

## **Legalising Vaping in Australia**

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## Executive summary

In spite of a substantial fall in the smoking rate over several decades, nearly three million or 15.2% of Australian adults still smoke tobacco. <sup>1</sup> Smoking remains the leading preventable cause of death and illness in Australia. <sup>2</sup> Smoking is especially prevalent in disadvantaged populations such as Indigenous people, low-income groups and those with mental illness or substance use and is a major contributor to health and financial inequalities.

The long-term decline in smoking rates in Australia has slowed considerably since 2013. <sup>1,3</sup> Many Australian smokers are unable to quit in spite of Australia having the highest cigarette prices in the world, plain packaging and strict tobacco control laws. Ever-increasing tobacco prices place a huge financial burden on low-income smokers and are almost certainly contributing to a growing illicit tobacco industry. New and effective strategies are needed.

One option being widely used overseas is vaping (using an e-cigarette). Vaping is a reduced-risk alternative to smoking for adult smokers who are unwilling or unable to quit. <sup>4</sup> Vaping delivers the nicotine smokers are addicted to along with the hand-to-mouth ritual smokers enjoy, but without most of the harmful toxins present in smoke. <sup>4</sup>

Australia imposes a de facto ban on vaping and is increasingly out of step with other similar countries, such as New Zealand, the United Kingdom, the European Union, Canada and the United States. Smoking rates are declining faster in many countries where vaping and other reduced-risk nicotine products are legal and readily available.

Ironically, it is illegal to possess nicotine liquid for vaping in Australia without a prescription from a doctor although smokers can readily purchase higher-risk cigarettes from supermarkets and most corner shops.

Vaping is not risk-free, but long-term use is estimated by several reputable authorities to be no more than 5% as harmful as smoking. <sup>4-6</sup> There is convincing scientific evidence that vaping helps some people quit smoking, including a recent, large randomised trial which found that vaping is nearly twice as effective as conventional nicotine replacement therapy. <sup>7</sup> Vaping is now the most popular quitting method in the United Kingdom, <sup>8</sup> the United States <sup>9</sup> and the European Union. <sup>10</sup>

Vaping provides another quitting strategy at no cost to the public purse. Smokers who switch to vaping can expect substantial improvements in health as well as large financial savings, of special importance to low-income groups.

Fears of vaping being a gateway to youth smoking, renormalisation of smoking and uptake by non-smokers have not materialised to any significant extent in over 10 years of overseas experience so far. <sup>4,5</sup>

Legalising vaping has enormous potential to improve public health, particularly for disadvantaged smokers who are disproportionately affected by smoking-related diseases.

We recommend that vaping products should be primarily regulated as consumer goods rather than as a therapeutic, medicinal or tobacco product. Regulation should aim to maximise the benefit for adult smokers while reducing any potential risks to users and harm to the wider population, especially young people who have never smoked. Regulation should be proportionate to the risk of vaping.

The authors strongly recommend that Australia's successful tobacco control policy continues and is supplemented by two changes: first, ending the de facto ban on vaping; and second, re-introducing appropriately funded mass media campaigns and supporting counselling to increase quitting rates.

# Legalising vaping in Australia

## 1. Smoking in Australia

### History of tobacco smoking

Tobacco was introduced to Indigenous people in northern Australia by Indonesian fisherman in the early 1700s. A second wave arrived with the First Fleet in 1788. Pipe and cigar smoking were commonplace through the 1800s. Cigarettes became increasingly popular in the late 1800s with the introduction of mechanised manufacturing leading to a cheap and plentiful supply. By 1945, 72% of Australian men and 26% of women reported smoking cigarettes.<sup>11</sup>

In the 1950s an alarming picture of serious illness and premature death associated with smoking began to emerge. The 1962 report of the UK Royal College of Physicians on smoking was the first to highlight the link between smoking and lung cancer and a range of serious diseases.<sup>12</sup>

The first tobacco control measures were introduced in Australia in the mid-1970s. Over time these measures have included advertising bans, mass media campaigns, bans on smoking in public places, tobacco tax increases and plain packing. Australian public health practitioners were among international leaders in tobacco control. Smoking rates in Australia have declined steadily for decades but have recently slowed significantly..<sup>11</sup>

### Who still smokes in Australia?

Nearly three million people or 15.2% of Australian adults smoked tobacco products in 2017-18.<sup>1</sup> Of these, 13.8% smoked daily and an additional 1.4% smoked less than daily. Daily smoking rates were higher in males than females (16.5% vs 11.1%).<sup>1</sup> Smoking is especially concentrated in disadvantaged populations. The daily smoking rate for adults in the most disadvantaged areas is three times higher than in the least disadvantaged areas (21.7% vs 6.8%). This gap is not decreasing.<sup>1</sup>

Aboriginal and Torres Strait Islanders have particularly high smoking rates. According to the most recent data, 45% of Indigenous adults smoked in 2014-15,. Although Indigenous smoking rates have declined, the gap between Indigenous and non-Indigenous people has not changed over the past 20 years.<sup>13</sup> High smoking rates are also found in other vulnerable populations including people with mental illness, substance use, prisoners and homeless people.

