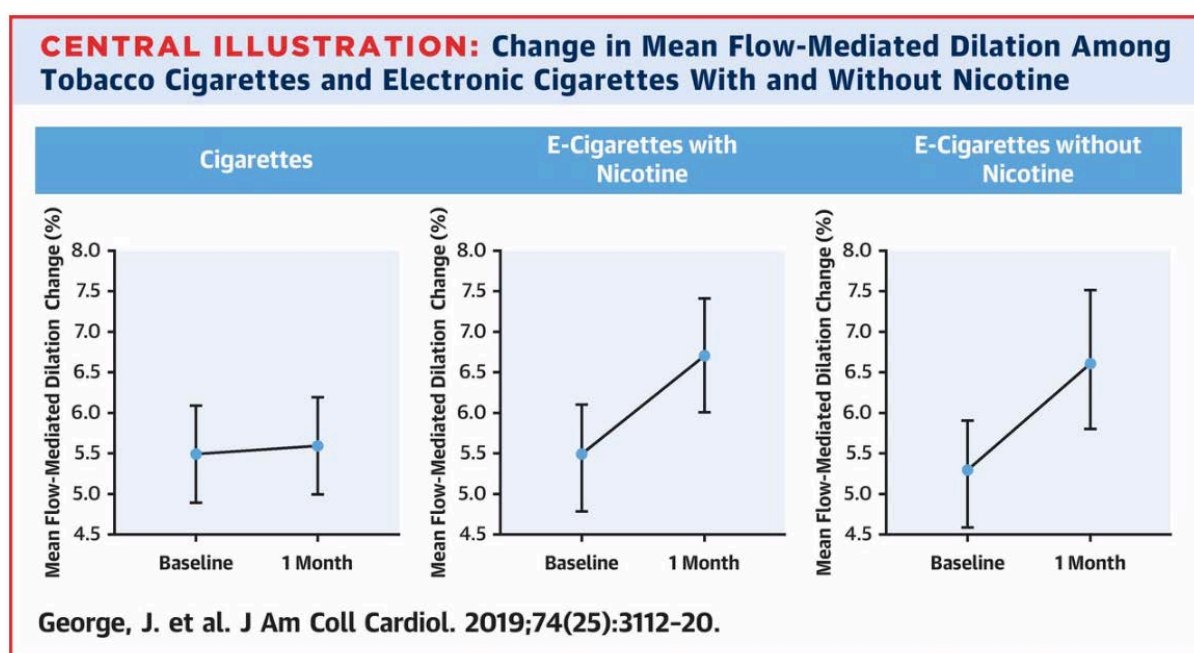
<sup>14</sup> <http://www.onlinejacc.org/content/74/25/3112>

observed within a month of switching. The study also found females recorded the most benefit by switching from smoking to vaping.

Key findings of the study are set out here:

- The main findings from this present study are that within 1 month of switching from TC to EC, smokers demonstrate a significant improvement in vascular function.
- First, there is an early benefit to vascular function from switching from TC to EC. Within the switching time frame of 1 month, chronic smokers demonstrated significant improvements in vascular endothelial function. This is consistent with the recent review by Benowitz and Fraiman (20) that switching from TC to EC might result in overall benefit to public health.
- Second, vascular stiffness was also significantly reduced within 1 month of switching in smokers of  $\leq 20$  pack-years compared with in those who smoked  $>20$  pack-years, suggesting that the trend toward lower blood pressure in the EC arms could be important.
- Third, switching to EC from TC may benefit females more than males and this is also seen in females who were less compliant (dual use).
- Fourth, those who complied best with allocated therapy, as indicated by exhaled CO levels, benefitted the most in terms of improvement in endothelial function.
- Finally, there was no difference observed between the 2 EC arms (with and without nicotine) for this short-term study.

The graph below depicts the recorded improvement in vascular function observed among test subjects in the first month of the VESUVIUS trial. These findings are beyond compelling.



Source: <http://www.onlinejacc.org/content/74/25/3112>

Across the Tasman in New Zealand there is near universal support for vaping as a proven harm-reduction and smoking cessation tool. The New Zealand Government (in a bi-partisan spirit), the New Zealand Medical Association, Maori advocacy groups and public health advocates all firmly support vaping as a proven harm-reduction measure, and vaping is a key component that will help the nation achieve its Smoke Free 2025 goal.

The New Zealand Government has launched an official website dedicated to promoting vaping as a healthier, and cheaper, alternative to smoking and encouraging New Zealand smokers to make the switch from cancer-causing combustible products to safer smoke free alternatives.

The New Zealand Ministry of Health Promotion's Vaping Facts website ([www.vapingfacts.health.nz](http://www.vapingfacts.health.nz)) provides a wealth of science-based and fact-checked advice, support and information for New Zealand smokers about the benefits of vaping over smoking. Notable examples of the plain-speaking and unambiguous advice include:

- Vaping is a way to quit cigarettes by getting nicotine with fewer of the toxins that come from burning tobacco.
- You get to stay social, spend less, and once you've quit smoking you'll feel better for it.
- For those who smoke, switching to vaping is likely to substantially reduce health risks.
- The difference between smoking and vaping is that smoking delivers nicotine by burning tobacco, which can cause smoking-related illnesses, and vaping can deliver nicotine by heating a liquid in a much less harmful way.

The New Zealand Medical Association (NZMA) firmly supports the use of e-cigarettes as a safer alternative to traditional cigarettes as well as a quit smoking method. The NZMA Position Statement, Smokefree 2025 New Zealand states:<sup>15</sup>

- It is likely that e-cigarettes will be an effective tool for smokers who want to quit. There is general scientific consensus that the exclusive use of nicotine-containing e-cigarettes is considerably less harmful than smoking.
- We support making nicotine-containing e-cigarettes legally and readily available in New Zealand for adults, contingent on an appropriate regulatory regime that ensures due care for unintended harms and risks.

Based on the inclusion and promotion of vaping as a critical weapon in its anti-smoking arsenal, New Zealand may well become the first nation in the world to become smoke-free, demonstrating in blunt terms how putting aside ideology and emotion and pursuing evidence-based policy in a mature, responsible and clear-eyed way can deliver vast improvements to the quality of life for citizens.

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<sup>15</sup> [https://global-uploads.webflow.com/5e332a62c703f653182faf47/5e332a62c703f60bd72fc64e\\_Smokefree-New-Zealand-Position-Statement\\_July-2017\\_FINAL.-docx.pdf](https://global-uploads.webflow.com/5e332a62c703f653182faf47/5e332a62c703f60bd72fc64e_Smokefree-New-Zealand-Position-Statement_July-2017_FINAL.-docx.pdf)

The US National Academies of Science Engineering and Medicine (NASEM) was commissioned by the US FDA to assess the evidence on vaping and made a number of important findings including<sup>16</sup>:

- Conclusion 18-1. There is *conclusive evidence* that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes.
- Conclusion 5-3. There is *substantial evidence* that except for nicotine, under typical conditions of use, exposure to potentially toxic substances from e-cigarettes is significantly lower compared with combustible products.

In January 2020, the Royal Australian College of General Practitioners (RACGP) also updated its *Supporting smoking cessation* guidelines to endorse the use of e-cigarettes as a quit smoking tool.<sup>17</sup>

In April 2020, the Royal Australasian College of Physicians (RACP) updated its policy position to endorse vaping as a safer alternative to traditional cigarettes and as a proven quitting aid. Specifically, the RACP stated in its submission to the New Zealand Parliamentary Committee reviewing the country's proposed vaping laws:<sup>18</sup>

For those who do smoke, the RACP believes that vaping has potential as a smoking cessation tool.

