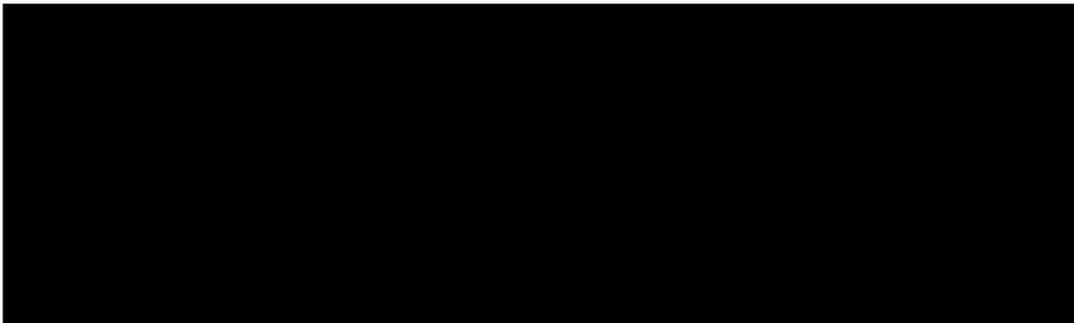


**SUBMISSION TO THE THERAPEUTIC GOODS  
ADMINISTRATION (TGA) JOINT ADVISORY COMMITTEE  
ON MEDICINES SCHEDULING (ACMS)/ADVISORY  
COMMITTEE ON CHEMICALS SCHEDULING (AACS)**



Member Group of the **Australian Retailers Association**

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

**Schedule 7 – Amend Entry – to exempt Nicotine in tobacco  
prepared and packed for heating**

10 February 2020

[www.arvia.org.au](http://www.arvia.org.au)

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# ARVIA SUBMISSION TO TGA

## 1. 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 heated tobacco products (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 the long-term health implications of vaping are not clearly understood. Notwithstanding this, available peer-reviewed evidence as at February 2020 is that vaping and e-cigarettes deliver the nicotine smokers crave but without the cancer-causing cocktail of chemicals and carcinogens that cause so much of the harm associated with combustible tobacco use.

Not only do we wholeheartedly support vaping and e-cigarettes becoming legal, it is our members' strongly held view that any decision which serves to restrict Australian adults' access to e-cigarettes or nicotine vaping products is a deliberate and calculated decision by governments purporting to act in the public interest to enthusiastically endorse lethal tobacco products and the harms associated with their use.

## 2. ARVIA Recommendation

ARVIA supports, in principle, the application by Phillip Morris International (PMI) to the Therapeutic Goods Administration (TGA) to exempt Heated Tobacco Products (HTPs) from the poisons schedule; however, we believe nicotine liquids should also be made exempt.

### RECOMMENDATION

ARVIA recommends the TGA and the Secretary of the Department of Health approve the PMI 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 vaporising***.

Given scientific evidence supports both HTPs and nicotine vaping, we do not believe it will be in the public interest to approve only one category of non-combustible nicotine products for sale, as it will significantly reduce the choices available to smokers wishing to quit smoking. Moreover, HTPs are currently only sold and marketed by tobacco companies whilst vape liquids (both nicotine and non-nicotine) remain largely the domain of small, independent businesses that detest tobacco products. To exclusively approve the tobacco industry product and maintain a ban on nicotine liquids would send the wrong message to both smokers and the broader community that the Australian Government and its regulators continue to operate a protection racket for big tobacco.

It is illogical and defies common-sense for the TGA to continue restricting non-combustible nicotine products whilst endorsing combustible tobacco products and the deaths and diseases they cause.

### 3. The Australian retail vape landscape

ARVIA estimates there are up to 400 physical or 'bricks and mortar' retail vaping shops and nearly 1,000 Australian online sellers of vape liquids, devices and accessories. Most Australian vape vendors are ex-smokers who are primarily motivated to help smokers quit smoking, and completely reject the tobacco industry and its tactics. To ARVIA's knowledge, no Australian vape vendor sells any combustible tobacco product, while some tobacco retailers are now selling a limited range of vape products and accessories.