Smoking rates also vary by location. The Northern Territory (20.7%) and Tasmania (23.5%) have the highest smoking rates and the ACT (9.5%) has the lowest.<sup>3</sup> Smoking is most common in remote communities (24.6%), followed by inner regional areas (17.6%) with the lowest rates in major cities (14.2%).<sup>3</sup>

## Death and disease from smoking

While anti-smoking initiatives have led to smoking rates in Australia declining considerably, tobacco smoking still remains the leading cause of preventable death and illness in Australia.<sup>2</sup>

According to the most recent estimate, , 18,762 Australians died prematurely in 2011 as a direct result of smoking.<sup>2</sup> Up to two out of three lifelong Australian smokers die prematurely from a smoking-related disease, half of them in middle age.<sup>14</sup> Smokers live 10 years less on average than non-smokers.<sup>14</sup>

Smoking accounts for more deaths and costs to the economy annually in Australia than alcohol, illicit drugs and prescription drugs combined. Smoking causes 9% of the overall burden of disease in Australia, a measure of the total years of healthy life lost from disease and death.<sup>2</sup> This is substantially more than any other risk factor such as high body mass (5.5%), alcohol use (5.1%), physical inactivity (5.0%) and high blood pressure (4.9%).<sup>2</sup>

Tobacco smoking harms almost every organ of the body, causing a wide range of diseases such as coronary heart disease, stroke, chronic obstructive pulmonary disease (COPD), asthma, rheumatoid arthritis and osteoporosis.<sup>15</sup> Smoking is responsible for 20% of all cancer deaths in Australia.<sup>16</sup>

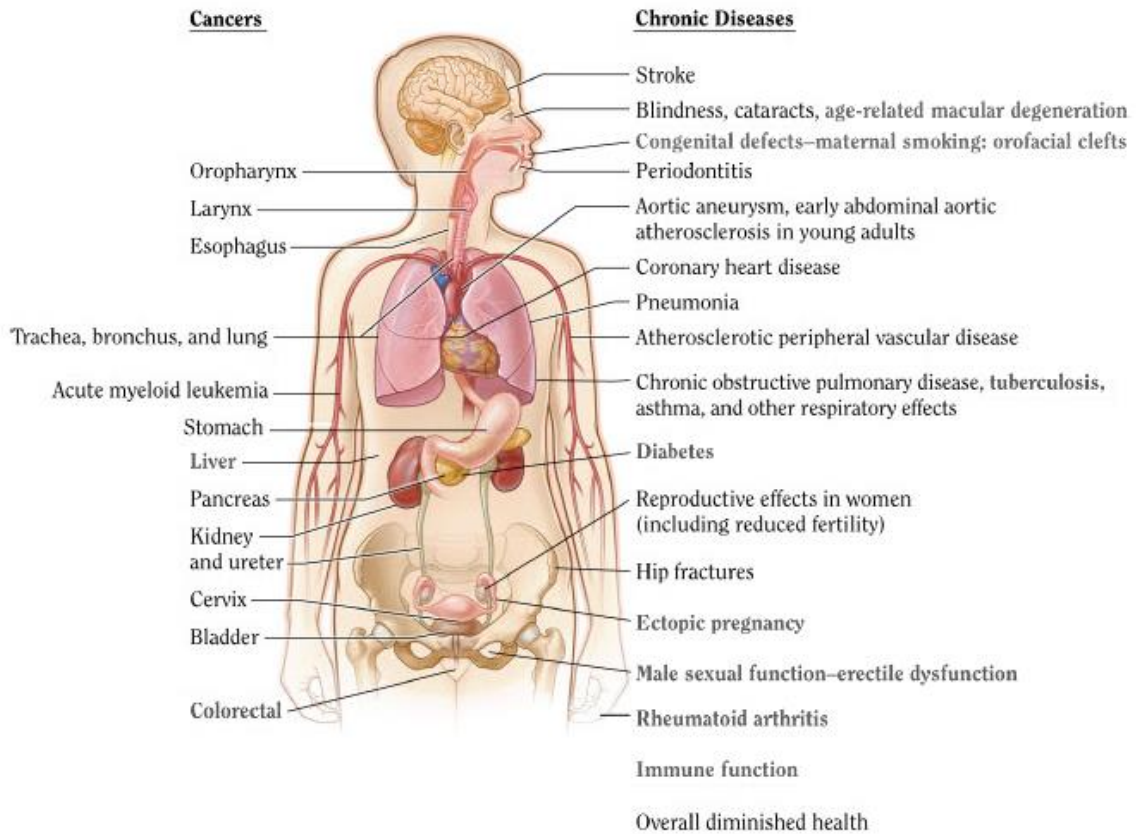


Figure 1.1: The effects of smoking on the human body <sup>15</sup>

Passive exposure to tobacco smoke causes coronary heart disease and lung cancer in adults, and low birth weight, sudden infant death, middle ear disease and respiratory disease in children. <sup>15</sup> Even light smoking is very harmful. Smoking one cigarette a day carries half the risk of a heart attack and stroke as smoking 20 cigarettes. <sup>17</sup>

Overall smoking-related deaths across Australia are strongly associated with socio-economic disadvantage. This means that the more disadvantaged regions have higher smoking rates and higher smoking-related death rates. <sup>18</sup> These areas also have higher than average rates of lung cancer and other smoking-related cancers. <sup>19</sup>

## Quitting smoking is very difficult

Smoking is a powerful addiction based on a physical dependence on nicotine, the familiar hand-to-mouth habit and psychological and social factors. <sup>20</sup> Professor Michael Russell in the UK identified in 1976 that ‘people smoke for the nicotine but die from the tar’. <sup>21</sup>

Nicotine is delivered rapidly to the brain from smoking. <sup>22</sup> Stopping smoking leads to powerful urges to smoke and unpleasant withdrawal symptoms such as anxiety, irritability and depression, which are only relieved by having



another cigarette.<sup>22</sup> Smokers are exposed to regular triggers to smoke during the day. Smoking becomes associated with specific activities, moods and situations such as stress, a cup of coffee or the smell of smoke. Exposure to those triggers can cause powerful urges to have a cigarette.