Professor Chris Bullen, representing the RACP, told the New Zealand Parliamentary Committee considering the nation's proposed vaping regulations:<sup>19</sup>

- I think there has been a growing body of research evidence that gives us greater confidence in suggesting that for smokers, e-cigarettes should be something that they should be encouraged to move towards if they can't directly quit smoking through the other established evidence based means of smoking cessation support.
- Our position is that vaping is not for non smokers, but it is something that should be available for smokers who are keen to improve their health and move away from cigarette smoking. As I said, the evidence for vaping is growing.
- We think in making e-cigarettes more available, we believe there's an opportunity to reduce some of the tobacco related health inequalities in New Zealand, which contribute to several years of life expectancy difference and a whole host of other health consequences.

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<sup>16</sup> <https://www.nap.edu/resource/24952/012318ecigaretteConclusionsbyEvidence.pdf>

<sup>17</sup> <https://www.racgp.org.au/getattachment/00185c4e-441b-45a6-88d1-8f05c71843cd/Supporting-smoking-cessation-A-guide-for-health-professionals.aspx>

<sup>18</sup> [https://www.racp.edu.au/docs/default-source/advocacy-library/racp-submission-to-the-health-select-committee-smokefree-environments-and-regulated-products-vaping-amendment-bill.pdf?sfvrsn=fe0ce81a\\_6](https://www.racp.edu.au/docs/default-source/advocacy-library/racp-submission-to-the-health-select-committee-smokefree-environments-and-regulated-products-vaping-amendment-bill.pdf?sfvrsn=fe0ce81a_6)

<sup>19</sup> <https://athra.org.au/wp-content/uploads/2020/04/RACP-oral-submission-to-NZ-inquiry-16April2020.pdf>



- **Cigarette smoking is the most harmful behavior people can do generally around the globe. We think vaping isn't perfect, it's not completely safe, but it is proportionately much less harmful than continuing to smoke.**

The Royal Australian and New Zealand College of Psychiatrists (RANZCP) has endorsed vaping since October 2018 in recognition of the high smoking prevalence amongst people with mental health or psychiatric conditions, and the fact that smoking causes the most harm to this cohort of patient.<sup>20</sup>

The RANZCP policy states:

**In recognition of the disproportionately high smoking prevalence, and low quit rates, among people living with mental illness, the Royal Australian and New Zealand College of Psychiatrists (RANZCP) supports the legalisation and regulation of nicotine-containing e-cigarettes and other vaporised nicotine products to facilitate their use as harm reduction tools.**

And:

**E-cigarettes and vaporisers may provide a less harmful way to deliver nicotine to those who are unable or unwilling to stop smoking tobacco.**

In addition to the three major Australian medical colleges that endorse vaping, a number of highly regarded international medical organisations also support the use of vaping, including:

- The New Zealand Health Promotion Agency
- The New Zealand Medical Association
- Hāpai Te Haora (Maori Public Health)
- The New Zealand College of General Practitioners
- Heart Foundation New Zealand
- Cancer Society New Zealand
- Quitline NZ
- Pharmacy Guild of New Zealand
- Public Health England
- The British National Health Service
- Royal College of General Practitioners
- Royal College of Physicians
- Royal College of Psychiatrists
- The Royal College of Midwives
- Royal College of Nursing
- Cancer Research UK
- The British Medical Association
- The British Lung Foundation
- The British Heart Foundation
- The US National Academies of Sciences Engineering Medicine (NASEM)

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<sup>20</sup> <https://www.ranzcp.org/news-policy/policy-and-advocacy/position-statements/e-cigarettes-and-vaporisers>

The TGA cannot simply ignore the overwhelming evidence outlined above or dismiss the carefully considered science-based positions of these highly respected international medical and research bodies. The various policy positions referenced in this section represent only a small handful of the many organisations globally that also support vaping as a safer alternative to traditional cigarettes.

Australian vapers, smokers and their families deserve a satisfactory justification if the TGA chooses to reject the science-based positions advocated by these highly esteemed Australian and international organisations, particularly in light of the TGAs continued and active explicit legal endorsement of traditional cigarettes which currently kill 58 Australians every day.

### Most effective quit tool

The available evidence establishes nicotine vaping and e-cigarettes are more effective than pharmacologically approved products, including those that are subsidised by the taxpayer through the Pharmaceutical Benefits Scheme (PBS).

The British National Health Service (NHS) have concluded that e-cigarettes are twice as effective as Nicotine Replacement Therapy (NRT) for quitting smoking.<sup>21</sup>

The Cochrane Review, one of the most comprehensive research studies into the efficacy of e-cigarettes and relied on by Public Health England and many others, found that e-cigarette use with nicotine does help smokers stop smoking.<sup>22</sup>

While pharmacological methods have been through rigorous TGA approvals process to enable them to be sold with a therapeutic health claim, a number of studies now confirm that it is nicotine vaping and e-cigarettes that are the most effective.

As Mendelsohn, Hall and Borland have researched, nicotine vaping and e-cigarettes are driving the major reductions in smoking rates in a number of countries around the world.<sup>23</sup>

The RCGP Policy Statement states:<sup>24</sup>

**“Since late 2013, ECs have become England’s most popular quitting aid. There is now growing evidence to suggest that ECs are helping users to stop smoking, with it being estimated that ECs contributed to an additional 18,000 long-term ex-smokers in England in 2015.”**

### ‘Gateway’ Theory

There has been some concern that vaping will cause teenagers and even adult non-smokers to become attracted to vaping, because it is significantly safer and tastes better than smoking, and then be tempted to switch to combustible tobacco, which is universally accepted taste terrible and cause death and disease. This is known as the ‘gateway theory’

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<sup>21</sup> <https://www.nhs.uk/news/heart-and-lungs/e-cigs-twice-effective-nicotine-patches-gum-or-sprays-quitting/>

<sup>22</sup> <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub3/abstract>

<sup>23</sup> <https://colinmendelsohn.com.au/wp-content/uploads/2020/01/Mendelsohn-C-Hall-W-Borland-R.-Could-vaping-help-reduce-smoking-rates-in-Australia.-Drug-Alcohol-Rev-2020.pdf>

<sup>24</sup> <https://www.rcgp.org.uk/-/media/Files/Policy/2017/RCGP-E-cig-position-statement-sept-2017.ashx?la=en>



and postulates that e-cigarettes will either attract people that would otherwise not smoke or 'normalise' smoking and undo decades of tobacco control and reductions in smoking rates.

While ARVIA is very concerned to ensure that teens or 'never smokers' do not start smoking or vaping, the reality is there is simply no published peer-reviewed evidence to support that the 'gateway theory' has occurred in practice anywhere in the real world.

In fact the evidence consistently contradicts the 'gateway theory', and in nations where vaping is legal, teen smoking rates as well as overall smoking rates overall continue to decline.<sup>2526</sup>

The Levy et al study (16) shows that smoking among 15-21 year olds in the US fell three times faster after vaping became popularized.

