TOBACCO HARM REDUCTION:

A formula to save 500,000 Australian Lives

A joint report by the Australian Taxpayers’ Alliance & MyChoice Australia

Satyajeet Marar – February 2018
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Executive Summary

Tobacco smoking is one of the greatest public health challenges facing our society today, causing the deaths of 19,000 Australians every year with estimated annual social, health and economic costs over $31.5 billion. It is a known cause of cancer, cardiovascular disease, respiratory illness and general decline in welfare and wellbeing. Smoking also disproportionately affects marginalised groups including the poor, who are more addicted, less responsive to tobacco excise hikes, less likely to quit and more likely to smoke as relief from stress or depression.

Despite punitive moves by the government, including excise hikes and plain packaging laws, the latest figures reveal that more Australians smoked in 2016 than they did in 2013. By contrast, the UK which has traditionally lagged behind us in reducing their smoking rates, is now experiencing similar smoking prevalence to Australia and smoking rates in the USA are falling faster than ever. Tobacco Harm Reduction experts recognise that our government has an imperative to take a more compassionate approach by providing access to safer alternatives that are proven to mitigate the health risks of smoking and encourage quitting.

Although smokers smoke to satisfy nicotine cravings, it is the tar, toxins and carcinogens produced by tobacco combustion in a cigarette that are primarily responsible for ill health effects. Nicotine itself is a mild stimulant that is “no more harmful to health than caffeine”, according to the Royal Society for Public Health.

Electronic Nicotine Delivery Systems (ENDS), or ‘vapes’ are innovative products that mimic the action of smoking, while delivering nicotine to satiate a smoker’s cravings without the harmful chemicals or toxins produced by burning tobacco.

The UK Royal College of Physicians concluded that the harm from vaping nicotine is highly unlikely to exceed even 5% of the harm caused by smoking, and multiple studies have

2 Surgeon General of the United States. The Health Consequences of Smoking—50 Years of Progress. Centers for Disease Control and Prevention (US) 2014. [link]
5 Australian Institute of Health and Welfare (2017), National Drug Strategy Household Survey 2016, Table 2 [link]
7 Tobacco Advisory Group to the Royal College of Physicians (UK) 2016, ‘Nicotine without smoke: Tobacco harm reduction’
8 Royal College of Physicians (London), Nicotine without smoke: tobacco harm reduction. 28 April 2016. [link]
found no material health risks to even passive vapers. These products hence offer the greatest opportunity seen in the tobacco harm reduction space.

By 2014, an estimated 6 million Europeans had quit smoking by switching to ENDS since the technology was introduced, with surveys indicating that 65% of Australians would consider quitting smoking if the e-liquids necessary to vape nicotine were legally available. If most Australian smokers switched to vaping, over 500,000 lives would be saved from premature death.

Nicotine e-liquids are legally sold in the USA, UK and European Union, and are currently being legalised in Canada and New Zealand. However, they remain illegal in Australia despite ample scientific and statistical evidence that they reduce smoking-related harms.

Persons can already purchase Nicotine Replacement Therapy products such as patches and gum through supermarkets. However, research has shown that early ENDS devices with poor nicotine delivery were at least as effective as these products and newer generation ENDS products are significantly more effective. Public policy therefore dictates this life-saving technology is legalised with appropriate regulation.

The Australian Taxpayers’ Alliance and MyChoice Australia hence recommend the legalisation of nicotine for use in ENDS products within an appropriate regulatory framework.

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11 Australia Adult Smoker Survey (2015) Factasia. [link]
Foreword: Time to rethink nicotine

Dr Colin Mendelsohn

Associate Professor Colin Mendelsohn is a Tobacco Treatment Specialist at the School of Public Health and Community Medicine, University of New South Wales, Sydney.

Once a world leader in tobacco control, Australia is now falling behind the pack. Three million Australians continue to smoke in spite of strict tobacco control regulations, plain packaging and the highest cigarette prices in the world. Smoking rates have stagnated over the last 3 years for the first time in decades.

Tobacco harm reduction with electronic cigarettes may be the breakthrough we need. E-cigarettes are battery operated devices which heat a nicotine solution into an aerosol that the user inhales. Essentially, they simulate the hand-to-mouth action and sensory aspects of smoking and deliver the nicotine that smokers need but without the thousands of toxic chemicals caused by burning tobacco. Nicotine is addictive but is relatively harmless in the doses used in smoking and vaping.
Tobacco harm reduction is a pragmatic solution. It recognises that many smokers want to stop but are unable to do so and aims to minimise the huge risks to health from smoking by providing a much safer and acceptable alternative. The potential benefits are huge. Up to two in three Australian smokers will be killed prematurely by their habit if they continue to smoke.

E-cigarettes are not risk-free but there is growing scientific evidence that they are a far safer substitute for smoking and that smokers who switch to vaping can expect substantial improvements in health. Millions of smokers globally have now made the switch from combustible tobacco to vaping.

In spite of this clear evidence, Australia is one of the few OECD countries to effectively ban vaping with nicotine. Opponents of vaping argue that e-cigarettes will be a gateway to youth smoking, will 'renormalise' smoking and may delay quitting.

However, overseas experience suggests the opposite. There is no good evidence that e-cigarettes are luring children to smoke. Smoking rates in countries where e-cigarettes are available, are continuing to fall, in some cases such as the US, faster than ever. Research suggests that is likely that e-cigarettes are contributing to this rapid decline in smoking.

Modelling studies have all found that these small and theoretical fears about vaping are far outweighed by the benefits of e-cigarettes in helping adult smokers to quit tobacco.

Australia needs to establish a balanced regulatory framework now to allow legal access to nicotine-containing e-cigarettes for adult smokers who are unable or unwilling to quit, while setting safety and quality standards and minimising risks to non-smokers, including youth.

If two in three Australian smokers switch to e-cigarettes over the next 10 years, over 500,000 premature deaths from smoking will be averted, according to modelling based on the US population.

We need more research, but we can’t wait another twenty years for absolute certainty. Evidence is never perfect, but there is enough scientific evidence available now to make a rational decision.

The cost of inaction is too high. The lives of thousands of Australian smokers depend on it.
Introduction

The World Health Organisation (WHO) estimates that a billion people worldwide will die prematurely in the 21st century as a direct result of the ill health impacts of tobacco smoking.

This report focuses on an emerging technology that is proving to be both popular and extremely useful in the fight to quit smoking. However, it continues to remain a controversial and polarising issue in some countries including Australia, despite its reported success in other nations that have embraced it.

This report will therefore canvas the latest in a large and growing body of independent research and evidence that attests to the impacts of legalised e-cigarettes or personal vapourisers (known as ‘vapes’), also referred to as ENDS or Electronic Nicotine Delivery Systems, as well as smoke-free tobacco or snus.

Tobacco Harm Reduction (THR) experts increasingly concur that ENDS provides smokers with an effective quitting aid by allowing them to obtain the nicotine they find difficult to give up despite the known dangers of burning tobacco – the component of smoking that exposes smokers to the deadly cocktail of chemicals and carcinogens.

Demand for safer alternatives is well established amongst Australian smokers. Yet, Australian public health authorities have hitherto chosen to ignore or dismiss evidence and expert opinion that has been embraced in the UK, USA, Canada and New Zealand. This report seeks to examine the reasons for this and considers future options.

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The compilation of this report coincides with:

- The latest figures revealing a stagnating smoking cessation rate in Australia for the first time in years and more Australians smoke in 2016 than they did in 2013. Conversely, the opposite trend reported in the USA and UK where safer alternatives to tobacco are legal.

- The latest report from international accounting firm KPMG indicating that the black market in illicit tobacco has grown into a $15 billion/year domestic industry, with both Federal and Victorian police finding that the black market funds other criminal enterprises.

- Evidence that a punitive approach of hiking tobacco excise rates further without providing access to safer alternative products is no longer effective in encouraging cessation, and represents regressive taxation as poor smokers are more likely to struggle with quitting and spend a greater proportion of their income on cigarettes.

- The release of the latest report on vaping in the UK from Public Health England (6th February 2018). This report found that an estimated 20,000+ British smokers are quitting their habit every year by transitioning to vaping, and that vaping is driving a spike in both quit attempts and quitting success across the country.