For many people, smoking is part of their 'identity'. For others it is a 'friend' which provides company and temporary relief of anxiety or depression. Giving up this identity or familiar friend can be very challenging. Two out of three Australian smokers want to quit<sup>3</sup> and about 40% try to stop smoking at least once each year.<sup>23</sup>

However, quit rates are low. Only one in 25 unaided quit attempts ('cold turkey') is successful six to 12 months later.<sup>24</sup> Even with best-practice treatment of professional counselling and stop-smoking medication, 75% are still smoking a year later.<sup>25</sup> The average 40-year-old smoker has had 20 unsuccessful quit attempts.<sup>23</sup> Of those who do finally quit, there is a steady attrition over time due to high relapse rates. After being abstinent for 12 months, one in two quitters will subsequently relapse.<sup>26</sup>

## Benefits of quitting

Quitting leads to rapid and substantial improvements in physical and mental health, improved quality of life, a longer life and considerable financial savings.

The risk of smoking-related diseases declines after quitting. A reduction in heart attack risk occurs rapidly while the decline in lung cancer risk is slower. In many cases, the risk of disease falls over time to the level of someone who has never smoked. However, for some diseases, with heavier smoking and longer smoking duration, some residual risk remains long after quitting.<sup>2827</sup>

Quitting also increases life expectancy. Smokers who quit before the age of 35 years will live 10 years longer on average than continuing smokers. Smokers who quit at 40, 50 and 60 years will gain 9, 6 and 3 years of life respectively.<sup>29</sup> Quitting at any age leads to health improvements.

## Tobacco control

Australia has an impressive tobacco control record and has introduced a comprehensive range of effective public health strategies. Tobacco policy aims to minimise initiation of smoking, encourage and assist smokers to quit and

reduce the harm resulting from smoking. The three pillars of tobacco control are demand reduction, supply reduction and harm reduction.<sup>30</sup>

### *Demand reduction*

Most effort has been invested in lowering the demand for smoking by tax increases, advertising and display bans, smoke-free public places, plain packaging and graphic health warnings, mass media campaigns, education and smoking-cessation support.<sup>11</sup> Mass media campaigns are designed to change social norms about smoking and to motivate smokers to quit.<sup>11</sup> Although they have been successful in the past, national campaigns were ceased in 2012.

<sup>11</sup> They need to be reintroduced, well-funded and sustained.

For best results, mass media campaigns need to be accompanied by professional smoking cessation services to help convert motivation to quit into successful quitting as many smokers need assistance.<sup>31</sup> Cessation support has been chronically underfunded in Australia. There is no national treatment system and a limited range of professional quitting support services are available.<sup>32</sup>

### *Supply reduction*

Strategies to reduce availability and accessibility include restricting sales to minors and limiting illicit trade.

### *Harm reduction*

Tobacco harm reduction refers to strategies to reduce the health, social and economic costs from the continuing use of combustible tobacco products. This has been supported in principle, but not in practice by Australian governments and is discussed below.

## Tobacco tax

Tobacco excise was introduced in 1901. It has risen substantially since 2010.<sup>33</sup> A 25% tax increase was implemented in 2010. A 12.5% tax rise was applied annually from 2013-2018 and will be applied in 2019 and 2020 on the first day of September each year.<sup>33</sup> As well, excise rates increase twice yearly, based on average weekly ordinary time earnings (AWOTE).<sup>33</sup> As a result, the retail price of tobacco has tripled over the last decade.<sup>34</sup>

The current tobacco excise in Australia is 81 cents per cigarette and \$1,076 per kg of loose tobacco.<sup>35</sup> The tax on cigarettes including GST is around 65% of the retail price.

Including GST, tobacco generated \$12.5 billion in government revenue in 2017-2018 or 3% of gross revenue.<sup>36</sup> Only a tiny fraction of the revenue raised from tobacco products is allocated to tobacco control and smoking cessation programs, although generously funding tobacco control activities from tobacco revenue are recommended by the World Health Organisation.<sup>37</sup>

Increasing tobacco taxes has been an effective strategy for reducing smoking rates and has contributed to the steady decline in smoking in Australia.<sup>38</sup> However, the current very high taxes may be less effective than in the past.<sup>39,40</sup> Possible explanations for this may include readily available, cheaper illicit tobacco products and a more resistant population of smokers.

We support a high taxation approach to tobacco products, but we do not support the current policy of swingeing taxation. There is a widespread community perception that high taxation levels are more about raising revenue than about improving public health, especially at a time of record low wage growth.<sup>41</sup>

## The financial costs of smoking

The most recent estimate of the cost of tobacco to the Australian economy was for the financial year 2004-5.<sup>42</sup> The estimated tangible and intangible cost was \$31.5 billion, or 56% of the total cost of all drugs of abuse, including alcohol and illicit drugs.