Because of the prohibition on e-cigarettes and nicotine vaping, Australian vape retailers currently only sell non-nicotine containing liquids as well as vape devices and accessories designed to vaporise liquids. To obtain the nicotine liquid required to substitute vaping for traditional cigarettes, Australian vapers must import nicotine from overseas under the [TGA approved Personal Importation Scheme \(PIS\)](#). The PIS requires vapers to obtain a valid prescription from an Australian-registered medical practitioner and which must be for the purposes of smoking cessation.

In addition to vape retailers, there are thousands of mainstream or ordinary retail businesses around Australia such as supermarkets, convenience stores, petrol stations, newsagents, and indeed tobacconists, that currently sell tobacco products but which also want less harmful e-cigarettes legalised in Australia.

While vape vendors naturally compete with mainstream retailers selling tobacco products, many vape vendors acknowledge and accept the desire by tobacco retailers to transition to selling e-cigarettes, and welcome the opportunity to work together in pursuit of a common objective.

Ultimately, the Australian Government and its regulators (including the TGA) could make traditional cigarettes illegal immediately, but choose to continue to ensure combustible tobacco products are widely available and remain the product of choice for Australian smokers.

Despite the Australian Government's continued protection and support for tobacco products, Australian vape shops are proud of their role as modern day quit smoking clinics, and are arguably more effective at helping lifelong smokers quit smoking permanently than the combined impact of all other Australian public health measures ever attempted. In fact, we submit that with up to 300,000 current vapers in Australia, vape retailers are responsible for the largest movement of Australian smokers away from traditional cigarettes than any single government measure currently in place.

Through ARVIA and other industry initiatives, Australia's retail vape sector is committed to the highest standards of excellence, probity and ethics. In the absence of any domestic regulations, ARVIA is working with its members and other stakeholders to develop a Code of Conduct, minimum product standards, and best practice guidelines to ensure the Australian vape industry can continue to progress with tobacco harm reduction principles as well as the safety and health of vapers as its highest priorities.

### 4. The evidence base in support of vaping

International peer-reviewed science clearly and unambiguously supports both vaping and e-cigarettes as safer alternatives to cigarettes. The available scientific 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 (including the rate of teenage smoking), and that legalising smoke-free products will deliver savings to the health system and the broader economy.

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 poses 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 harm-reduction opportunities are being maximised.

In Australia, opposition to vaping is anti-scientific and 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, traumatic and ultimately unnecessary deaths every year.

#### (i) Smoking is the leading cause of preventable death in Australia

There are currently around 2.8 million daily smokers and we estimate between 250,000 and 300,000 vapers in Australia. Smoking is the single largest cause of preventable death in Australia, causing 21,000 smoking related deaths every year, or 58 deaths every day.

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

The Australian Institute of Health and Welfare (AIHW) estimates that smoking-related harm costs the community \$136.7bn per annum in social and economic costs.

Smoking rates have also failed to decline significantly in recent years, with the AIHW reporting a modest 0.6% fall between 2013-2016.<sup>1</sup>

There have been no vaping or e-cigarette related deaths ever reported in Australia.

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<sup>1</sup> <https://www.aihw.gov.au/reports/alcohol/alcohol-tobacco-other-drugs-australia/contents/interactive-data/tobacco>

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### (ii) Vaping and e-cigarettes less harmful than combustible tobacco

Public Health England (PHE) has categorically and emphatically declared that nicotine vaping is at least 95 per cent less harmful than traditional cigarettes. PHE first published this finding in a 2015 expert review which examined a decade's worth of data:<sup>2</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>3</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.**

The Royal College of Physicians (RCP) is the oldest and most respected medical college in the world. The RCP was founded in 1518, and has successfully championed a range of major public health initiatives since it was formed. For example, the 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 its members and the wider medical community throughout its existence.