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14 Australian Institute of Health and Welfare (2017), National Drug Strategy Household Survey 2016, Table 2 [link]
16 KPMG’s 2016 Full-Year Report “Illicit Tobacco in Australia”, March 2017. [link]
17 Australian Broadcasting Corporation, 12th May 2016 “Illegal Tobacco fuelling drug trafficking and terrorism” [link]
18 Herald Sun, 15th December 2015, “police bust alleged illicit tobacco importation gang” [link]
19 Australian Institute of Health and Welfare (2017), National Drug Strategy Household Survey 2016, Table 2 [link]
Australian & International Approaches

In general, **European nations** and the **USA** have adopted a progressive approach by allowing consumers the choice of legally available ENDS products with nicotine. The US Food & Drug Administration (FDA) recently announced strong support for e-cigarettes in tobacco harm reduction,22 with FDA Commissioner Dr. Scott Gottlieb declaring that “Envisioning a world where ... adults who still need or want nicotine could get it from alternative and less harmful sources, needs to be the cornerstone of our efforts.”23 By contrast, **Asia-Pacific nations** tend to be regressive on the issue.

**New Zealand**24 and **Canada**25 are currently in the process of legalising nicotine for use in e-cigarettes.

In the **UK**, nearly 3 million adults now use e-cigarettes,26 and both public health authorities, (over 20 organisations including Public Health England and NHS Scotland), and doctors, now ‘encourage’ smokers to use them as a quit smoking aid.27 28 The products are sold as consumer goods and can also be sold through a therapeutic goods pathway after securing approval of the relevant regulator.

The **European Union** has also adopted a dual system, whereby there is an ordinary consumer market but also potential for a therapeutic market.29

By contrast, ENDS products are banned in **Singapore**.

**Australia** has a mixed record in public health policy. While we were slow to embrace technological innovations including seat belts and motorcycle helmets, we have been a lot quicker to adopt policies such as needle exchange for drug users. The current approach of a ban on innovative ENDS technology is a regressive approach. However, despite reluctance from policy-makers, a number of experts and leading medical professional bodies including The Royal Australian and New Zealand College of Psychiatrists,30 and Drug and Alcohol Nurses of Australasia,31 have called for legalised ENDS.


23 [link]


26 The Guardian, 8th May 2017, “majority of vapers have quit tobacco” [link]


30 [link]

31 DANA Position Statement on E-Cigarettes, 2017 [link]
Smoking in Australia

The harms of smoking are both significant and well documented. Smoking is the leading, preventable cause of respiratory disease, cardiovascular illness, cancer and impaired welfare and wellbeing.32

Cancer Council Australia estimates that two out of every three deaths in long-term smokers can be directly attributed to smoking, and that smoking is responsible for approximately 20% of Australia’s cancer disease burden.33

Smoking directly causes the premature deaths of 19,000 Australians every year and costs Australia an estimated $31.5 billion a year in health, social and economic costs.34 77.2% of these costs are ‘intangible’ and although less than 8% of the tangible costs are borne by the public sector, this is still a considerable figure as it places a $1.5 billion burden on Federal and State budget outlays every year.35

Smokers are disproportionately likely to be disadvantaged. People from low socioeconomic backgrounds, the unemployed, and those living in outer, rural and regional areas are overrepresented in smoking statistics.36 Aboriginal and Torres Strait Islanders (ATSI) are also disproportionately likely to be smokers, as are LGBTQ+ identifying individuals.37

One in three individuals suffering from mental illness are smokers and these individuals also experience lower quitting rates than the general population, with smoking identified as the major contributor to the health gap between the mentally ill and the general population.38

“In the UK, nearly 3 million adults now use e-cigarettes, and both public health authorities, (over 20 organisations including Public Health England and NHS Scotland), and doctors, now ‘encourage’ smokers to use them as a quit smoking aid.”

33 [link]
35 Ibid.
36 Ibid.
37 Ibid.
Is Nicotine the problem?

Nicotine is a mild stimulant, traditionally derived from the nightshade plant family. It is understood to be the main addictive component of smoking tobacco. However, it is non-carcinogenic and is not the cause of smoking-related morbidity or mortality.

Like caffeine, nicotine is a naturally occurring alkaloid and does not significantly alter mind/body function or provide pharmacological effects like a medicine.

It is possible to become addicted to caffeine or nicotine. However, the human body is able to regulate these substances. Users can easily adjust intake based on their individual response to the stimulants, with typical dosage ranges in coffee or ENDS fall far short of that which is necessary to cause any harm. In fact, there is recent public health industry consensus that a lethal dose of nicotine is 8-16 times greater than even previously thought.40

ENDS products facilitate a consumer’s ability to moderate their nicotine dosage. A 2016 study found that experienced ENDS users were better able to titrate their nicotine dosage with nicotine solutions of different concentrations than using cigarettes.40

Tobacco smoking-related harms are overwhelmingly caused by the inhalation of toxic particles and gases containing tar and other products generated when tobacco combusts, as it does in a cigarette. This is a long-recognised fact, with even early studies noting that “people smoke for the nicotine, but die from the tar.”41

The Royal College of Physicians (UK) sums up the effects of nicotine as follows:

“At low doses, nicotine is a stimulant, which in the short term increases heart rate and may improve attention, memory and fine motor skills. Although potentially lethal at very high doses, at the blood levels typically achieved by smoking nicotine does not result in clinically significant short- or long-term harms.”42

In relation to the ill impacts of smoking, they note that:

“Of the three main causes of mortality from smoking, lung cancer arises primarily from direct exposure of the lungs to carcinogens in tobacco smoke, COPD from the irritant and proinflammatory effects of smoke, and


cardiovascular disease from the effects of smoke on vascular coagulation and blood vessel walls. None is caused primarily by nicotine."^43

“As use of nicotine alone in the doses used by smokers represents little if any hazard to the user, complete substitution of smoking with conventional Nicotine Replacement Therapy [NRT] products is, for practical purposes, the equivalent of complete cessation in almost all areas of harm to the user.”^44

This view echoes the stance of the UK’s Royal Society of Public Health, who found that:

“Nicotine is no more harmful to health than caffeine.”^45

Similarly, U.S. Food and Drug Administration Commissioner, Dr. Scott Gotlieb notes that:

“The nicotine in cigarettes is not directly responsible for the cancer, lung disease, and heart disease that kill hundreds of thousands of Americans each year… it’s the other chemical compounds in tobacco, and in the smoke created by setting tobacco on fire that directly and primarily cause the illness and death, not the nicotine.”^46

Clive Bates, the former Director of Action on Smoking and Health (London) as well as a founder of the NGO Framework Convention Alliance has also stated that:

“Pure nicotine is not completely benign, but it is widely sold in medicinal form and does not cause any serious illness. The US Surgeon General has made a detailed assessment of nicotine risks, and though it is possible to measure many effects on the body, these are trivial compared to smoking: for health, it is always better to vape than to smoke.”^47

The abovementioned findings are supported by evidence that widely sold NRT products such as patches and gums, which have been legally available for decades, have not been linked to any disease and do not bear any significant correlation to any

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^43 [link]
^45 Tobacco Advisory Group to the Royal College of Physicians (UK) 2016, ‘Nicotine without smoke: Tobacco harm reduction’
^46 U.S. Food and Drug Administration Website, July 28 2017 [link]
disease despite the existence of long-term studies.\textsuperscript{48}

Claims have been made based on animal studies, that nicotine may have effects on brain development. These claims are highly questionable at best as the studies were performed on animals which fail to provide an accurate or reliable comparison to humans,\textsuperscript{49} feature chronic or extreme doses of nicotine that fall outside typical dosage range in ENDS products,\textsuperscript{50} and are not corroborated by any human studies of extended use of NRT products and long-term studies of snus, a low-risk oral tobacco product which delivers high levels of nicotine. NRT products have consistently been approved for smokers as young as 12 years old for 30 years, yet no evidence of adverse effects on adolescent brain development have emerged.\textsuperscript{51}

A 2016 study published in \textit{Nicotine and Tobacco Research} found that after switching from tobacco to e-cigarettes, nicotine exposure remains unchanged, while "exposure to selected carcinogens and toxicants is substantially reduced."\textsuperscript{52}

A European study similarly concluded that where cigarettes were assigned a 100% rating for ‘maximum relative harm’ (MRH), e-cigarettes were only given a 4% rating of MRH.\textsuperscript{53}

A long-term cross-sectional study also found that transition to ENDS from smoking drastically lowered the levels of tar, toxins and carcinogenic chemicals found in the bodies of both former smokers and current dual users of both cigarettes and e-cigarettes.\textsuperscript{54}

Notably and regardless of its benign health impacts, millions of ENDS users go on to quit nicotine completely and thus eliminate their exposure to even nicotine itself.\textsuperscript{55}

\begin{figure}[h]
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\caption{A long-term cross-sectional study also found that transition to ENDS from smoking drastically lowered the levels of tar, toxins and carcinogenic chemicals.}
\end{figure}


\textsuperscript{49} Naiura R. Re-thinking nicotine and its effects, Schroeder Institute, Truth Initiative, United States. 2 December 2016.