Professor John Britton, Director of the UK Centre for Tobacco & Alcohol Studies at the University of Nottingham said in response to the Levy study:<sup>27</sup>

**"This study demonstrates that the availability of electronic cigarettes in the USA appears to have contributed to further declines in smoking among younger and older smokers, and more specifically that any gateway effect into smoking is more than offset by the effects of vaping among young people who would otherwise have smoked, and use of electronic cigarettes as a gateway away from smoking.**

**"The figures show similar trends to those observed in the UK, where electronic cigarettes have contributed substantial public health gains, and will hopefully help to reassure US commentators who have to date emphasised the risks of gateway progression in advocating restrictive policies on electronic cigarette use."**

Another study examining tobacco use in England, Scotland and Wales among 248,324 young people concluded that there was no renormalisation of youth smoking as a result of e-cigarettes.<sup>28</sup>

Since 2016, the Royal College of Physicians has clarified that e-cigarettes are not a gateway to smoking and do not result in normalisation of smoking. Its clear and unambiguous advice as published on its website<sup>29</sup>:

- ***E-cigarettes are not a gateway to smoking** – in the UK, use of e-cigarettes is limited almost entirely to those who are already using, or have used, tobacco.*
- ***E-cigarettes do not result in normalisation of smoking** – there is no evidence that either nicotine replacement therapy (NRT) or e-cigarette use has resulted in renormalisation of smoking. None of these products has to date attracted significant use among adult never-smokers, or demonstrated evidence of significant gateway progression into smoking among young people.*

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<sup>25</sup> <https://athra.org.au/wp-content/uploads/2018/11/Levy-D.-Examining-the-relationship-of-vaping-to-smoking-initiation-among-US-youth-and-young-adults.-Tob-Control-2018.pdf>

<sup>26</sup> <https://www.sciencedirect.com/science/article/abs/pii/S0376871617300236?via%3Dihub>

<sup>27</sup> <https://www.sciencemediacentre.org/expert-reaction-to-smoking-rate-and-popularity-of-vaping-in-the-u-s/>

<sup>28</sup> <https://tobaccocontrol.bmj.com/content/early/2019/03/08/tobaccocontrol-2018-054584>

<sup>29</sup> <https://www.rcplondon.ac.uk/news/promote-e-cigarettes-widely-substitute-smoking-says-new-rcp-report>

- ***E-cigarettes and quitting smoking*** - among smokers, e-cigarette use is likely to lead to quit attempts that would not otherwise have happened, and in a proportion of these to successful cessation. In this way, e-cigarettes can act as a gateway from smoking.
- ***E-cigarettes and long-term harm*** - the possibility of some harm from long-term e-cigarette use cannot be dismissed due to inhalation of the ingredients other than nicotine, but is likely to be very small, and substantially smaller than that arising from tobacco smoking. With appropriate product standards to minimise exposure to the other ingredients, it should be possible to reduce risks of physical health still further. Although it is not possible to estimate the long-term health risks associated with e-cigarettes precisely, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure.

In fact, there are no studies available from anywhere in the world that can demonstrate a direct causation between e-cigarette use and smoking. Of course, this is one of the central arguments that the ideological and pathological opponents of vaping often cite, however it is an argument with absolutely no basis in fact.

The consistent observation that all of the available literature shows is that there is an 'association' or a 'correlation' between people that tend to smoke and use e-cigarettes, but there is no evidence that using one leads to the other. Correlation Bias, or Illusory Correlation, is a very basic hazard of any type of research and it is concerning that a handful of apparently highly qualified scientists in the field of tobacco research are unable to grasp the concept, let alone recognise that they are guilty of committing such bias in their own research or identifying it in the research of others.

The 'gateway theory', as baseless as it is, is one of the last remaining vestiges of anti-vaping groupthink as all of the other absurd claims and assertions used to defend combustible tobacco and oppose vaping are systematically dismantled one by one. The 'gateway theory' is the very definition of 'fake news' if ever one was needed.

## Risk to bystanders

There is no health risk to bystanders posed by e-cigarette vapour according to peer-reviewed research by Public Health England.<sup>30</sup>

**To date, there have been no identified health risks of passive vaping to bystanders. Reporting of some academic studies has been misleading.**

## Health system savings

There are also significant health system savings to be achieved if Australia were to follow the lead of every other civilised nation in the world and make nicotine vaping legal. A major study conducted by researchers from the University of Otago and the University of Melbourne into

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<sup>30</sup> <https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review/evidence-review-of-e-cigarettes-and-heated-tobacco-products-2018-executive-summary#health-risks-of-e-cigarettes>

New Zealand's science-based endorsement for nicotine vaping found that liberalising access to e-cigarettes delivers net health gain and cost savings.

The study, "Potential country-level health and cost impacts of legalizing domestic sale of vaporized nicotine products.", published in the journal *Epidemiology*, found:<sup>31</sup>

**"Compared with continuation of baseline trends in smoking uptake and cessation rates and negligible vaporized nicotine use, we projected liberalizing the market for these products to gain 236,000 QALYs (95% uncertainty interval [UI] = 27,000 to 457,000) and save NZ\$3.4 billion (2011 NZ\$) (95% UI = NZ\$370 million to NZ\$7.1 billion) or US\$2.5 billion (2017 NZ\$)."**

This important research confirms that supporting vaping will not only improve the quality and length of life for all citizens, but it will also save taxpayers money on expensive smoking related health costs.

The study concluded that on a population basis, every New Zealand citizen would achieve a per person health system cost saving of NZ\$780 over their lifetime. The study authors suggest the results of this research are applicable to Australia.<sup>32</sup>

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[https://journals.lww.com/epidem/Citation/2019/05000/Potential\\_Country\\_level\\_Health\\_and\\_Cost\\_Impacts\\_of.14.aspx](https://journals.lww.com/epidem/Citation/2019/05000/Potential_Country_level_Health_and_Cost_Impacts_of.14.aspx)

<sup>32</sup> <https://about.unimelb.edu.au/newsroom/news/2019/march/easier-access-to-nicotine-vaping-products-highly-likely-to-improve-public-health-and-reduce-health-system-costs-study>

## Potential vaping related risks

The international scientific consensus supports vaping as a safer option than smoking and establishes with a high degree of certainty that the benefits of vaping far outweigh the potential risks. However, as humans should really only ever breathe in clean air, there may still be some risks associated with the use of e-cigarettes that are not clearly understood.

The current ‘head in the sand’ approach by all Australian governments and public health groups to vaping and e-cigarettes only serves to heighten the potential risks that vaping may pose. In the short term not only does this expose Australians to an unacceptable level of potential risk right now, but in the longer term it makes managing potential risks and adverse health events associated with vaping more difficult.

Australia’s regulators and policymakers cannot continue to ignore the substantial scientific evidence in support of vaping and its benefits on one hand, while selectively and deliberately misrepresenting some of the modest and very manageable risks of vaping on the other.

As an industry, one of our highest priorities is to better understand any risk associated with vaping and to completely eliminate these risks if possible.

## Unknown long-term risks

As e-cigarettes have only been around for a relatively short amount of time, there is not yet enough evidence to fully understand the long-term adverse health impacts, if any, e-cigarette (EC) vapour exposure may pose on users.

The harm associated with traditional cigarettes is caused by the burning of the tobacco, which releases a cocktail of lethal chemicals, toxicants and carcinogens that we know cause cancers and other diseases. Vaping and e-cigarettes work by heating liquid or tobacco which releases a vapour that either does not contain these toxicants or contains far lower levels of harmful toxicants.

The most recent Public Health England (PHE) Evidence Review provides the most rigorous systematic review of the available evidence on both adverse reactions to EC and the overall effect of EC vapour on users. The review examines the composition of EC and EC aerosol, including the biomarkers for exposure of EC compared to combustible tobacco.<sup>33</sup>

The main conclusion of the updated review remains that **“EC were substantially less harmful than smoking”** and **“that most toxins responsible for health damage from smoking are absent in EC aerosol and that those present are there at much lower levels (below 5% and mostly below 1%) than in tobacco cigarettes”**.