Tobacco prices in Australia are now the highest in the world.<sup>43</sup> A 20-pack of the leading brand of cigarettes costs \$28.55 in Australia or \$10,420 per year for a pack-a-day smoker. In Australian dollars, the same pack costs only \$17.97 in the UK, \$9.78 in the US and \$1.51 in Vietnam.

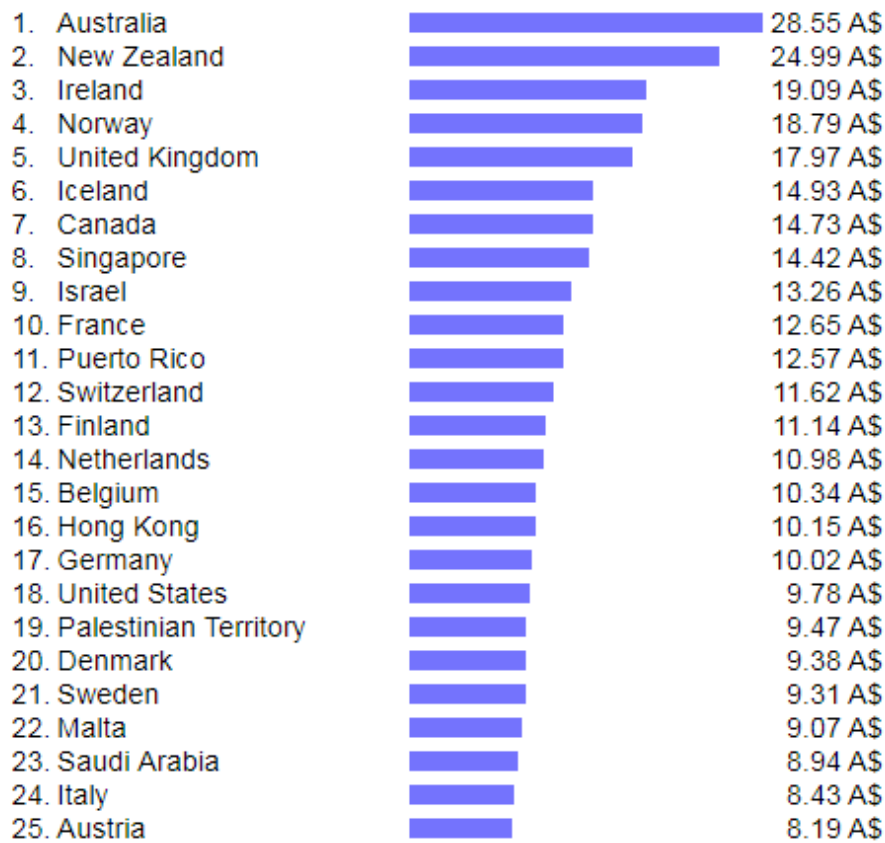


Figure 1.2 - Price of a 20-pack of the leading brand of cigarettes in AUD<sup>43</sup>

Low-income smokers are more likely to be addicted to smoking, smoke more heavily and have more difficulty quitting. For low-income smokers who are unable to quit, high prices cause financial hardship<sup>44</sup> and increase health inequalities.<sup>45</sup> A pack-a-day smoker on Newstart spends an estimated 72% of their annual income on smoking, leaving very little for food, accommodation and other essentials (based on a pack of 20 cigarettes of the leading brand daily<sup>43</sup> and the maximum Newstart payment for a single person without children).<sup>46</sup>

## The Illicit tobacco industry

An unwanted consequence of high tobacco prices appears to have been the growth in the illicit tobacco industry. As with other illicit drug markets, it is difficult to estimate the size of the illicit tobacco industry in Australia, but estimates range from 6-28% of the total tobacco market.<sup>47-49</sup>

Illicit tobacco is seen as a high-return, low-risk crime and is dominated by organised crime networks. Illicit tobacco is smuggled largely from Asia where cigarettes are extremely cheap. Illegal tobacco crops appear to be increasing in Australia. <sup>49</sup>

Negative effects of the illicit tobacco industry include:

- Undermining the financial incentive to quit by providing cheap tobacco alternatives.
- Depriving the government of up to \$3.8 billion in lost revenue per year. <sup>47,49</sup> The government has recently established an Illicit Tobacco Taskforce to try to contain the illicit market. <sup>48</sup>
- Proceeds are used to fund criminal activities. <sup>47,49</sup>

## Recent slowing of decline in smoking rates in Australia

Smoking rates in Australia have been declining steadily since the 1970s but have recently slowed in spite of Australia having the highest cigarette prices in the world, plain packaging and strict tobacco control laws.

For the first time in decades there was no statistically significant fall in the rate of smoking in two consecutive national surveys covering the period 2013-2016 and 2014/5-2017/8. <sup>1,3</sup> In the most recent state surveys, smoking rates have remained stable in Queensland <sup>51</sup> and Western Australia <sup>52</sup> but have increased significantly in New South Wales <sup>53</sup> and South Australia. <sup>54</sup>