\textsuperscript{51} Lee PN, Fariss MW. A systematic review of possible serious adverse health effects of nicotine replacement therapy. Archives of toxicology. 2016.


\textsuperscript{55} Royal College of Physicians. Nicotine without smoke: Tobacco harm reduction. London: RCP. 2016. [link]
What is vaping?

Tobacco harm reduction is the process of minimising or eliminating the harms inflicted upon smokers by tobacco.

Although ‘cold turkey’ is the most desirable method of smoking cessation, the method has a low success rate.\(^{56}\) Most of those attempting to quit smoking completely, experience relapses and many struggle for the rest of their lives to quit despite bonafide intentions and persistent attempts to do so.\(^ {57}\)

Tobacco control experts have understood this problem for decades, resulting in the development and approval of ‘Nicotine Replacement Therapy’ (NRT). These products (including patches and gums) provide smokers with controlled doses of nicotine and are intended to ease the smokers’ transition out of smoking by targeting their nicotine withdrawals and cravings.\(^ {58}\)

NRT products have existed on the market for decades and are sold as consumer goods to individuals as young as 13. Some of these products are even covered under Australia’s Pharmaceutical Benefits Scheme.\(^ {59}\)

Recently, a new class of products has emerged that not only addresses the issue of nicotine withdrawals, but offers a more viable and effective alternative for smokers to transition away from smoking.

These products include e-cigarettes or ‘vapes’, ‘personal vapourisers’ (known as ENDS or Electronic Nicotine Delivery Systems), smokefree tobacco and ‘heat not burn’ products.

Vapes were invented in China in 2003. They were commercialised a year later and have been available in most of the Western world since 2010, with significant uptake since 2012.

ENDS mimic the sensation of smoking without smoke from burning tobacco, thereby avoiding the deadly cocktail of chemicals which render cigarettes dangerous.

ENDS products produce no smoke as they avoid the process of tobacco


\(^{57}\) Ibid.


\(^{59}\) Department of Health (2016) PBS Schedule search: nicotine [link]
combustion entirely. Liquid-based ENDS products heat a small quantity of flavoured solution using an ‘atomizer’ until it diffuses into a colourless, odourless vapour. ENDS liquids that contain nicotine are hence able to satiate a smokers’ cravings using this medium.

Similarly, ‘heat not burn’ ENDS products produce vapour by heating a tobacco mixture instead of engaging in tobacco combustion.

Snus or ‘smokeless tobacco’ is a moist, powdered tobacco product that is placed under the consumer’s lip and absorbed into the bloodstream without the need for smoking. As a result, it has far lower levels of carcinogens than those released when smoking tobacco is consumed.60

60 Broadstock, Marita (February 2007). "Systematic review of the health effects of modified smokeless tobacco products" New Zealand Health Technology Assessment Report. 10 (1).[link]
The ideal tobacco substitute product

The ability to closely mimic ‘smoking’

Unlike conventional NRT products such as patches or gums, the action of ‘vaping’ closely mimics that of smoking. This enhances its value, appeal and effectiveness as a tobacco cessation device.

More effective delivery

The rate of absorption of nicotine is fastest when it is delivered through oral inhalation which results in absorption through the lining of the mouth and lungs, compared to the progressively slower rates of absorption observed through purely the mouth (as in nicotine gums) or skin (as in nicotine patches).

Customisable to the individual cigarette quitter’s needs

Smokers who switch to vaping are able to choose from an innovative range of ENDS products that can be tailored to their individual preferences, facilitating their transition out of smoking.

For example, some consumers prefer ENDS devices or liquids can deliver a similar physical sensation to the throat as a cigarette. ENDS products can achieve this effect without relying on carcinogenic tobacco smoke. They hence help recent quitters adjust more easily to life without a cigarette.

Pleasant flavours that incentivise smokers to quit

Most users vape with solutions that are flavoured, providing an appealing sensory experience that makes them a more attractive option than cigarettes and thus enhances their effectiveness as a quit smoking tool.

A 2016 Consumer Advocates for Smoke-Free Alternatives Association (CASAA) survey of 27,343 e-cigarette users found that 72% of respondents “credited tasty flavours with helping them give up tobacco.”61

Similarly, a 2013 internet study by leading researcher Konstantinos Farsalinos, concluded that flavourings in e-cigarettes “appear to contribute to both perceived pleasure and the effort to reduce cigarette consumption or quit smoking.”62

A pleasant smelling vapour also ensures that passive vapers in the vicinity are spared exposure to far more odorous and dense tobacco smoke which, unlike vapour generated by ENDS products, sticks to clothes.

61 “Large Survey Finds E-Cigarettes Do Help Smokers Quit,” Vape Ranks (website), January 12, 2016, [link]
More effective than conventional NRT patches and gums

The practical advantages of vaping over conventional NRT products are also supported by the statistics. Randomised controlled trials of early devices with low nicotine delivery were found to be at least as effective as NRT. Studies of more modern devices have shown them to be even more effective.\textsuperscript{63}

Effectiveness enhanced by the addition of nicotine

The Cochrane Collaboration, an internationally recognised independent assessor of therapeutic effectiveness, canvassed the results of multiple studies and found that e-cigarettes containing nicotine increased the odds of long-term successful smoking cessation than using e-cigarettes which do not contain nicotine.\textsuperscript{64}

\textbf{Unlike conventional NRT products such as patches or gums, the action of 'vaping' closely mimics that of smoking. This enhances its value, appeal and effectiveness as a tobacco cessation device.}

\textsuperscript{63} Hitchman SC. Associations between e-cigarette type, frequency of use and quitting smoking. Nicotine Tob Res 2015.

\textsuperscript{64} [link]
The benefits of switching from smoking to vaping

Vapes and other ENDS products are invaluable in tobacco harm reduction as they are both an effective smoking cessation tool as well as an effective method for minimising smoking-related harms for both active and passive smokers. They are also more effective in this regard than conventional NRT products.

Harm Reduction

The UK Royal College of Physicians has found that nicotine delivery products such as vapes and heat-not-burn products such are AT LEAST 95% less harmful* than conventional smoking of combustible tobacco as they virtually eliminate a smoker’s exposure to carcinogens found in tobacco. For example, the two most dangerous carcinogens in tobacco smoke: Acrylonitrile and 1,2-butadiene, account for more than three-quarters of the cancer risk from smoking and are not found in vapour at all.

Electronic Nicotine Delivery Systems (supported by an appropriate regulatory framework)

Reduce carcinogen exposure: A long-term, cross-sectional study recently found that transitioning from cigarettes to alternative nicotine delivery products drastically lowers the build-up of carcinogens and tar in the bodies of smokers.

Carry minimal risk for passive smokers:
Multiple studies have found that alternative nicotine delivery products do not pose any material risk to passive smokers. For this reason, Public Health England recommends that smoke-free workplace laws and laws which prohibit indoor smoking do not apply to alternative nicotine delivery products in recognition of the lack of risk these products pose for passive smokers.