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[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/684963/Evidence\\_review\\_of\\_e-cigarettes\\_and\\_heated\\_tobacco\\_products\\_2018.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/684963/Evidence_review_of_e-cigarettes_and_heated_tobacco_products_2018.pdf)

The evidence review on the biomarker exposure data, on p171, concludes that:

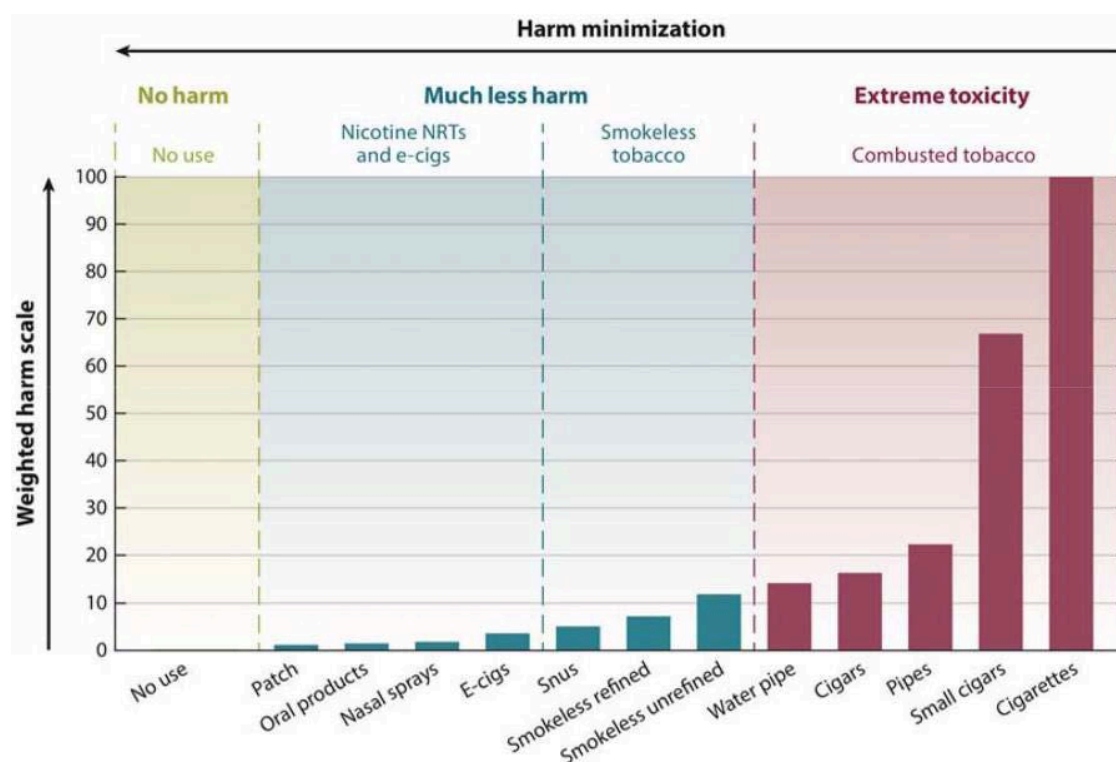
**“The biomarker data assessed in this section are consistent with significant reductions in harmful constituents and in EC users some biomarkers show similar levels to non-smokers or smokers abstaining from smoking.”**

The review warns that animal and cell studies, which many vaping opponents seek to rely on, are the weakest form of evidence **“because their relevance for estimating effects of vaping for human exposure is unclear”**.

The review states that the strongest evidence for relative risk **“will eventually come from actual health outcomes in cohorts of EC users compared to cohorts of smokers and non-smokers.”**

The only reported adverse harm contained in the review was an increased rate of chronic bronchitis symptoms such as coughing, wheezing phlegm and bronchitis among adolescents who tried EC. However, when smoking status was controlled for, the association disappeared, and in fact **“small scale or uncontrolled switching studies from smoking to vaping have demonstrated some respiratory improvements”**.

However, in acknowledging that there are potential risks, it is important to put the relative risk of vaping into perspective. Compared to combustible tobacco, the risks of vaping and EC are miniscule, as shown on the harm minimization continuum below.

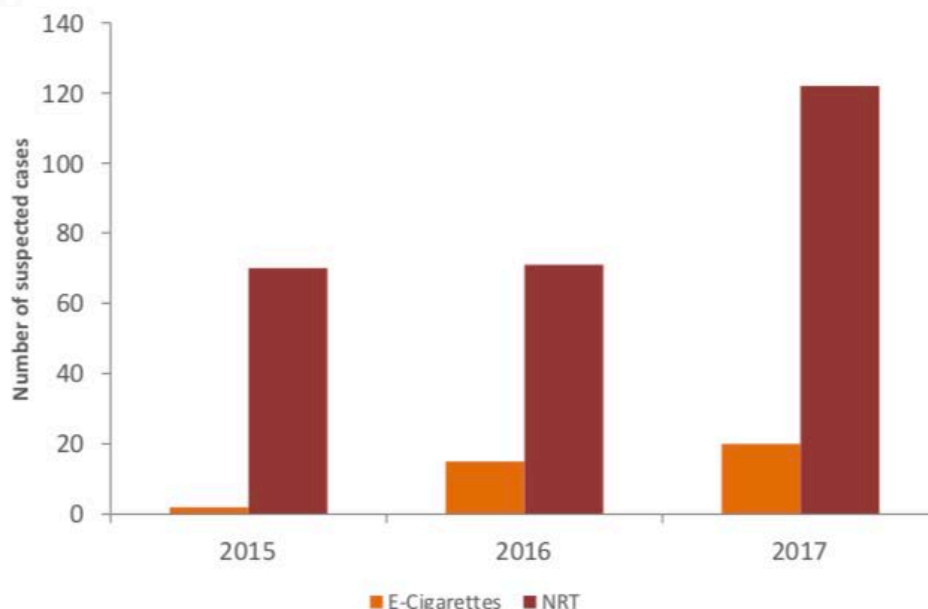


Products along the harm minimization continuum. Adapted from Nutt et al., 2014 and reproduced from Abrams et al., 2018 The figure depicts four panels representing classes of products ranging from exceptionally low harm to exceptionally high harm. Panel 1 (*left*) depicts no use and thus no exposure. Panel 2 (*left middle*) depicts the class of nicotine delivery products without any tobacco (e-cigs/e-vapor products and nicotine replacement therapies - NRTs). Products containing tobacco are depicted as noncombusted or smokeless (panel 3, *right middle*) and combusted or smoked (panel 4, *right*). Panels 2 and 3 constitute the broader supra-ordinate category of non- combusted nicotine products (NNPs).

Source: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6934253/>

The PHE evidence review surprisingly showed that vaping poses fewer risks to users than pharmacologically approved Nicotine Replacement Therapies (NRT), with significantly higher adverse reactions reported by NRT users than EC users.

**Figure 31: Number of reports of a suspected adverse reaction to EC or NRT**



Source: p151, [Evidence review of e-cigarettes and heated tobacco products 2018](#)

The PHE evidence review also concludes “that there is no clear evidence that specific flavourings pose health risks”, and the levels of “metals identified in e-cigarette aerosol do not give rise to any significant safety concerns”.

Importantly, the review states that: “An advantage of EC is that particular constituents can be removed or minimized in a way that is not feasible with tobacco cigarettes.”