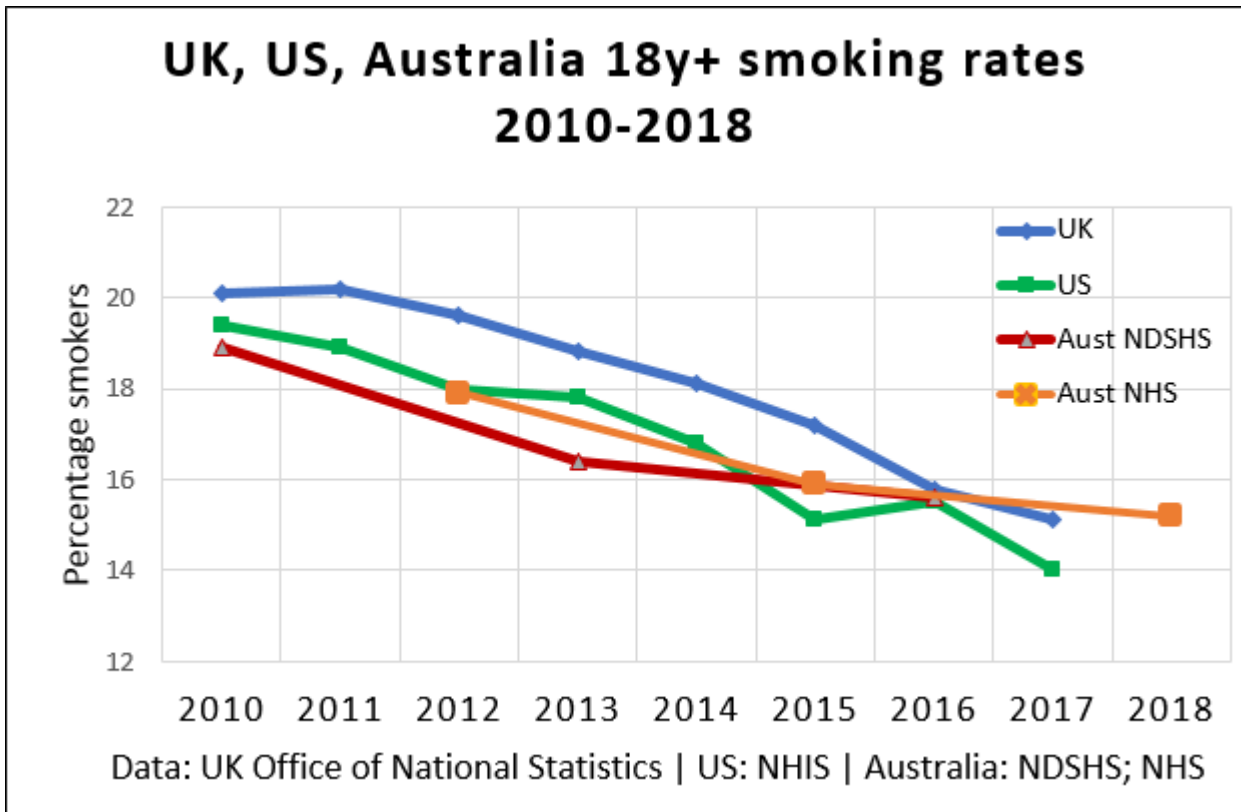
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1. From AIHW NDSHS 2016 'While smoking rates have been on a long-term downward trend since 1991, the daily smoking rate between 2013 and 2016 did not significantly decline and only decreased slightly from 12.8% to 12.2%.'
2. From ABS NHS 2014/5-2017/8, 'Over recent years, the daily smoking rate remained relatively similar (14.5% in 2014-15']

As a result, the 10% adult daily smoking target set by the National Tobacco Strategy for 2018 was not met. <sup>30</sup>

Smoking rates are now declining faster in many other countries than in Australia, especially where tobacco harm reduction strategies are available. Smoking rates in the UK and US are lower than in Australia for the first time as shown in Figure 1.3.

Data: UK Office of National Statistics | US: NHIS | Australia: NDSHS; NHS



Smoking rates have also fallen dramatically in Sweden,<sup>10</sup> Norway,<sup>55</sup> Iceland,<sup>56</sup> Japan<sup>57</sup> and South Korea<sup>58</sup> as increasing numbers of smokers have switched to vaping, Swedish snus or heated tobacco products. Cigarette sales in Japan decreased by an unprecedented 27% during 2017-18 after heated tobacco products were introduced.<sup>57</sup>

Australia now needs additional, effective strategies to complement the traditional tobacco-control strategies which have worked well in the past, but are not longer sufficient.

## 2. Tobacco Harm Reduction

### What is tobacco harm reduction?

Complete cessation of all tobacco and nicotine consumption is always the ideal goal. However, a large proportion of smokers are unable or unwilling to quit unaided or with conventional therapies and therefore remain at high risk. Tobacco harm reduction (THR) aims to reduce the health risks in continuing smokers. This involves switching from combustible tobacco to a lower-risk smokeless alternative that delivers the nicotine smokers are addicted to, but without the smoke. This is not ideal but is still far less harmful than smoking.

Almost all the harm from smoking is caused by burning tobacco, which produces thousands of chemicals, tars, carbon monoxide, other toxic gases and solid fine particles. Contrary to popular belief, nicotine has only a minor role in smoking-related disease.<sup>5</sup> It does not cause cancer or lung disease and plays only a small part in cardiovascular disease.<sup>15</sup> The most popular THR aids are nicotine vaporisers (e-cigarettes), Swedish snus and heated tobacco products. Swedish snus is a moist, finely ground tobacco product usually supplied in sachets like small teabags, which are placed under the upper lip. Heated tobacco products (also called heat-not-burn products) are electronic devices which heat processed tobacco without burning it.

This report focuses on nicotine vaporisers.

Nicotine-containing products involve a continuum of risk. Combustible products such as cigarettes and cigars are very high risk whereas non-combustible products like vaporisers and snus are located at the lower end of the risk spectrum.