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65 Royal College of Physicians (London), Nicotine without smoke: tobacco harm reduction. 28 April 2016. [link]
66 Stephens WE. Comparing the cancer potencies of emissions from vapoured nicotine products with those of tobacco smoke. Tob Control 2017 [link]
Are recommended to smokers by medical professionals:
The Royal College of Physicians and Public Health England not only recommend the legalisation of alternative nicotine delivery products, but advise doctors to recommend these products to patients who wish to quit smoking.\(^{70}\)

Are endorsed by academics and public health institutes:
Nicotine vaping is also recommended as a safer alternative to smoking by other independent public health authorities including the UK Centre for Tobacco and Alcohol Studies\(^{71}\)and the Canadian Institute for Substance Use Research (CISUR).\(^{72}\)

Help users moderate their nicotine intake:
ENDS also reduces harm by allowing the user a greater degree of control over their nicotine dosage, facilitating moderate use. A 2016 study found that experienced ENDS users were able to adjust their nicotine intake at levels according to their specific needs.\(^{73}\) This is because the use of liquid solutions available in containers with a fixed capacity make it far easier to estimate and control intake than tobacco leaves or cigarettes.

Are of special benefit to smokers suffering from mental illness:
Dr. Colin Mendelsohn, tobacco treatment specialist and Conjoint Associate Professor of Public Health and Community Medicine at the University of New South Wales, notes that “E-cigarettes could be of special benefit to smokers with mental illness, who are more likely to smoke and smoke more heavily than other smokers. Smoking is the leading cause of the poor health of this population.”\(^{74}\) This claim is also supported by the Royal Australia and New Zealand College of Psychiatrists.\(^{75}\)

Are less addictive than cigarettes:
Pharmacological dependence on smoking is partly driven by non-nicotine agents present in tobacco such as monoamine oxidase inhibitors.\(^{76}\) Vapers are not exposed to these ingredients. It is hence likely that ENDS has less physiological dependency-forming impacts than tobacco.

Reduce the cardiovascular disease risk of smokers who transition:
Potentially toxic ingredients are present at far lower concentrations in vaping solutions than cigarettes, and benefits of e-cigarettes and vapour devices. University of Victoria, BC: Centre for Addictions Research of BC. 2017.

\(^{70}\) UK Government policy paper, “towards a smoke-free generation” 18 July 2017 [link]  
\(^{74}\) [link]  
\(^{75}\) [link]  
the risk of cardiovascular illness is far lower for vapers than smokers.\textsuperscript{77}

Pose a far smaller fire hazard than smoking:

Collins & Lapsley estimated that tobacco costs the Australian government $65 million annually (or $85 million annually, adjusted for inflation) due to fires.\textsuperscript{78} ENDS carry far lesser fire risk. Legalised ENDS is therefore likely to minimise tobacco-related fire damage.

Georgetown University's Comprehensive Cancer Centre estimates a reduction of 21 percent in smoking-attributable deaths and 20 percent in life years lost as a result of use of e-cigarettes in people born in 1997 or after, compared to what would have happened if e-cigarettes were not an option.\textsuperscript{79} Another study considered the public health impacts of vaping in the US over a 10 year period. It found that even under conservative estimates about the rate of uptake in vaping by smokers and relative harm, it is likely that 6.6 million Americans will avoid premature deaths with 86.7 million fewer life years lost due to ENDS.\textsuperscript{80} If the study’s results are applied to Australia, over half a million premature deaths will be prevented should our domestic smoking population transition to vaping.\textsuperscript{81}

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\textsuperscript{77} Ibid.

\textsuperscript{78} Collins, David John, and Helen M. Lapsley. \textit{The costs of tobacco, alcohol and illicit drug abuse to Australian society in 2004/05}. Canberra: Department of Health and Ageing, 2008. [link]


\textsuperscript{80} Levy DT. Potential deaths averted in USA by replacing cigarettes with e-cigarettes. Tobacco Control 2017 [link]

\textsuperscript{81} Ibid; Dr. Colin Mendelsohn – Tobacco Treatment Specialist, 3rd October 2017 “Switching to e-cigarettes could save the lives of half a million Australian smokers” [link]
Smoking cessation

Proven track record

Since they have been available around the world, vapes have been almost exclusively taken up by current smokers attempting to quit or reduce their smoking.\textsuperscript{82, 83} As of 2014, over 6 million Europeans had given up smoking completely by transitioning to vapes,\textsuperscript{84} and it is likely that this figure has increased substantially since then. Similarly, over 1.5 million British smokers had quit as of 2016 with the aid of vaping,\textsuperscript{85} and the latest figures from Public Health England (2018) estimate that 20,000+ British smokers a year continue to quit with the aid of vaping.\textsuperscript{86} Approximately 770,000 of these went on to quit both smoking and vaping completely. The track record of vaping as a cessation aid is also supported by circumstantial evidence. The UK government found that while the fall in the country’s smoking rate began to stall late in the last decade, smoking sharply reduced between 2012 and 2014 – a period coinciding with rapid uptake of vaping. By 2014, it had hit a record low of 17.4%.\textsuperscript{87} The only significant tobacco control measure implemented by the UK government during this time were cigarette display bans which did not come into effect until 2015, towards the period’s end.\textsuperscript{88} A similar trend is observed in the United States where adult smoking rates have fallen rapidly between 2010 and 2017 – from 19.4% to a record low of 14.4% - below Australia’s smoking rate despite the prevalence of far stricter tobacco control regulations including plain packaging and the world’s highest cigarette prices in Australia.\textsuperscript{89}

\textsuperscript{85} ASH. Use of electronic cigarettes (vapourisers) among adults in Great Britain. Fact sheet. May 2017 [link]
\textsuperscript{86} Evidence review of e- cigarettes and heated tobacco products 2018. A report commissioned by Public Health England [link]
\textsuperscript{87} Office of National Statistics (UK), Adult Smoking Habits in Great Britain1974-2014. 18 February 2016 Table 1 [link]
\textsuperscript{88} Ibid.
\textsuperscript{89} CDC, National Health Interview Survey, 2017 [link]}
Vaping aids smoking cessation attempts

Smokers in the US who attempt to quit with the aid of e-cigarettes were over 73% more likely to succeed than those who do not use vapes. Studies have found that vapes are at least as effective as other nicotine replacements to aid smoking cessation, and are likely to reach more smokers due to their suitability as a cigarette substitute. A UK study observed 15,532 recent smokers and found that those who use e-cigarettes daily were thrice as likely to have quit smoking by the end of the study than those who had never used e-cigarettes.

Vapers are more likely to attempt quitting

Data from the United States’ 2014/15 Tobacco Use Supplement-Current Population Survey (TUS-CPS) found that both quit attempts and the success rate of quit attempts were positively correlated with vape use. A survey of over 15,000 American smokers also found that vapes are now more popular than FDA-approved medications as a tobacco cessation aid. They are also the most popular quitting aid in the UK.

Vapes are more effective than nicotine patches and gums in helping smokers to quit

Randomised controlled trials of early devices with low nicotine delivery were found to be at least as effective as NRT. Studies of more modern devices have shown them to be even more effective.

For these reasons, the Royal College of Physicians notes that policy or laws that make vapes less easily accessible, less palatable or acceptable, more expensive, less consumer-friendly, less pharmacologically effective or which hinder development and innovation of new products, effectively perpetuate smoking and its harms.

Public health objectives hence call for the repeal of Australia’s current prohibition on nicotine-loaded vaping juices.

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90 Zhu S. E-cigarette use and associated changes in population smoking cessation. BMJ 2017
91 Clearing the Air: a systematic review on the harms and benefits of e-cigarettes and vapour devices. University of Victoria, Centre for Addictions Research BC, Canada. January 2017
93 Giovenco DP. Prevalence of population smoking cessation by electronic cigarette use status in a national sample of recent smokers. Addict Behav 2017
97 Hitchman SC. Associations between e-cigarette type, frequency of use and quitting smoking. Nicotine Tob Res 2015.
98 Royal College of Physicians (London), Nicotine without smoke: tobacco harm reduction. 28 April 2016
Myths about vaping

“Vaping serves to ‘re-normalise’ cigarettes. It acts as a ‘gateway’ to smoking tobacco”

- This claim is not supported by the evidence, which instead finds that vapourised nicotine has almost exclusively been taken up by smokers attempting to quit or lower their intake, therefore acting as a ‘gateway’ away from tobacco smoking.