And that: “Regulations should therefore be flexible to ensure any emerging evidence of constituent harmfulness can be acted upon, such that products are modified to remove any components shown to pose avoidable risks.”

It is clear that the available evidence at this point in time tells us that vaping and e-cigarettes are much safer than smoking, and that the relatively low level of known and unknown risk and potential harms both in the short and long term are not sufficient to justify banning them.

ARVIA is concerned that while all Australian vape vendors seek to operate in accordance with world’s best practice, the current lack of minimum standards and regulations in Australia still leaves vapers exposed to potentially avoidable risks with no formal mechanisms or frameworks in place to deal with product safety issues should they arise.

## E-cigarette, or Vaping, product use Associated Lung Injury (EVALI)

The widespread and sensational reporting of the 2019 outbreak of E-cigarette, or Vaping, product use Associated Lung Injury (EVALI) in the United States caused alarm and concern about the safety of all vaping products around the world. Throughout August and September of 2019 there was a large and sudden spike in hospital presentations of mostly young men in the US with a range of vaping related lung injuries.

Given that roughly 50 million people around the world were still vaping with no adverse health impacts, it was obvious to legitimate medical experts from the outset of the EVALI outbreak that the incidences of lung injuries was mostly contained to the US, and was most likely linked to particular ingredients in particular products and did not reflect the broader safety of nicotine vaping or e-cigarette products.

For example, the Australian Tobacco Harm Reduction Association (ATHRA) identified as early as 7 September 2019, before the name 'EVALI' was even formulated, that:

**The mysterious lung disease in the US is almost certainly due to vaping contaminated THC (the psychoactive ingredient in cannabis) and has nothing to do with vaping nicotine to stop smoking.**

And:

**The Centres for Disease Control and Prevention (CDC) has reported that most victims are using THC oil and most tests have identified significant amounts of Vitamin E Acetate.**

Notwithstanding that the emerging and published evidence from the CDC had already identified THC and Vitamin E Acetate as the cause of lung injuries, Australia's Chief Medical Officer Brendan Murphy nonetheless sought to exploit the outbreak and the tragic deaths in the US in order to continue to the Australian Government's and the Health Department's unscientific anti-vaping agenda, and protect the primacy of combustible tobacco in Australia.

In an advisory published on 13 September 2019, the CMO ignored the CDC early findings and shamelessly attempted to link the safety of all nicotine vaping products to the US lung injury outbreak, despite there being no evidence to support this conclusion. The CMO advice stated:<sup>34</sup>

- **There is growing evidence implicating e-cigarettes in a range of harms to individual and population health.**
- **International evidence is emerging of a possible link between the use of e-cigarettes and lung disease. This includes severe lung disease requiring intensive care support and, as at 11 September 2019, at least six fatalities being linked with vaping in the United States.**

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<sup>34</sup> <https://www.health.gov.au/news/e-cigarettes-linked-to-severe-lung-illness>



Not only was this advice designed to deliberately mislead Australians about the real causes of the outbreak as the CDC had identified, but it also failed to adequately warn vapers specifically about the harmful ingredients of concern cited by the CDC, being THC and Vitamin E Acetate. Instead, the CMO abused his position and the trust placed in his office to spread fear and misinformation about nicotine vaping more generally.

A group of 31 prominent and concerned Australian medical experts comprehensively rebutted the incorrect and misleading CMO advice in order to give the Australian community the up-to-date, accurate and evidence-based advice that the CMO irresponsibly failed to provide.

The critique, published on 18 September 2019, addresses the deceitful CMO characterization of the causes of the EVALI outbreak in the following way:<sup>35</sup>

**“The outbreak of clusters of an acute respiratory illness in the US since June 2019 has affected 380 people (confirmed and probable cases) and caused six deaths as of 12 September 2019. The pattern of this outbreak is typical of what occurs when a bad batch of illegal drugs hits the streets.**

**The investigation is ongoing, but it is increasingly clear that the outbreak is due to illicit street drugs and has nothing to do with vaping nicotine products from reputable suppliers. Not one case has been linked to nicotine vaping.**

**Where a cause has been identified, almost all cases are linked to THC liquid contaminated with vitamin E acetate.**

**This oily thickening agent has recently started to be used by black market suppliers, mostly in states where THC is illegal.**

**Many cases are described as lipoid pneumonia or pneumonitis, which is consistent with the inhalation of oil-based liquid into the lungs. Nicotine e-liquid is alcohol-based and does not contain oily ingredients.**

**The statement from the Australian health authorities uses the terms ‘e-cigarettes and vaping’ which imply vaping nicotine as a substitute for smoking and is very misleading and incorrect.**

**According to the US Food and Drug Administration (FDA) on 13 September 2019, ‘Many of the samples tested by states or by the FDA as part of this ongoing investigation have been identified as vaping products containing THC, and further, most of those samples with THC tested also contained significant amounts of vitamin E acetate’.**

The critique of the CMO advice by public health professionals was unprecedented but clearly warranted. The rebuttal ensured that Australians were given the correct information about the causes of the EVALI outbreak as well as an accurate overview of the evidence regarding nicotine vaping generally, especially in light of sensationalised and incorrect media reporting.

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<sup>35</sup> <https://athra.org.au/wp-content/uploads/2018/08/Critique-of-CMO-Statement-WEB-18Sept2019-.pdf>



Gartner, Bonevski and Hall reviewed this shameful episode in Australian public health and found that the impact of health authorities deliberately misleading about the causes of the outbreak would ultimately erode public trust in the media and health authorities:<sup>36</sup>

**The failures of the Australian and international media to accurately convey the facts about this outbreak put public trust in the media, and the health authorities in these reports, at risk and may encourage the public to ignore future warnings in the midst of serious health emergencies.**

**Many of the responses to the outbreak proposed in these stories, such as banning flavoured vaping products or preventing access to nicotine vaping products, do not address the cause of the outbreak identified by US authorities, namely, the vaping of illicit cannabis products cut with vitamin E acetate.**

To date the Australian Chief Medical Officer Brendan Murphy has failed to update or correct his false, misleading and incorrect advice about EVALI and about nicotine vaping more broadly. The CMOs credibility has been significantly tarnished and compromised and as a result, Australians have lost trust in the institution of the CMO. The loss of trust in the CMO is evident in the public's concern about his handling of the COVID-19 response, especially as conflicting and confusing advice has led different state and territory governments to develop their own health advice, in contradiction to the Commonwealth advice.

It is extremely concerning that the very same CMO who misled the community about EVALI, Brendan Murphy, is expected to take up the role of Secretary of the Department of Health, and as such he will be the final decision-maker on this TGA application and a previous application to amend the scheduling of nicotine being considered in the March meeting of the ACMS/ACCS.<sup>37</sup> If the CMO is prepared to mislead the Australian public about the US EVALI deaths, then what else is he prepared to mislead the community about, and can he be trusted to fairly, impartially and objectively consider the scientific evidence in support of vaping? And what other critical issues will Brendan Murphy make decisions about on the basis of ideology and emotion rather than the scientific evidence?

Ultimately, the EVALI deaths in the US should serve as a serious wake-up call to all unelected Australian Health autocrats to abandon their pathological and ideological opposition to vaping and to legalise and regulate e-cigarettes to better protect public health.

### Young people vaping

The evidence that vaping is not a 'Gateway' to smoking has been outlined in an earlier chapter, and the 'youth vaping' argument has been systematically dismantled as large scale population study after large scale population study puts the claim to rest. The evidence consistently demonstrates that e-cigarettes are displacing and replacing combustible cigarettes but without a concomitant increase in regular or daily vaping among young people.