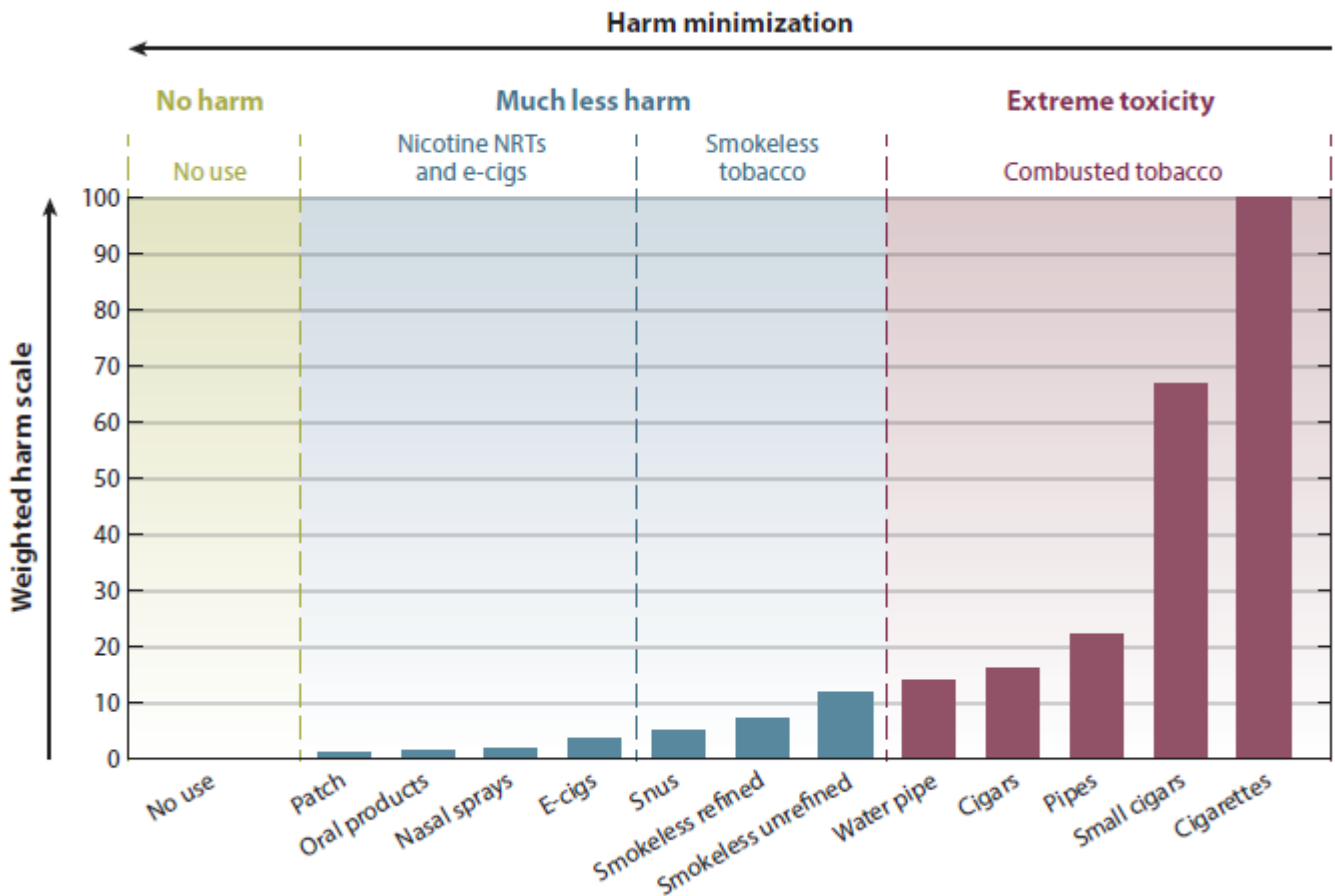


Figure X: Harm minimisation and tobacco control, reframing societal views of nicotine use to rapidly save lives. *Ann Rev Pub Health* 2018<sup>59</sup>

Harm reduction has already been successfully employed in other fields such as HIV, road safety and injecting drug use. Here government programs have addressed high-risk behaviour (e.g. unsafe sex) through strategies, education and products to help people change to lower-risk behaviour. THR should not be treated as though it is somehow different.

Most new pragmatic harm reduction strategies for psychoactive drugs face vigorous initial resistance which declines over time. Needle syringe programs, methadone treatment, condom promotion and Medically Supervised Injecting Centres were all fiercely resisted for some time but have proved to be effective and slowly gained majority support. THR has had minimal implementation in Australia despite it being mandated by Australia’s international treaty commitments and the National Tobacco Strategy:

- As a signatory to the World Health Organisation’s Framework Convention on Tobacco Control (FCTC), Australia is obliged to introduce THR strategies along with other tobacco control measures under Articles 1(d) and 1(f).

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- THR is one of the pillars of the National Tobacco Strategy 2012-2018, to “reduce harm associated with continuing use of tobacco and nicotine products” (Part 5.2, page 11). THR is complementary to and not a replacement for conventional tobacco control strategies.<sup>30</sup>

## Vaping

Using a vaporiser is known as ‘vaping’.