On the issue of vaping/e-cigarette use, the RCP's advice is clear, and as recently as 25 October 2019 it circulated a Position Statement firmly stating that **"vaping is still far less harmful than smoking tobacco."**<sup>4</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>5</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."**

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<sup>2</sup> <https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update>

<sup>3</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)

<sup>4</sup> <https://www.rcplondon.ac.uk/projects/outputs/rcp-advice-vaping-following-reported-cases-deaths-and-lung-disease-us>

<sup>5</sup> <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction>

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The Royal College of General Practitioners (RCGP) also supports e-cigarette (EC) use, with its official advice to Primary Care Clinicians (PCCs) outlined in its 2017 position statement:<sup>6</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.**
- **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. Its current policy position on e-cigarettes states:<sup>7</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>8</sup>

The BMA’s advice to its 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**

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<sup>6</sup> <https://www.rcgp.org.uk/-/media/Files/Policy/2017/RCGP-E-cig-position-statement-sept-2017.ashx?la=en>

<sup>7</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>8</sup> <https://www.bma.org.uk/collective-voice/policy-and-research/public-and-population-health/tobacco/e-cigarettes>

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**smoking-related disease are absent or significantly reduced in e-cigarette vapour.**

In New Zealand, there is near-universal support for vaping as a proven harm reduction and smoking cessation tool. The New Zealand government (on a bi-partisan basis), 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, fact-checked advice, support and information for New Zealand smokers about the benefits of vaping over smoking. Notable examples of this plain speaking, 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 smoking cessation method. The NZMA Position Statement, *Smokefree 2025 New Zealand*, states:<sup>9</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

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<sup>9</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)

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become smoke-free, demonstrating in stark fashion how putting aside ideology and emotion and pursuing evidence-based policy in a mature, responsible and objective way can deliver vast improvements to the quality of life of its citizens.

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>10</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, 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. This update is significant because it marks the first time any major, influential, mainstream Australian medical body has started to acknowledge and accept the global scientific consensus on vaping.<sup>11</sup>

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 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 explanation if the TGA chooses to reject the science-based positions advocated by these highly esteemed Australian and international organisations, particularly in light of the TGA's continued and actively explicit legal endorsement of traditional cigarettes, which currently kill 58 Australians every day.

### (iii) Most effective quit tool

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

The British National Health Service (NHS) has concluded e-cigarettes are twice as effective as Nicotine Replacement Therapy (NRT) for quitting smoking.<sup>12</sup>

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<sup>10</sup> <https://www.nap.edu/resource/24952/012318ecigaretteConclusionsbyEvidence.pdf>

<sup>11</sup> <https://www.racgp.org.au/getattachment/00185c4e-441b-45a6-88d1-8f05c71843cd/Supporting-smoking-cessation-A-guide-for-health-professionals.aspx>

<sup>12</sup> <https://www.nhs.uk/news/heart-and-lungs/e-cigs-twice-effective-nicotine-patches-gum-or-sprays-quitting/>

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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 e-cigarette use with nicotine does help smokers stop smoking.<sup>13</sup>

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

As Mendelsohn, Hall and Borland found, nicotine vaping and e-cigarettes are driving the major reductions in smoking rates in a number of countries around the world.<sup>14</sup>

The RCGP Policy Statement states:<sup>15</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.”**

### (iv) ‘Gateway’ Theory

There has been some concern that vaping will cause teenagers 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 it is universally accepted tastes terrible and causes death and disease. This is known as the ‘gateway theory,’ 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 determined 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 the notion the ‘gateway theory’ has occurred in practice anywhere in the 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 – continue to decline.<sup>16,17</sup>

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

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<sup>13</sup> <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub3/abstract>

<sup>14</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>15</sup> <https://www.rcgp.org.uk/-/media/Files/Policy/2017/RCGP-E-cig-position-statement-sept-2017.ashx?la=en>

<sup>16</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>17</sup> <https://www.sciencedirect.com/science/article/abs/pii/S0376871617300236?via%3Dihub>

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Professor John Britton, Director of the UK Centre for Tobacco and Alcohol Studies at the University of Nottingham, said in response to the Levy study:<sup>18</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>19</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:

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<sup>18</sup> <https://www.sciencemediacentre.org/expert-reaction-to-smoking-rate-and-popularity-of-vaping-in-the-u-s/>

<sup>19</sup> <https://tobaccocontrol.bmj.com/content/early/2019/03/08/tobaccocontrol-2018-054584>

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- **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.
- **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.