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<sup>36</sup> <https://onlinelibrary.wiley.com/doi/full/10.1111/dar.13024>

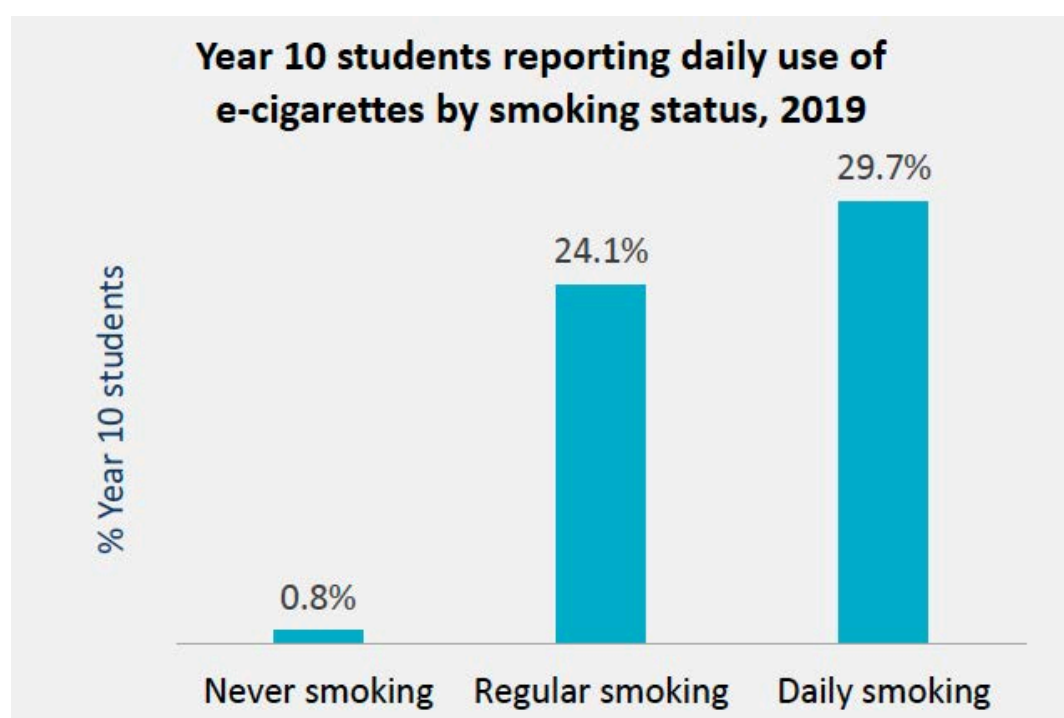
<sup>37</sup> <https://ama.com.au/gp-network-news/professor-brendan-murphy-appointed-department-health-secretary>

While this can only be described as a win for public health given that e-cigarettes are at least 95 per cent safer than traditional cigarettes, it is still far preferable that young people never take up smoking or vaping at all.

Despite a widespread perception that there is a ‘youth vaping epidemic’ sweeping across the United States, a recent review of data from the 2018 National Youth Tobacco Survey (NYTS) concluded:<sup>38</sup>

**“Data from the NYTS do not support claims of a new epidemic of nicotine addiction stemming from use of e-cigarettes, nor concerns that declines in youth tobacco addiction stand to be reversed after years of progress. Among current e-cigarette users who had never tried tobacco products, responses consistently pointed to minimal dependence.”**

A 2019 survey of more than 28,000 Year 10 students in New Zealand found that fewer than 1% of students who never smoked reported using e-cigarettes daily.<sup>39</sup> The results show that smokers are four times more likely to try vaping than non-smokers, and that vaping experimentation by non-smokers does not lead to daily, ongoing or regular e-cigarette use.



Source: [ASH New Zealand 10 Year Snapshot 2019](#)

The New Zealand data reflects the consistently observed trend in the US and the UK where, despite youth experimentation with e-cigarettes, there is little youth vaping take-up by non-smokers, and the youth that do smoke are increasingly turning to less harmful vaping products.

<sup>38</sup> <https://www.qeios.com/read/article/391>

<sup>39</sup> [https://d3n8a8pro7vnm.cloudfront.net/ashnz/pages/70/attachments/original/1583197938/2019\\_ASH\\_Y10\\_Snapshot\\_E-cigs\\_and\\_vaping\\_FINAL.pdf?1583197938](https://d3n8a8pro7vnm.cloudfront.net/ashnz/pages/70/attachments/original/1583197938/2019_ASH_Y10_Snapshot_E-cigs_and_vaping_FINAL.pdf?1583197938)

A comprehensive systematic review of five UK youth smoking and e-cigarettes use prevalence surveys also bears this out.<sup>40</sup> The study, *Young People's Use of E-Cigarettes across the United Kingdom: Findings from Five Surveys 2015–2017*, meticulously demolishes any correlation between vaping experimentation, vaping 'ever use', and ongoing regular vaping among young non-smokers.

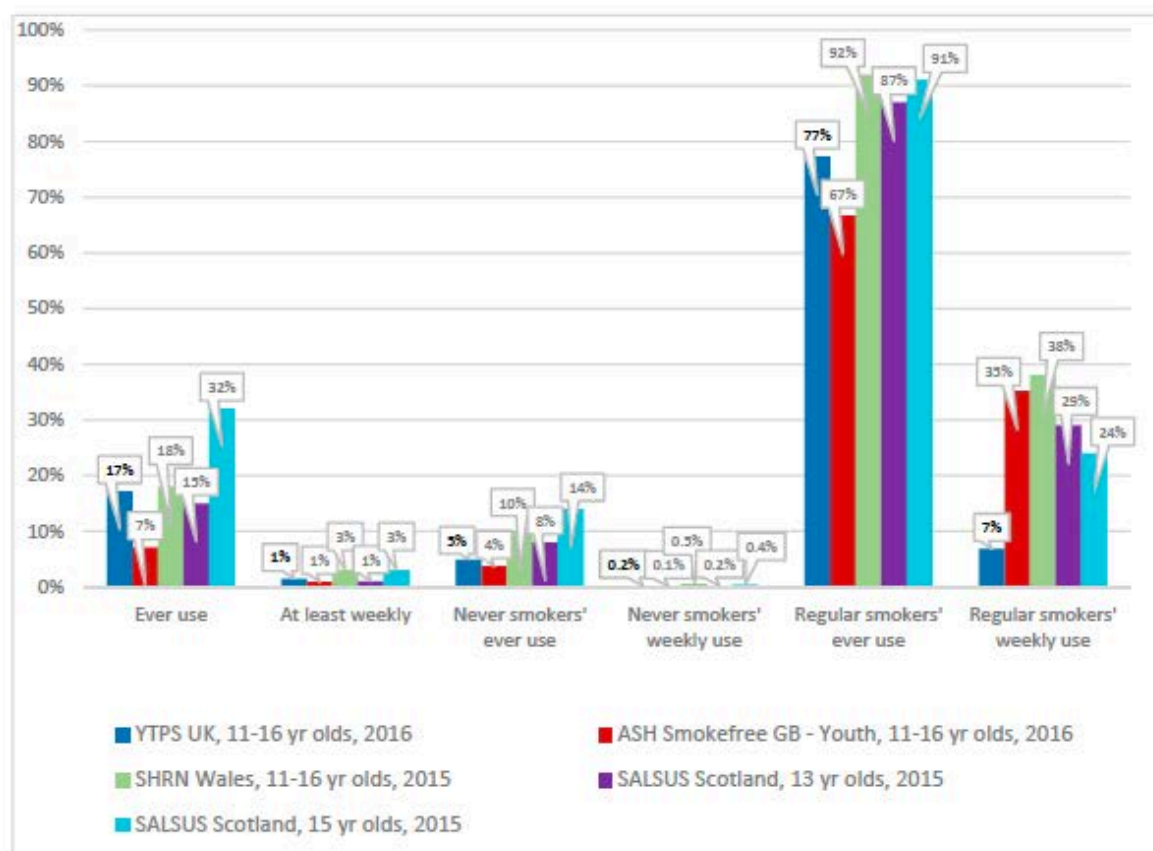
Relevant findings of the study that Australian policymakers ought to be aware of:

**Never Smokers: Ever Use of E-Cigarettes:** Across the surveys, reports of 'ever use' of e-cigarettes, among never smokers, ranged from 4% to among 10% among 11 to 16 year olds.