Vaping replicates smoking in two ways:

- It delivers nicotine and relieves the urge to smoke; and
- It provides a ‘smoking-like experience’ – it addresses the behavioural (hand-to-mouth action), sensory (‘throat hit’, taste, inhaling and exhaling a visible ‘smoke’), social aspects and pleasure of the smoking ritual – but without most of the harmful toxins found in smoke.

Vaping has helped millions of smokers to quit<sup>61</sup> and the overwhelming scientific consensus is that it is substantially less harmful than smoking.<sup>4,5</sup> Some former smokers continue to vape long-term to avoid relapsing to smoking.<sup>62</sup> Others use vaping devices briefly as a quitting aid, switching to vaping for a time, then ceasing vaping altogether.

## How many Australians vape?

According to the National Drug Strategy Household Survey, 1.2% of Australians aged 14 and over were current e-cigarette users in 2016 and 0.5% were daily users.<sup>3</sup> Current use was most common in the 18-24 year age group (6.8%). Based on ABS data, this equates to about 227,000 Australian vapers.<sup>63</sup> Among current users, the main reasons for use were ‘to help me quit smoking’ (46.7%), ‘I think they are less harmful than regular cigarettes’ (42.4%) and ‘to try to cut down on the number of cigarettes smoked’ (36%) and ‘to try to stop me going back to smoking regular cigarettes’ (31.2%).<sup>3</sup>

Current vaping rates in other countries are 6.2% in Great Britain,<sup>64</sup> 4.5% in the US,<sup>65</sup> 2% in the EU<sup>10</sup> and 1.5% in New Zealand.<sup>66</sup> Euromonitor International estimates that there are currently around 40 million vapers globally.<sup>67</sup>

## Legal status of vaping overseas and in Australia

### *Other countries*

Vaping with nicotine is legal in most high-income countries such as the UK, the US, the 27 countries of the European Union, Canada and New Zealand. According to the World Health Organisation, 30 countries have banned vaping.<sup>69</sup>

Countries regulate e-cigarettes as tobacco products, medicinal/pharmaceutical products, consumer products, e-cigarettes or poisons or as a combination of these categories.<sup>68</sup>

## *Australia*

In Australia, e-cigarette devices and nicotine-free e-liquids are classified as legal consumer goods and can be used and sold in all states and territories. However, it is illegal to sell an e-cigarette in Western Australia.

Under Commonwealth law, nicotine is classified as a Schedule 7 'dangerous poison' in the Poisons Standard and its use is strictly regulated.<sup>70</sup> However, there are two pathways under which nicotine e-liquid can be accessed legally for a 'therapeutic use' i.e. to quit or reduce smoking or to prevent relapse. Both pathways require the user to have a prescription from a registered Australian medical practitioner. However, the great majority of users do not have a prescription.

### **1. TGA Personal Importation Scheme**

Users can legally import nicotine from overseas under the Therapeutic Goods Administration (TGA) Personal Importation Scheme.<sup>71</sup> Three months' supply at a time can be imported for personal use, up to a total of 15 months' supply per year.

### **2. Australian compounding pharmacies**

Authorised Australian compounding pharmacies can legally prepare nicotine e-liquid for a therapeutic purpose under the 'Compounding exemption' in item 6 of Schedule 5 to the Therapeutic Goods Regulations 1990.<sup>72</sup>

There are serious penalties for using or possessing liquid nicotine unless it is prescribed by a doctor. Financial penalties vary from a \$45,000 fine in Western Australia to \$1,100 in New South Wales. Offenders can potentially be jailed for up to 2 years in the ACT and Tasmania and 12 months in the Northern Territory.<sup>73</sup>

It is not an offence to import nicotine e-liquid into Australia.<sup>74</sup> However, it is an offence to take possession of imported nicotine without a prescription or if other requirements of the TGA Personal Importation Scheme are not met.<sup>72</sup>

The sale, marketing, display and use of vaping products are covered under state tobacco laws. Regulations differ between states but in general:

- Liquid nicotine cannot be sold without approval

- Sale to minors (under 18 years) is an offence
- Vaping is banned in smoke-free areas
- Display of vaping products is restricted or banned
- Advertising and promotion are banned
- Vaping is not allowed in cars with children under 16 years old

At the time of writing, South Australia and the Northern Territory had passed regulations for vaping but these have not yet been enacted. Full details of laws for each state and territory are available on the Australian Tobacco Harm Reduction Association website.<sup>73</sup>

In March 2018, the House of Representatives Standing Committee on Health, Aged Care and Sport delivered its Report on the 'Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia'.<sup>75</sup> The report was characterised by conflicting views of its members, three of which ultimately added to the final report with two dissenting reports of their own. The report was informed by 352 submissions and 45 exhibits, as well as letters on behalf of almost 1,700 individuals. Ultimately, the committee found by majority that the questions over the legalisation of nicotine products, including e-cigarettes, should be a question for experts within health bodies in Australia, such as the Therapeutic Goods Administration, rather than politicians themselves.

The report recommended that the National Health and Medical Research Council 'fund an independent and comprehensive review of the evidence relating to the health impacts of electronic cigarettes'. The report recommended that such a review be updated every two years, taking into account further research on the health impacts of e-cigarettes. It also argued that the Department of Health convene an international panel of experts to discuss the issue. These recommendations are not unreasonable based on the committee's conclusion that there is currently insufficient evidence to recommend vaping. The evidence is rapidly increasing as new studies emerge.

The committee also recommended that the TGA continue its role in determining the classification of nicotine.