- As of 2018, three separate surveys using a large sample size have found that a miniscule 0.3% of adult vapers are people who have never smoked.

- The notion that vaping uptake has ‘normalised’ or acted as a gateway to smoking for young people is also not supported by the evidence. For example, vaping experienced rapid uptake after 2011. Amongst American high school students, cigarette use fell from 15.8% in 2011 to 9.3% by 2015 and use of pipes and cigars reduced significantly as well.

- A vast majority of American teens who vape do not use nicotine-loaded solutions, and almost all of those who do use nicotine-loaded solutions had previously tried at least one cigarette.

- Use in youths who have never smoked is at a very low level and is mostly experimental.

- It is also likely that any adolescents who have taken up vaping would have taken up cigarette smoking in lieu of e-cigarettes.

- There is no evidence that e-cigarettes provide a ‘gateway’ to smoking for youths as they enter adulthood.


103 Christopher Ingraham (25 August 2016) ‘Teen vaping is not what you think it is, researchers say’ Washington Post [link]


105 O’Leary R, MacDonald M, Stockwell T, Reist D. Clearing the Air: A systematic review on the harms and benefits of e-cigarettes and vapour devices.
• There is also no evidence that the miniscule number of never-smoking youth who took up ENDS have progressed to smoking.\textsuperscript{106}

• A 2014 study in the American Journal of Preventative Medicine found that the few ENDS users who were not smoking previously, used the product only 1-2 days a week, indicating that any residual harm from legalised ENDS is minimal.\textsuperscript{107}

• Similarly, evidence from large, national cross-sectional studies also show no evidence that vaping uptake increases the ranks of future smokers in countries where ENDS is legal.\textsuperscript{108}

“Nicotine adversely affects brain development”

• This claim is also baseless. The only evidence linking nicotine to brain development issues are animal studies which do not provide a reliable or accurate comparison to humans.\textsuperscript{109}

• Furthermore, these studies also usually feature chronic or extreme doses of nicotine,\textsuperscript{110} which fall far outside typical use in vaporisers or e-cigarettes.

• There has been no evidence linking nicotine and brain development issues in humans despite large populations which have been exposed to more than two centuries of nicotine use through tobacco and more recently introduced NRT products as well as smokeless tobacco or ‘snus’.

• NRT products have existed and been approved for smokers as young as 12 years old for 30 years, yet no evidence of adverse effects on adolescent brain development have emerged.\textsuperscript{111}

“Vaping nicotine may expose users to harmful chemicals such as formaldehyde”

• This claim is based on a single study which produced formaldehyde from an e-cigarette by deliberately


\textsuperscript{108} Kozlowski L, Warner K. Adolescents and e-cigarettes. Objects of concern may appear larger than they are. Drug Alc Depend 2017 [link]; Polosa R. A critique of the U.S. SG’s conclusions regarding e-cig use among youth and young adults in US. Harm Red J 2017 [link]

\textsuperscript{109} Niaura R. Re-thinking nicotine and its effects, Schroeder Institute, Truth Initiative, United States. 2 December 2016.


\textsuperscript{111} Lee PN, Fariss MW. A systematic review of possible serious adverse health effects of nicotine replacement therapy. Archives of toxicology. 2016.
overheating it, thus engaging in unsafe use which is atypical of normal practice and akin to the dangerous effects of coffee being inferred from the consumption of an entire carton of coffee powder in a single sitting.\textsuperscript{112} Notably, Australia’s status quo of banning ENDS actually encourages unadvisable practices as it prevents the issuance of warnings or safety information.

- Subsequent research has confirmed that ‘The high levels of aldehyde emissions that were reported in a previous study were caused by unrealistic use conditions that create the unpleasant taste of ‘dry puffs’ to e-cigarette users and are thus avoided.’\textsuperscript{113}

- Under realistic conditions, new-generation ENDSs emit minimal formaldehydes/g liquid at both low and high power.\textsuperscript{114}

“Vaping causes ‘popcorn lung’”

- Flavouring agents in some e-cigarette solutions have been found to contain trace amounts of diacetyl, acetyl, propionyl, and acetoin.\textsuperscript{115} Some of these chemicals have been linked to the medical condition ‘popcorn lung’ which is commonly experienced by workers in popcorn factories who inhale large amounts of these chemicals over years of work.\textsuperscript{116}

- Contrarily, no link has ever been established between the condition and such insignificant quantities of these chemicals as those found in some ENDS solutions.

- Notably, cigarette smoke contains the same chemicals in far larger quantities, yet neither tobacco nor smoking have been linked to popcorn lung either in terms of correlation or causation.

- In any event, these chemicals are easily replaced in flavoured solutions and this can be encouraged through either public information to deter use of these particular solutions or through regulations governing the manufacture and/or sale of these solutions.

- Ironically, such regulations or information campaigns are impractical under the Australian status quo where nicotine vaping is prohibited.


\textsuperscript{113} Farsalinos K. E-cigarettes emit very high formaldehyde levels only in conditions that are aversive to users. Food Chem Tox. 2017.


\textsuperscript{115} Joseph G. Allen, et al., “Flavoring Chemicals in E-Cigarettes: Diacetyl, 2,3-Pentanedione, and Acetoin in a Sample of 51 Products, Including Fruit-, Candy-, and Cocktail-Flavored E-Cigarettes,” \textit{Environmental Health Perspectives} 124 (June 2016): 733–9 [link]

\textsuperscript{116} Brent D. Kerger and M. Joseph Fedoruk, “Pathology, Toxicology, and Latency of Irritant Gases Known to Cause Bronchiolitis Obliterans Disease: Does Diacetyl Fit the Pattern?” \textit{Toxicology Reports} 2 (2015): 1463 1472 [link]
“Legalising ENDS will increase the risk of nicotine overdose”

- The extreme levels of nicotine required to overdose, far exceed the amounts consumed by even those who vape heavily. Moreover, vapers are likely to cease vaping due to the natural inclination that they have vaped too much well before the overdose level required for most of these risks eventuates.117

- In fact, legalised and regulated ENDS in Australia will actually lower the risk of nicotine overdose as solutions would be sold in regulated concentrations and legalised ENDS will encourage the provision and dissemination of information regarding safe and appropriate use. This is not currently possible under the status quo.

- It is especially concerning that 99% pure nicotine solutions can be purchased online from overseas.118 The availability of legal, regulated solutions in safe concentrations will discourage consumers from procuring dangerous products from the black or grey market, lowering the risk of nicotine overdose.

- The notion of overdose applies to caffeine as well as many other legal substances found in common household products which, if consumed in excess far outside normal use, can trigger negative side effects. Policy-makers should trust adult consumers with the ability to exercise the basic cognitive function of self-preservation and common sense.

“Legalising ENDS will increase the risk of accidental nicotine poisoning”

- In 2017, the following justification was given by Australia’s Therapeutic Goods Administration (TGA) as part of its decision to maintain the legal classification of nicotine solutions as a ‘poison’ under Australian law: “In the USA, accidental poisonings associated with e-cigarettes have increased from one per month in 2010 to 215 per month in 2014 including one death.” However, this statement is misleading and deceptive and is asserted without context.

- E-cigarettes were barely used prior to 2010 and it is likely that the proliferation of any product will give rise to some increase in accidental incidents above the negligible starting point. The rapid uptake of vapes in the United States between 2010 and 2014 is a material


118 Bates C. Regulators and the compliance fallacy - buying 99% nicotine e-liquid from China, The Counterfactual [link]
circumstance which the TGA failed to consider in its review.

- Moreover, the TGA’s cited source for its claim does not support the ‘accidental poisoning rate’ it alleges.\textsuperscript{119} The figure provided actually refers to the incidence of ‘exposures’ to nicotine. This will include instances outside intended use such as ingestion, inhalation, and absorption through skin or eyes. Many of these will have been minor or trivial exposures with little or no material ill effects and hence cannot be called ‘poisonings’.

- The TGA also cites a single fatality as a result of accidental nicotine poisoning. However, the death in question was one which occurred is in fact a suicide as it followed deliberate intravenous injection.