**Never smokers: Regular (at Least Weekly) Use of E-Cigarettes:** Among never smokers, the regular use of e-cigarettes was very low in all surveys, ranging from 0.1% to 0.5%

The compilation of graphs below illustrates the consistent, undeniable finding in all surveys that there is little youth vaping among never-smokers, and that e-cigarettes are overwhelmingly being accessed by young people that already smoke.

**Prevalence of E-Cigarette Use:** the prevalence of 'ever use' and 'at least weekly use' of e-cigarettes firstly from all respondents from each of the surveys conducted in 2015/16 and then separately for never smokers and regular smokers.



Source: <https://www.mdpi.com/1660-4601/14/9/973>

<sup>40</sup> <https://www.mdpi.com/1660-4601/14/9/973>

Public Health England have summarised the UK experience as well as available evidence about youth vaping trends:<sup>41</sup>

The evidence shows that e-cigarette use remains largely confined to those who already smoke or ex-smokers, who have now quit using an e-cigarette, while quitting smoking remains the key motivation among adult vapers.

As e-cigarettes have become the quit aid of choice for adult smokers, some have speculated that there will be a surge in young people using them regularly, with particular concern in the US about products such as Juul. But our report shows that this is not happening in Britain. While experimentation is increasing, vaping among young people remains low.

Rising experimentation is unsurprising but the crucial point is that we are not seeing a surge in regular use among young people, which remains low (1.7%) and mainly confined to those who already smoke. Only 0.2% of those who have never smoked are regular e-cigarette users.

Beyond this report, the evidence suggests that vaping helps people stop smoking rather than leading them to start in the first place. The proportion of e-cigarettes users who are ex-smokers has increased over recent years and adult smoking rates continue to decline.

Notwithstanding that there is no youth vaping epidemic, ARVIA does not support the Australia Government's 'head in the sand' approach to youth vaping. Instead, we encourage Australian health authorities to be more proactive in educating young people about the risks and benefits of vaping compared to smoking and not smoking and introduce uniform national laws to ensure that vaping products and e-cigarettes can only be purchased by adults both online and in-store.

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<sup>41</sup> <https://publichealthmatters.blog.gov.uk/2019/02/27/e-cigarette-evidence-update-patterns-and-use-in-adults-and-young-people/>

## International regulation of nicotine vaping

Internationally, dozens of civilised nations already recognize and accept the science behind vaping and are ambitiously embracing the opportunity to save the lives of many millions of smokers right now.

Nicotine vaping and e-cigarette products are legal and regulated (or in the process of being regulated) in a number of nations including:

- New Zealand
- Canada
- United States
- United Kingdom
- Ireland
- Japan
- Korea
- France
- Italy
- Denmark
- Norway
- Finland
- Netherlands
- Switzerland
- Sweden
- Spain
- Portugal
- Belgium
- Germany
- Austria
- Iceland
- Poland
- Hungary
- Estonia
- Latvia
- Slovenia
- Slovakia
- Croatia
- Serbia
- Czech Republic
- Romania
- Bulgaria
- Greece
- United Arab Emirates
- Belarus
- Georgia
- Moldova
- Macedonia
- Tunisia
- Morocco
- South Africa
- Namibia
- Indonesia
- Malaysia
- Cambodia
- Vietnam
- Malta
- Philippines

Further to these countries, e-cigarettes and nicotine vaping products are legally permitted in many other nations where there are no specific laws either banning or legalising them.

While Australia usually maintains consistency with places like New Zealand, the UK, the EU, Canada and the United States, we are now lagging behind these nations when it comes to vaping and tobacco harm reduction more broadly.

Peer-reviewed research has shown that in markets where vaping is legal and encouraged, such as New Zealand and the United Kingdom, vaping is more effective at helping smokers quit than in nations where vaping remains illegal or highly restricted such as Australia.<sup>42</sup> The study concluded:

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<sup>42</sup> <https://academic.oup.com/ntr/article/19/11/1268/3061874>

**This study shows that in a less restrictive EC regulatory environment, use of ECs during a quit attempt facilitates, but in a more restrictive environment, it inhibits, short-term sustained abstinence. The findings underscore the need for careful consideration on how best to regulate this emerging product so that EC benefits for smoking cessation are maximized and its risks to public health are minimized.**

The implications of this research cannot be overstated – it clearly links government policy on nicotine vaping and e-cigarettes to their success as quitting aids. In the case of Australia, with its restrictive and regressive regulatory regime, it is clear that we could achieve much more success to reduce our plateauing smoking rates if governments liberalized, legalised and regulated vaping.

In the United Kingdom, many National Health Service (NHS) hospitals are now opening vape shops and permit patients to vape on hospital grounds to encourage them to stop smoking.<sup>4344</sup>

In New Zealand, where vaping has been legal for some time now, the parliament is currently legislating a sensible and risk-proportionate regulatory regime that gives access to nicotine vaping and e-cigarette products for adults that need them, manages potential youth take-up and provides appropriate safety standards.

The gap between Australia and the rest of the civilised world continues to widen. Internationally we are seeing the proliferation of evidence-based and compassionate harm-reduction policies aimed squarely at saving lives. Sadly, in Australia, progress is being frustrated by a powerful elite of taxpayer funded health groups and unelected health autocrats who remain hellbent on prosecuting a cruel, irrational, pathological, ideological and unscientific agenda on vaping.

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<sup>43</sup> <https://www.telegraph.co.uk/news/2019/07/09/vape-shops-open-nhs-hospital-sites-bid-stub-smoking/>

<sup>44</sup> <https://www.bbc.com/news/uk-england-devon-51312778>

## Australian governments' policy approach to vaping

ARVIA remains extremely concerned with the current policy position and approach of the Australian Government, state and territory governments, and their regulators when it comes to nicotine vaping.

It appears that the so-called 'precautionary principle' that Australian health officials continue to hide behind is merely designed to maintain the tobacco industry's monopoly on nicotine and protect an estimated \$17 billion in tobacco tax revenue.

Federally, the Australian Government, the Department of Health and the TGA continues to actively and explicitly provide strong legal support and protection for combustible tobacco products which kill 21,000 innocent Australians every year and costs the community over \$136 billion in social and economic costs.

At a state and territory enforcement level, there is an observable hostility towards vape vendors, who regularly experience government sanctioned bullying, harassment and intimidation at the hands of state enforcement agencies and individual officers.

### Lack of regulations

There are a number of risks and consequences to Australia's blanket and illogical ban on vaping and e-cigarettes, which not only undermines current tobacco harm reduction efforts and but also potentially compromises public health.