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

### (v) 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 New Zealand's science-based endorsement of nicotine vaping found that liberalising access to e-cigarettes delivers net health gains 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>20</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\$).”**

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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)

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This important research confirms that supporting vaping will not only improve quality and length of life for all citizens, but 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 capita health system cost saving of NZ\$780 over their lifetime. The study authors suggest the results of this research are applicable to Australia.<sup>21</sup>

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<sup>21</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>

## 5. EVALI and other 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 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, 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.

### (i) Unknown long-term risks

As e-cigarettes have only existed 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 tobacco, which releases a cocktail of lethal chemicals, toxicants and carcinogens that cause cancers and other diseases. Vaping and e-cigarettes work by heating liquid nicotine or tobacco to release 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>22</sup>

The main conclusion of the updated review is 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)

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

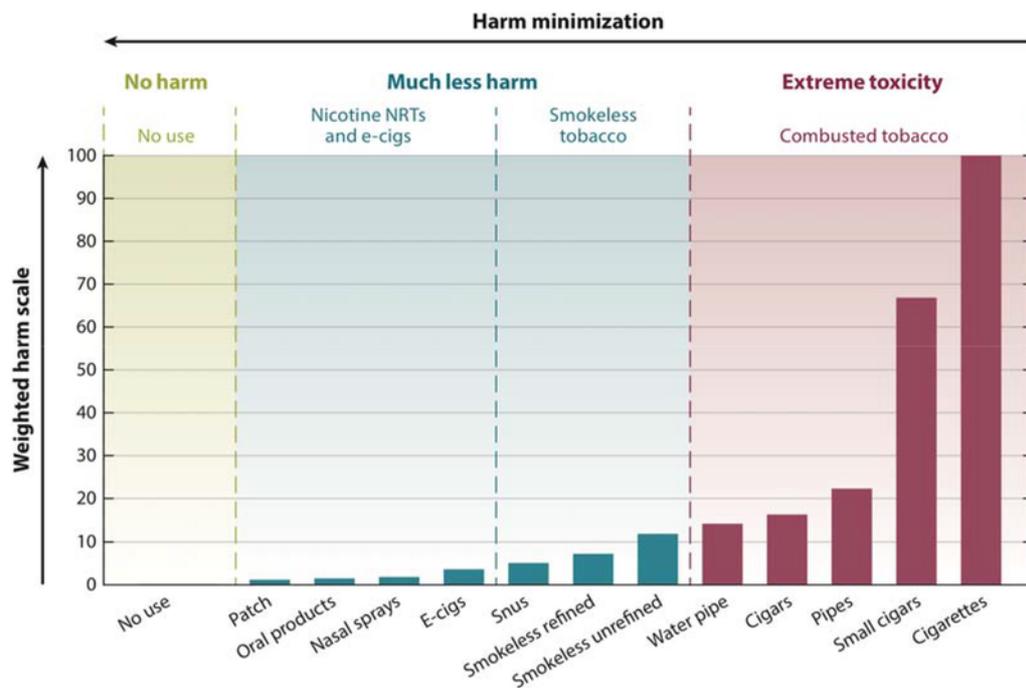
**“The biomarker data assessed in this section are consistent with significant reductions in harmful constituents and in EC users some biomarkers show similar levels to non-smokers or smokers abstaining from smoking.”**

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.