- Even if we assume the TGA’s cited figure is correct, 255 reported exposures in 2014 is a small fraction of the 4000+ exposure calls, most of them dealing with common household items, to US poison centres.\textsuperscript{120} The American Association of Poison Control Annual report from 2014 found that accidental nicotine exposures are rare compared to other household risks.\textsuperscript{121} They are a small fraction of the reported exposures for sedatives, cleaning substances, alcohol and cosmetics which each accounted for 150,000+ exposures in 2014.

- The ‘exposure’ rate of nicotine due to vape usage has actually declined significantly since 2014.\textsuperscript{122} It is likely that this will occur in Australia as well once ENDS is legalised as regulations and information that encourage safe use can be made widely available and applied.

\textsuperscript{119} CDC MMWR. Notes from the Field: Calls to Poison Centers for Exposures to Electronic Cigarettes — United States, September 2010–February 2014 April 4, 2014 / 63(13);292-293


\textsuperscript{122} Bates C. Regulators and the compliance fallacy - buying 99% nicotine e-liquid from China, Counterfactual 4 May 2016
Consumer perception and demand

A 2015 survey of Australian smokers revealed the following:

- 84% of adult smokers agree that tax/regulatory strategy should be used to encourage healthier alternatives tobacco smoking for adults and should eliminate non-adult smoking entirely:
- 82% agree that “It would be wrong for the government to prevent or delay the introduction of less harmful alternatives to regular cigarettes for adult smokers.”
- 93% agree that “if a new product is scientifically proven to have the potential to reduce the risk of smoking as compared to conventional cigarettes, adult smokers should have the right to access this information.”
- 75% agreed that e-cigarettes were a ‘positive alternative’ to tobacco smoking and;
- 65% affirmed that they would consider switching to vaping if e-liquids were legal, met quality/safety standards and were conveniently available.\(^\text{123}\)

These statistics show strong demand for safer alternatives to cigarettes. Policy makers should favour consumer choice and autonomy by fostering a legalised, regulated consumer good market for vaping solutions that contain nicotine.

As New Zealand is currently in the process of legalising nicotine solutions, Australian consumers will soon find it easier to import solutions produced in that country. Legalising ENDS in Australia will prevent benefits from flowing overseas rather than to domestic businesses and industry.

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123 Factasia Asian Nations Smokers Survey 2015 – Australia [link]
International regulatory approaches

The regulations which govern vaping in various countries and jurisdictions have developed and evolved over time with the benefit of emerging evidence about best practice. The current regulatory paradigm in Western nations attests to a shift from simply allowing ENDS products to be brought to market towards encouraging and incentivising smokers to transition to ENDS. These models provide ample source material for Australia to draft its own regulations governing a legalised ENDS market which promotes responsible and safe use while encouraging innovation and minimising risk.

Australia:

Under the status quo, ‘nicotine’ is classified as a ‘dangerous poison’ under the Australian Poisons Standard. This means that it can only be consumed as part of a cigarette or through conventional NRT products such as patches and gums unless a medical prescription, which is extremely difficult to obtain, is procured. A limited amount may be imported, however this is also impractical. Worryingly, smokers illegally use nicotine-loaded vaping juices as a better choice for their own health can be fined more than 40,000 under laws in states such as Western Australia. In the ACT and Tasmania, the possession of nicotine without an authority can result in up to two years jail. The classification of nicotine as a ‘poison’ was re-affirmed by the Therapeutic Goods Administration in 2017 in a review that was plagued by severe methodological flaws, such as the flaws noted in the “myths about vaping” section of this report. This status quo has helped to perpetuate smoking and has turned ordinary vapers making informed decisions about their health into criminals while facilitating the growth of a nicotine black market that directly supports criminal enterprises.

New Zealand:

Legalising e-cigarettes is a key component of the New Zealand government’s Smokefree 2025 regulatory strategy to encourage smoking cessation and to minimise the harm from tobacco. This approach has also been endorsed by the New Zealand Medical Association, the peak body of medical practitioners in New Zealand, which has released a statement recommending ready availability of nicotine-containing e-liquids for use in ENDS and the implementation of a regulatory framework to promote safe and responsible use. The government is also planning to establish a pre-market approval system for smokeless

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124 Poisons Standard November 2016, Federal Register of Legislation. [link]
125 Vaping360.com, July 14th 2016 “Queensland citizens turn vaping fiends” [link]
126 Ibid.
127 NZ government Press Release, 1 August 2017 [link]
tobacco, ENDS and other nicotine delivery products, according to Former Associate Health Minister Nicky Wagner: “There are a number of products available internationally — including heat-not-burn, snus, moist snuff, dissolvables and inhaled nicotine — that may be significantly less harmful than tobacco smoking. By creating a pathway to enable the sale of these products in New Zealand, smokers will have access to less harmful alternatives... Manufacturers will need to demonstrate their products are significantly less harmful than tobacco smoking and that their introduction into New Zealand will contribute to a smokefree future.”

Importantly, this process will be made cost and time-efficient through consideration of prior approvals and reviews obtained from trusted international regulators. A similar strategy can be implemented in Australia as New Zealand utilises similar regulatory standards and near-identical considerations to our own. Approvals for ENDS and other non-tobacco nicotine delivery alternatives such as smokeless tobacco, can hence be fast-tracked should the same product receive approval in New Zealand under a reciprocal recognition arrangement.

**United States of America:** The U.S. Food and Drug Administration has recently amended its Tobacco Control strategy in recognition of harm reduction approaches fostered by ENDS and other nicotine-delivery alternatives. The new approach acknowledges the vastly different risks of tobacco cigarettes compared to ENDS and aims to regulate each product in cogency with its risk level. Under prior proposals, ENDS were to be subjected to an expensive and burdensome pre-approval process, one to which tobacco cigarettes would not have been subject. Under the new approach, the implementation of the pre-approval process will be delayed pending consultation and implementation of measures to reduce the regulatory and cost burden connoted by the process which would have been prohibitive for several ENDS businesses, thereby reducing ENDS’ tobacco harm minimisation potential by setting up inequitable barriers of entry within the ENDS market. Importantly, regulations have also been flagged which could reduce the nicotine content of existing combustible cigarettes in order to facilitate smoker transition to safer alternatives like ENDS. Regulations will also be placed on ENDS products to promote safety, to the benefit of the consumer. This strategy is commensurate with U.S. Food and Drug Administration Commissioner Dr. Scott Gottlieb’s vision of “a world where cigarettes lose their addictive potential through reduced nicotine levels. And a world where less harmful alternative forms, efficiently delivering satisfying levels of nicotine, are available for those adults who need or want them.”

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129 NZ government Press Release, 2 August 2017 [link]
130 ibid.
131 U.S. Food and Drug Administration Website, July 28 2017 [link]
- A delay in the implementation of the requirement for pre-market applications for ENDS until 2022, giving vaping product manufacturers another four years to remain on the market and to prepare the necessary application materials.

- New guidance for the pre-market applications will be developed in order to simplify the requirements and reduce the burden and cost of preparing these applications.

- Safety standards for ENDS will be developed, addressing issues such as battery safety, e-liquid ingredients, and flavourings.

- The FDA will examine the effectiveness and feasibility of requiring a reduction of nicotine levels in tobacco cigarettes to a non-addictive level.

Ideally, the reduction of nicotine levels in real cigarettes would be paired with the development and promotion of electronic cigarettes and vaping products viable alternatives to smoking.

United Kingdom:

Under the UK government’s 2017 Tobacco Control plan, facilitating access to ENDS is a key component of their harm reduction and smoking cessation strategy. The government’s report “Towards a Smokefree Generation” states that: ‘Stopping smoking is hard and many smokers are turning to e-cigarettes to help them in their attempts. Many smokers are turning to e-cigarettes to help them in their attempts. In 2016, it was estimated that 2 million consumers in England had used these products and completely stopped smoking and a further 470,000 were using them as an aid to stop smoking. The Department of Health recognises that reducing harm in smokers who cannot quit, for example with e-cigarettes, is an important complementary strategy to existing tobacco control policy, such as mass media campaigns, smoking clinics and high tobacco taxation… The best thing a smoker can do for their health is to quit smoking. However, the evidence is increasingly clear that e-cigarettes are significantly less harmful to health than smoking tobacco.”132 Accordingly, the government has committed to the following:

- Ensuring that safer alternatives to smoking such as ENDS are widely available.