For example, the lack of any consumer protections and minimum standards on vaping and e-cigarette products is leaving Australians exposed to avoidable risks. There are no child-resistant tamper-proof container requirements, no product labelling laws, no manufacturing standards, no product notification systems, no adverse incident reporting processes and the industry is currently self-regulating to the best of its abilities. The longer Australia keeps its head in the sand on these issues rather than adopt sensible risk-proportionate regulations, such as the [EUs Tobacco Product Directive \(TPD\)](#), the greater the risk of injury or death.

### Reliance on tobacco taxes, illicit tobacco trade and missed opportunity to tax e-cigarettes

The tobacco excise now represents the fourth largest source of revenue for the federal budget. The government's reliance on the tobacco tax to prop up the national budget, deliver a surplus and to repay government debt is unfair because it disproportionately affects poorer and more marginalised sections of our community.

ARVIA submits that the imposition of an unreasonably large overall tax burden on vulnerable people in the form of a 'sin tax', which has no measurable impact on reducing smoking rates, is lazy, regressive and is no substitute for the serious tax reform that needs to occur.

Out of \$17 billion raised in tobacco tax per year, the government dedicates just \$5 million a year in specific anti-smoking initiatives. This huge disparity reinforces our conclusion that the tobacco tax is not designed to deter people from quitting smoking, but rather it is relied upon as a guaranteed annual revenue stream funded from the nicotine addiction of poor and marginalised Australians.

The illicit tobacco trade in Australia is already substantial and will continue grow as tobacco taxes rise and e-cigarettes remain illegal. A 2019 report by KPMG into the value of the illicit tobacco trade estimated that illegal tobacco consumption represented 14% of the market, costing the Australian economy \$2 billion a year.<sup>45</sup>

According to senior Australian law enforcement agencies, the astronomical rate of tobacco excise is driving unprecedented involvement in the illicit tobacco trade by organized crime syndicates.<sup>46</sup>

The Police Federation of Australia stated:<sup>47</sup>

**Another issue that is becoming indisputable is that the high rate of tax on tobacco is making its illegal sale very attractive to the crime groups who are using the proceeds of illicit tobacco sales to fund other criminal activity.**

Not only does the punitive tobacco tax promote illicit trade and other associated criminal activity, the Australian Government is also missing an opportunity to generate significant taxation revenue on nicotine liquids. At present the 300,000 Australian vapers who purchase both nicotine and non-nicotine flavoured liquids do not pay any specific tax on these products except for the 10 per cent Goods and Services Tax (GST). While we don't believe that reduced-risk products such as e-cigarettes and nicotine liquids should be taxed at the extremely harsh level that tobacco is taxed, there should nonetheless be a reasonable level of tax applied to such products, and we recommend that all revenue raised from such taxes be used to support smoking cessation measures.

## Fairness, equity and human rights

There is a strong human rights element to the current ban on vaping, not only in reference to the disproportionate impact of punishing tobacco taxes on poorer people, but the unfairness and injustice of knowingly depriving adults' legal access to a less harmful nicotine product, and forcing them to continue using the most harmful and a deadlier version of nicotine.

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<sup>45</sup> <https://www.medianet.com.au/releases/176600/>

<sup>46</sup> <https://www.smh.com.au/politics/federal/organised-crime-licks-its-lips-as-tobacco-excise-set-to-hit-1-a-stick-20200222-p543ap.html>

<sup>47</sup> Ibid



## Vape vendor trading conditions

States and territories set, control and enforce the day to day rules and regulations that govern the retail sale of vaping liquids (all of which contain no nicotine) and vaping accessories. It is clear that there is an official state-sanctioned campaign of terror, bullying, harassment and intimidation against Australian vape vendors by state governments.

The rules and regulations around vape retail sales remain opaque, unclear and confusing and are arbitrarily interpreted and applied by enforcement bodies as well as by the courts. There are no clear guidelines for vape vendors to follow to ensure they are abiding by the law, and there can be wildly different interpretations of the same state's laws from suburb to suburb, depending on the whims and predilections of individual enforcement officers. In many cases vape vendors are denied natural justice and any procedural fairness when enforcement decisions are made. It is not uncommon for vape vendors who are fined on spurious grounds to simply opt to pay the fine imposed, no matter how unreasonable, rather than risk an uncertain and potentially expensive appeals process through the courts against the unlimited taxpayer funded resources of enforcement agencies. This is frankly an unacceptable state of affairs for a modern and so-called civilised nation that prides itself on the rule of law.

We believe that the policy uncertainty at a federal level and the bullying and harassment by state and territory governments is designed to make day to day life intolerable for otherwise law-abiding small businesses. Vape vendors, who are modern day quit smoking clinics, are valued members of the communities they live in and serve. Vape vendors create jobs, employ local people, pay taxes and also help lifelong smokers quit a filthy and fatal habit.

Rather than recognise and reward vape vendors that are helping thousands of people quit smoking, state and territory governments are tightening the noose and are attempting to kill off the retail vape industry. ARVIA is becoming extremely concerned at the growing financial, emotional and psychological toll that the state-sanctioned campaign of bullying and harassment is having on law-abiding small businesses.

It is worth observing that while bricks and mortar vape stores are subject to strict state government enforcement actions, online sellers are obviously immune from the uncertainty posed by this state-sponsored terror campaign against law-abiding small businesses. One obvious potential consequence of harsh and unreasonable state and territory enforcement crackdowns is to move bricks and mortar businesses online, which will be a significant loss to the communities in which vape stores operate.

## Conclusion

ARVIA believes that this proposed amendment is illogical, regressive, unnecessary and is designed purely to make accessing non-combustible nicotine products more difficult for Australian vapers. Moreover, this application has been prepared and submitted by unelected and unaccountable autocrats from the Department of Health with a pathological, unscientific and ideological agenda against vaping.

There is simply no evidentiary basis upon which to justify even putting forward any of the proposed amendments, and certainly no good reason to approve them. We therefore urge the TGA to reject the application.

Providing Australian smokers with access to nicotine vaping and e-cigarette products is the best outcome that decision-makers can provide to Australian smokers, their families and to the broader community.

ARVIA urges the TGA to adopt our preferred recommendation to exempt nicotine vaping and e-cigarette products (including HTPs and nicotine liquids) from the Poisons Standard so that it is easier for more Australian smokers to access them.

If none of the available scientific evidence from around the world as at May 18, 2020 is enough to persuade the TGA about the relative risks of vaping versus smoking, then clearly no amount of evidence will ever convince the TGA either now or into the future.

As we have stated all along, the Australian retailers are committed to working with government and regulators to develop a strong, effective, sensible and risk-proportionate regulatory framework to govern how vaping and e-cigarette products ought to be manufactured, marketed and sold in Australia. We are firm in our view that nicotine vaping and e-cigarettes should only be marketed to adult smokers and that they are not suitable for never smokers and certainly not for teenagers and young people.

ARVIA encourages the TGA, the Secretary of the Department of Health, and indeed all unelected public officials, regulators and decision-makers to set aside their pathological and ideological opposition to vaping and to accept the international scientific consensus, a broad overview of which has been highlighted in this submission.

Vaping saves lives and any decision to restrict or ban vaping only serves to further protect and promote combustible tobacco which will lead to thousands of Australians dying needlessly. To continue to deny Australian adult smokers' access to scientifically proven life-saving technology is cruel and inhumane.

You have a moral and ethical responsibility to give Australian smokers access to scientifically proven safer alternatives to addictive, lethal, cancer-causing combustible tobacco products. We encourage you to exercise your decision-making in a compassionate, responsible and evidence-based manner.