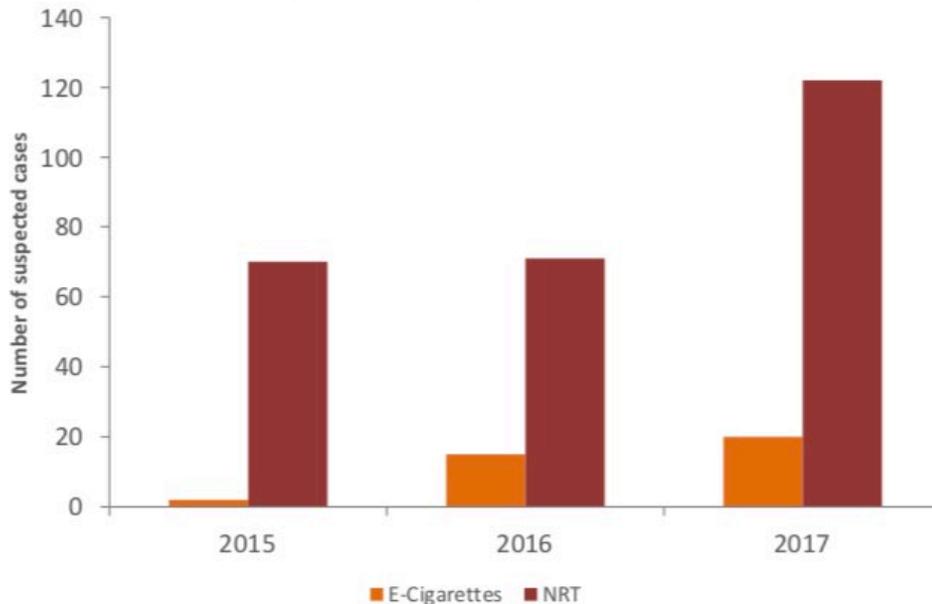
Products along the harm minimization continuum. Adapted from Nutt et al., 2014 and reproduced from Abrams et al., 2018 The figure depicts four panels representing classes of products ranging from exceptionally low harm to exceptionally high harm. Panel 1 (left) depicts no use and thus no exposure. Panel 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/>

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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 shows 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 issues should they arise.

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### (ii) 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. During August and September 2019, there was a large, sudden spike in hospital presentations of mostly young men in the US with a range of vaping-related lung injuries.

Given 50 million people around the world were still vaping with no adverse health impacts, it was obvious to medical experts from the outset of the EVALI outbreak that the incidences of lung injuries was mostly contained to the US, and was 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 Center 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 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 to continue the Australian Government's and the Health Department's unscientific anti-vaping agenda, and to protect the primacy of combustible tobacco in Australia.

In an advisory published on 13 September 2019, the CMO ignored the CDC findings and shamelessly attempted to link the safety of all nicotine vaping products to the US lung injury outbreak despite no evidence to support this conclusion. The CMO advice stated:<sup>23</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>23</sup> <https://www.health.gov.au/news/e-cigarettes-linked-to-severe-lung-illness>

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Not only was this advice designed to deliberately mislead Australians about the real causes of the outbreak the CDC had identified, but it also failed to adequately warn vapers specifically about the harmful ingredients of concern cited by the CDC, 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 CMO's incorrect and misleading advice in order to give the Australian community the accurate and evidence-based advice the CMO irresponsibly failed to provide.

Their critique, published on 18 September 2019, addressed the deceitful CMO characterisation of the causes of the EVALI outbreak in the following way:<sup>24</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 lipid 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's advice by public health professionals was unprecedented, but clearly warranted. The rebuttal ensured Australians were given the correct information about the causes of the EVALI outbreak and an accurate overview of the

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<sup>24</sup> <https://athra.org.au/wp-content/uploads/2018/08/Critique-of-CMO-Statement-WEB-18Sept2019-.pdf>

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evidence regarding nicotine vaping generally, especially in light of sensationalised and incorrect media reporting.

Gartner, Bonevski and Hall reviewed this shameful episode in *Australian Public Health*, and found 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>25</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.**

To date, the CMO has failed to update or correct his false, misleading and incorrect advice about EVALI and/or nicotine vaping more broadly. The CMO's 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 public concern about his handling of the Coronavirus (2019-nCov) response.

It is extremely concerning that the same CMO who misled the community about EVALI, Brendan Murphy, has since been appointed Secretary of the Department of Health, in which capacity he will be the final decision maker on the TGA application to which this submission refers.<sup>26</sup>

### (iii) Young people vaping

The evidence that vaping is not a 'gateway' to smoking has been outlined in an earlier chapter, but it is clear that e-cigarettes are replacing combustible cigarettes. While this can only be described as a win for public health given 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 the United States, a recent review of data from the 2018 National Youth Tobacco Survey (NYTS) concluded:<sup>27</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."**

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

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<sup>25</sup> <https://onlinelibrary.wiley.com/doi/full/10.1111/dar.13024>

<sup>26</sup> <https://ama.com.au/gp-network-news/professor-brendan-murphy-appointed-department-health-secretary>

<sup>27</sup> <https://www.qeios.com/read/article/391>

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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.