- Ensuring that ENDS are not routinely banned in smoke-free areas. Individual organisations are encouraged to make their own policies

- Ensuring that smokers are informed about the risks and benefits so they can make informed choices

132 UK Govt policy paper, 18 July 2017 [link]
• Ensuring that Health professionals are provided with support and guidance for assisting smokers to quit with e-cigarettes

• Ensuring that a range of safe and effective e-cigarettes are available on prescription

• Continuing monitoring of the impact of these products, including evidence on safety, uptake, health impact and effectiveness

Furthermore, Public Health England recommends that ‘smokefree’ legislation is not applied to ENDS products due to the lack of harm to passive vapers and to incentivise smokers to switch to the safer alternative. They further recommend that ENDS devices are not routinely included in the smokefree policies of private organisations and have produced guidance for employers and organisations looking to introduce policies concerning vaping in public to address this effect.\textsuperscript{133} The Tobacco and Related Products Regulations, implemented since May 2016, mandate the compilation of detailed data on ENDS sales and marketing with a focus on the impact of ENDS on smoking cessation in order to foster future policy and innovation to aid smoking cessation.\textsuperscript{134}

**Canada:** ENDS in Canada were previously governed by separate regulations in each province. However, the Canadian parliament is passing a bill into law which legalises and regulates ENDS solutions nationwide. Notably, the legislation (Bill S5) regulates ENDS as a separate class of non-tobacco product akin to the approach adopted by the Bill.\textsuperscript{135} Health Canada, the peak Health agency of the Canadian government, has noted that the rationale underpinning the bill is to foster nationwide availability of ENDS to consumers as it is a safer alternative to smoking.\textsuperscript{136}

"Many smokers are turning to e-cigarettes to help them in their attempts. In 2016, it was estimated that 2 million consumers in England had used these products and completely stopped smoking and a further 470,000 were using them as an aid to stop smoking."

\textsuperscript{133} Public Health England. ‘Use of e-cigarettes in public places and work places’. 6 July 2016. (viewed August 2017) [link]

\textsuperscript{134} [link]

\textsuperscript{135} Canadian Parliament. Bill S-5. An Act to amend the Tobacco Act and the Non-smokers’ Health Act and to make consequential amendments to other Acts. 2017. [link]

\textsuperscript{136} [link]
Vaping and the tobacco black market

The prohibition of legal and regulated ENDS products and other safer alternatives to tobacco smoking, coupled with multiple hikes to tobacco excise which have made Australia home to the world’s most expensive legally sold cigarettes, have fostered the illicit tobacco market. The black market in tobacco is a $15 billion a year domestic industry, according to international accounting firm KPMG.\(^{137}\)

It is a noted funder of other illicit enterprises worldwide including human trafficking,\(^{138}\) and even terrorism. Allowing smokers to switch to safer and regulated ENDS products will undermine this illicit industry and prevent funds and lost government revenue from flowing into the hands of criminals.

Furthermore, Australian businesses are moving offshore in order to be able to provide nicotine to the Australian market, resulting in a loss of commerce, GST and employment to other countries.

Australian Federal Police commissioner Wayne Buchhorn notes that illegal tobacco "is used to fund drug importations. There is also evidence it is utilised in other serious organised crime type activities," Mr Buchhorn said. "I would consider it [a national security threat] because [of] the potential for organised crime groups to attack the institutions of state, whether through corruption or through their infiltration of legitimate supply chains. That has the potential to cause corruption within government agencies and more broadly. So the potential for that to be a national security risk for me is very real."\(^{139}\)

The US State Department has also described international tobacco smuggling as a "threat to national security", while the United Nations and OECD have also recently raised serious concerns about the impact of the illicit trade.\(^{140}\) According to the World Health Organization Framework Convention on Tobacco Control, there are an estimated 600 billion counterfeit and smuggled cigarettes crossing national borders each year. This accounts for over 10% of all cigarettes consumed.\(^{141}\)

A Cato Institute report concludes that "a wide range of terrorist groups are known to use the proceeds from cigarette smuggling to fund their operation. For example, counterfeit cigarette tax stamps were found in an apartment used by members of the Egyptian Jihad cell that carried out the 1993 bombing of the World Trade Center."\(^{142}\) International terrorist outfits

\(^{137}\) KPMG’s 2016 Full-Year Report “Illicit Tobacco in Australia”, March 2017. [link]
\(^{138}\) According to the US Department of State [link]
\(^{139}\) Australian Broadcasting Corporation 5th December 2016, “Illegal tobacco trade fuelling drug trafficking and terrorism” [link]
\(^{140}\) Ibid.
\(^{141}\) Science20.com June 8th 2010, “Cigarettes Don’t Kill As Much As Counterfeit Cigarettes Do” [link]
including Hezbollah,143 and ISIS144 have directly benefited from illegal tobacco sales. This should be of special concern to Australia as many of these groups are active in our region. For example, ISIS is known to be an active threat in The Philippines.145

Legal access to ENDS will not only undermine the illegal tobacco market by providing a safer alternative that is proven to reduce both legal and illegal tobacco smoking rates worldwide, but will also make black market products less attractive and appealing to the consumer.

“a wide range of terrorist groups are known to use the proceeds from cigarette smuggling to fund their operation. For example, counterfeit cigarette tax stamps were found in an apartment used by members of the Egyptian Jihad cell that carried out the 1993 bombing of the World Trade Center.”

143 Ibid.
144 The Guardian, 28th November 2015 “How to beat Islamic State? Crack down on cigarette smuggling” [link]
145 New York Times, 23rd October 2017 “ISIS threat in Philippines spreads to remote battles” [link]
Policy Recommendations

The ATA recommends that nicotine is removed from Schedule 4 of the Australian Poisons Standard (‘therapeutic purposes only’). This will allow nicotine solutions to be sold as a consumer good in the same manner as cigarettes are currently sold. This will foster consumer access to the product and incentivise smokers to transition to the safer practice of vaping.

The ATA also recommends that nicotine is exempted from Schedule 7 of the Australian Poisons Standard, which prevents its sale in all states and territories in the country, provided that it is sold in solutions for self-administration with an electronic nicotine delivery system (‘personal vapouriser’ or ‘electronic cigarette’) at a specified maximum concentration to be determined and revised by periodic review of international best practice.

The ATA further recommends a new statutory or regulatory framework pertaining to nicotine solutions that is based upon best international practice. The objectives of the regulatory framework should include: consumer safety, preventing advertising/limiting appeal to minors and non-smokers, fostering innovation and incentivising smokers to transition from smoking to vaping.

Other specific regulations recommended:

1. Advertising:
   That the *Tobacco Advertising Prohibition Act 1992* is amended to exempt ENDS products from the advertising prohibition on tobacco and cigarettes. This is an important reform which is crucial to encouraging smokers to transition to ENDS in order to obtain the harm minimisation and smoking cessation benefits. Removing the prohibition on advertising will ensure that public information can be disseminated on safe, responsible and effective use. It will also ensure that targeted regulations can still be placed on ENDS products to ensure that advertising does not appeal to minors, targets current smokers and promotes responsible consumption of the product whilst discouraging irresponsible practices. This approach is consistent with socially responsible regulations adopted in the UK.\(^\text{146}\) The UK regulations preclude advertising that appeals to minors or targets non-smokers. ENDS advertisements cannot feature anyone appearing to be under the age of 25. These regulations can be adopted as standards and guidelines in Australia.

\(^{146}\) UK Advertising Code. UK Code of Non-Broadcast Advertising. 2016 [link]
2. Government promotion and information guidelines:
The Australian government should institute the promotion of ENDS as a safer alternative to smoking in guidelines for its anti-smoking advertisements and quit smoking campaigns. This approach is consistent with the 2017 UK Tobacco Control Strategy.\textsuperscript{147} Government guidelines should also be developed in consultation with industry groups, businesses and public health experts to promote responsible vaping and consumption strategies tailored to suit those who want to quit smoking with the aid of ENDS. Information guidelines should also be provided to medical practitioners, as they are in the UK. The latest report (2018) from Public Health England has found that many smokers continue to remain uninformed about the relatively low risk of harm incurred by vaping compared to tobacco.\textsuperscript{148} A comprehensive information strategy is therefore vital to ensure that consumers are making informed choices.