## 6. International regulation of nicotine vaping

Internationally, dozens of civilised nations already recognise and accept the science behind vaping, and are ambitiously embracing the opportunity to save the lives of many millions of smokers. Countries including New Zealand, the United Kingdom, the United States, Canada, Japan, Korea and the 27 member states of the European Union have embraced, legalised and are actively regulating e-cigarettes and nicotine vaping products.

While Australia usually maintains consistency with these jurisdictions on regulations and standards, especially with New Zealand, the UK, the EU and the United States, we are now lagging behind these nations when it comes to vaping.

The fact that a number of National Health Service (NHS) hospitals in the United Kingdom are now opening vape shops, and permit patients to vape on hospital grounds to encourage them to stop smoking, exposes the widening gap between the compassionate and evidence-based policies being adopted internationally, and the cruel, irrational and unscientific anti-vaping agenda that Australian health groups continue to prosecute.<sup>2829</sup>

Remarkably, Australia's current policy approach of vigorously protecting traditional cigarettes against safer smoke-free alternatives appears consistent with the approach of China and India, where these governments directly benefit from banning e-cigarettes because state-owned enterprises are heavily involved in or have a monopoly over the tobacco trade.<sup>3031</sup>

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<sup>28</sup> <https://www.telegraph.co.uk/news/2019/07/09/vape-shops-open-nhs-hospital-sites-bid-stub-smoking/>

<sup>29</sup> <https://www.bbc.com/news/uk-england-devon-51312778>

<sup>30</sup> <https://theprint.in/india/governance/govt-has-banned-vapes-but-owns-28-of-itc-indias-biggest-cigarette-maker/293547/>

<sup>31</sup> <https://theconversation.com/chinas-tobacco-industry-is-building-schools-and-no-one-is-watching-120961>

### 7. Australian governments' policy approach to vaping

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

It appears 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 annual tobacco tax revenue.

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

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

#### (i) 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 leaves 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 currently self-regulates to the best of its ability. The longer Australia keeps its head in the sand on these issues rather than adopt sensible, risk-proportionate regulations, such as the [EU's Tobacco Product Directive \(TPD\)](#), the greater the risk of injury or death.

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

The government's reliance on tobacco taxes 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 to specific anti-smoking initiatives. This huge disparity reinforces our

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conclusion that the tobacco tax is not designed to deter people from quitting smoking, but rather is relied on 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 to grow steeply as tobacco taxes rise and e-cigarettes remain illegal. The most recent 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>32</sup>

Not only does the punitive tobacco tax regime promote illicit trade and associated criminal activity, the Australian Government is 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 apart from 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.

### (iii) 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 punitive tobacco taxes on poorer people, but the unfairness and injustice of knowingly preventing adults legal access to a less harmful nicotine product and forcing them to continue using the most harmful, deadliest version of nicotine, i.e. combustible tobacco.

### (iv) 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 there is an official state-sanctioned campaign of terror, bullying, harassment and intimidation against Australian vape vendors by state governments.

Rules and regulations around vape retail sales remain opaque, confusing, and are arbitrarily interpreted and applied by enforcement bodies as well as by 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 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

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<sup>32</sup> <https://www.medianet.com.au/releases/176600/>

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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 policy uncertainty at a federal level and the bullying and harassment by state and territory governments are 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 who 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 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 is to move bricks and mortar businesses online, which will be a significant loss to the communities in which vape stores operate.

### 8. Conclusion

ARVIA maintains that providing Australian smokers with access to HTPs as well as nicotine liquids prepared for vaping is the best outcome that decision-makers can provide to Australian smokers, their families and to the broader community. We therefore urge the TGA to accept ARVIA's recommendation to approve the application submitted by PMI, and further, to introduce the additional exemption we propose with respect to nicotine liquids.

The vaping industry is 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 are 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 all public officials, regulators and decision-makers to set aside their ideological opposition to vaping and to accept the international scientific consensus that vaping is far safer than traditional cigarettes, a broad overview of which has been presented 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, lifesaving technology is cruel and inhumane.

Australia has a moral and ethical responsibility to give its citizens access to scientifically proven safer alternatives to addictive, lethal, cancer-causing combustible tobacco products. We encourage the TGA to exercise its decision-making in a compassionate, responsible and evidence-based manner.