3. Maximum nicotine concentration:
The rationale for a regularly revised standard rather than a specific standard, is the rapidly innovative nature of ENDS technology and the need to ensure that nicotine dosages are tailored to the consumer. For example, 6% of UK-based vapers utilise solutions with a concentration greater than 20 ml/mg. Many of these individuals require solutions with higher potency as they enable consumers who cannot use more complex devices to utilise devices such as Juul or NJoy Daily. These devices allow smokers suffering from mental illness or disability to transition to vaping. Setting a cap on nicotine concentration that is too low is also unlikely to achieve any practical outcome as the vaper is likely to respond to low concentrations by inhaling more often and deeper through ‘compensatory puffs’.\textsuperscript{149}

4. Safety:
Safety guidelines should include child-resistant packaging in order to prevent leakage or accidental exposure.

5. Monitoring:
Continuing monitoring of the impact of ENDS products, including evidence on safety, uptake, health impact and effectiveness, should be undertaken. There should also be a focus on monitoring smoking cessation rates and the effect of evolving ENDS

\textsuperscript{147} UK Govt policy paper, 18 July 2017 p. 16 [link]
\textsuperscript{148} Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England [link]
\textsuperscript{149} Kośmider, L., Kimber, C. F., Kurek, J., Corcoran, O., & Dawkins, L. E. (2017). compensatory puffing with lower nicotine concentration e-liquids increases carbonyl exposure IN e-cigarette AEROSOLS. Nicotine & Tobacco Research. [link]
6. **Expedited approvals process:**

In order to encourage innovation and put cutting-edge technology in the hands of consumers, an expedited approvals process should be instituted for ENDS products and devices which are intended to be sold as ‘therapeutic devices’. Fast-tracked TGA (Therapeutic Goods Administration) approval can be provided for devices and other products which have received approval from TGA-equivalent bodies in other countries, such as America’s FDA, where these countries have comparable or equivalent regulatory standards to Australia.

7. **Tax treatment:**

The ATA recommends that additional taxes are not imposed on ENDS devices or solutions in the vein of cigarettes, as increased prices will deter smokers, especially smokers from poor socio-economic backgrounds, from transitioning to vaping. It is however, submitted that government revenue can be increased through the collection of the GST which will apply to ENDS products.

8. **Exemption from Tobacco display bans:**

Under regulations applicable in NSW, ENDS products, including devices which do not contain nicotine, cannot be displayed at showcases or counters in vape stores. This damages small businesses such as vape shops and makes it more difficult for smokers who are considering the transition to vaping to peruse the options and devices available.

9. **Exemption from ‘smoke-free’ public place or workplace laws:**

In cognisance of studies which have found no material health risk to passive smokers due to vaping, and commensurate with the 2017 UK Government Tobacco Control Strategy, ENDS products should be exempt from smoke-free restrictions in workplaces and public places including airports. This will incentivise smokers to quit by transitioning to vaping.

10. **Research and data monitoring – funded by increased tobacco levy:**

Further research on tobacco harm reduction, including...
monitoring the efficacy of ENDS in Australia and the development of strategies to enhance its effectiveness and uptake as a smoking cessation aid, can be funded by an increase to the levy applied to tobacco and/or cigarettes. Although there is insufficient evidence that further tobacco excise hikes will be effective in lowering Australia’s smoking prevalence, the legal availability of ENDS substitute products which are priced at a lower rate will mitigate the price inelastic nature of tobacco, encouraging smokers to switch to vaping while assisting the government in developing its ongoing tobacco control and ENDS regulation frameworks.

“...allow nicotine solutions to be sold as a consumer good in the same manner as cigarettes are currently sold. This will foster consumer access to the product and incentivise smokers to transition to the safer practice of vaping.”
Smokeless Tobacco or ‘snus’ and tobacco harm reduction

Snus is a moist, powdered tobacco product that is placed under the consumer’s lip and absorbed into the bloodstream without the need for smoking. As a result, it has far lower levels of carcinogens than those released when smoking tobacco is consumed,\(^{151}\) and serves as another safer alternative to tobacco which promotes harm reduction. It is useful for smokers who cannot or are not inclined to transition to vaping.

Snus has been legally consumed in Norway and Sweden since 1968, gaining popularity since 1976. Between 1976 and 2002, Sweden’s smoking rate dropped from 40% to 15% - shrinking to well under half. Despite this, public health expert Dr. Coral Gartner of the University of Queensland school of population health, notes that the country recorded no increase in the rates of oral cancer or cardiovascular disease, and tobacco-related deaths in Sweden were among the lowest in the developed world.\(^{152}\) Gartner notes that tobacco addicts who consume snus have a lower risk of all cancers associated with tobacco, and that the product has not served as a ‘gateway’ to smoking despite being widely available and consumed in Sweden and Norway since the 1970s.\(^{153}\)

An advantage of snus is that it does not raise concerns of ‘re-normalising’ tobacco as chewing snus is not a visible habit and advertising prohibitions applicable to tobacco can continue to be applicable to snus.

Although snus has been widely consumed in Norway and Sweden for decades with no material health risk identified to its consumers and is currently being legalised in New Zealand,\(^{154}\) it has remained illegal in Australia since 1991. It is currently facing a challenge to its illegal status within non-Sweden parts of the European Union at the European Court of Justice as of February 2018. The challenge is mounted on the basis that the prohibition of this safer alternative to tobacco amounts to a breach of the ‘right to health’ portion of the European Union Charter of Fundamental Rights,\(^{155}\) and is seen as a test case for the rights of consumers to make informed choices about their own health.

According to a 2009 article commenting on snus in Australia, then Cancer Council Australia chief

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\(^{151}\) Broadstock, Marita (February 2007). “Systematic review of the health effects of modified smokeless tobacco products” New Zealand Health Technology Assessment Report. 10 (1). [link]

\(^{152}\) Sydney Morning Herald, Feb 23rd 2009, “calls to legalise snus in Australia” [link]

\(^{153}\) Ibid.

\(^{154}\) NZ government Press Release, 2 August 2017 [link].

\(^{155}\) New Nicotine Alliance, 17th January 2018, “Campaign to legalise snus – update on the ECJ case” [link]
executive Professor Ian Oliver noted that the case could be made for introducing snus in Australia on health grounds, adding that they appeared to be less harmful than cigarettes.\textsuperscript{156} He however, further noted that smoking rates at the time in Australia had declined significantly in previous years and that this was evidence that Australia did not need to legalise snus.\textsuperscript{157} Notably, the most recent statistics from the Australian Institute of Health and Welfare (a wing of the Australian government), reveal that more Australians smoke today than they did in 2013.\textsuperscript{158} It is therefore submitted that policy-makers have an imperative to legalise snus in Australia within a suitable regulatory framework that can empower smokers to quit their habit and drastically reduce their exposure to carcinogens.

\begin{figure}[h]
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\caption{
“Although snus has been widely consumed in Norway and Sweden for decades with no material health risk identified to its consumers and is currently being legalised in New Zealand, it has remained illegal in Australia since 1991.”
}
\end{figure}

\textsuperscript{156} Sydney Morning Herald, Feb 23\textsuperscript{rd} 2009, “calls to legalise snus in Australia” [\textcolor{blue}{link}]
\textsuperscript{157} Ibid.
\textsuperscript{158} Australian Institute of Health and Welfare (2017), National Drug Strategy Household Survey 2016, Table 2 [\textcolor{blue}{link}]}
Conclusion

ENDS and other safer alternatives to smoking tobacco are legally available and standardised in nations throughout the western, developed world. The evidence attests that they are at least 95% less harmful than tobacco smoking and are probably significantly even less harmful. More smokers around the world have quit smoking by using them than by using patches or gums. They have contributed significantly to the rapidly falling smoking prevalence rates in the nations which have embraced them, while Australia’s smoking prevalence continues to climb.

Australian adults deserve the right to choose if these products are right for them. The Australian Taxpayers’ Alliance is proud to fight for people’s rights to make the same choices about their own health that are available to smokers around the world – choices that have proven effective in the fight against the scourge of tobacco smoking.