A final recommendation was to 'establish a regulatory process for assessing and, if necessary, restricting colourings and flavourings used in electronic cigarettes'. This is sensible. As the long-term risk of inhaling flavour chemicals is unknown, flavours should be monitored for adverse outcomes. Certain flavours should be banned if there is evidence of potential harm eg diacetyl,<sup>76</sup> benzaldehyde<sup>77</sup> and cinnamaldehyde<sup>78</sup>.

## The effectiveness of vaping

There is now convincing scientific evidence that vaping helps some people transition from smoking.

A recent landmark randomised controlled trial of nearly 900 smokers in the UK found that those who were randomised to use a modern vaping device with nicotine were nearly twice as likely to have quit 12 months later as those using conventional nicotine replacement products like the patch and gum, alone or in combination.<sup>7</sup>

Vaping is now the most popular quitting method in the UK,<sup>8</sup> the US<sup>9</sup> and the European Union<sup>10</sup> and millions of smokers have reported switching to vaping. For example, an estimated six million people quit smoking by vaping in the European Union in a study in 2014.<sup>61</sup> In England, there are an estimated two million vapers who have now quit smoking while over three quarters of a million have quit both.<sup>79</sup>

Large population studies in both the US and UK have found that smokers who use vaping to quit have significantly higher quit rates than those who don't.<sup>80,81</sup> Vaping is most effective when used daily. Recent studies in the US have found that daily users were up to eight times more likely to quit than non-users.<sup>82,83</sup>

Some studies have suggested that vaping is not an effective quitting aid. However, a review found that many had design flaws which made their conclusions unreliable.<sup>84 85</sup> When only the most rigorous studies were considered, it was concluded that vaping was effective, with quit rates similar to nicotine replacement therapy.<sup>85</sup>

Another widely quoted review of the research concluded that vaping reduced quit rates.<sup>86</sup> However, this study has been widely criticised for poor scientific methodology.<sup>59,85,87</sup>

More real-world evidence of the effectiveness of vaping is that smoking rates are falling in countries where vaping is widely available, in some cases such as the UK and US, faster than ever.<sup>81,88</sup> Many experts argue that it is likely that vaping is contributing to the rapid decline.<sup>80</sup> However, in Australia where vaping is heavily restricted, the smoking rate has stalled slowed substantially since 2013.<sup>3</sup>

## Modelling

Where evidence for a new intervention is incomplete, 'modelling' studies can help estimate the likely health impact. Modelling or simulation studies take into account the potential risks and benefits based on what is known at the time and calculate an estimated overall impact.

Several high-quality modelling studies of vaping have been performed and have estimated a substantial positive net public health benefit from vaping.<sup>89-92</sup> However, modelling studies are only as good as the assumptions on which they are based. One other modelling study found the opposite effect.<sup>93</sup> However, this study has been criticised for unrealistic assumptions and poor methodology.<sup>94</sup>

## Safety of vaping

Vaping is not risk-free, but most scientists accept that it is far less harmful than smoking. According to the UK Royal College of Physicians report in 2016:<sup>5</sup>

‘Although it is not possible to quantify 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.’

This estimate is supported by Public Health England<sup>95</sup> and another expert group led by the distinguished UK scientist Professor David Nutt<sup>6</sup>. Others have questioned its accuracy without providing their own estimate.<sup>96</sup> Few doubt that vaping is less risky than smoking.

The substantial risk reduction associated with vaping is due to the fact that most of the harm from smoking is caused by the tar, carbon monoxide and 7,000 toxic chemicals produced by burning tobacco. In contrast, the aerosol inhaled from vaping devices contains a fraction of the chemicals and those present are mostly at concentrations less than 1% of that in smoke.<sup>4</sup> Vaporisers do not contain tobacco and there is no combustion or smoke.

According to the US National Academies of Sciences, Engineering and Medicine report in 2018:<sup>92</sup>

‘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.’

Other studies have shown that the levels of toxins in the body are greatly reduced when smokers switch exclusively to vaping.<sup>97-99</sup>

One analysis compared the chemicals in smoke and vapour and estimated that the cancer risk from long-term vaping is less than 0.5% that of smoking.<sup>100</sup>

The risk to bystanders from ‘passive vaping’ appears to be minimal. <sup>4,5,101</sup> Negligible amounts of nicotine and other chemicals are released into the air and evaporate almost immediately (within 10-15 seconds) after exhalation. <sup>102</sup> Some studies in laboratory and animal studies have raised concerns about potential risks from vaping. However, many of these studies do not use doses appropriate for humans and make no comparison with the risk from smoking. Studies also often overstate the significance of laboratory changes that have little or no relevance to human health. <sup>59</sup>

The evidence to date is reassuring on safety. However, like all new products, ongoing monitoring and research is essential as yet unknown risks from vaping may appear with long-term use.

## Divided opinions

Medical opinion on vaping is divided. Some health organisations supporting and opposing vaping are listed below.

Support for vaping	Opposition to vaping
Royal Australian and New Zealand College of Psychiatrists	Australian Medical Association
Drug and Alcohol Nurses Australasia	Thoracic Society of Australia and New Zealand
UK Royal College of Physicians	Royal Australasian College of Physicians
British Medical Association	Lung Foundation Australia
Royal College of General Practitioners	Cancer Council Australia
New Zealand Medical Association	National Heart Foundation
American Heart Association	Public Health Association of Australia
Cancer Research UK	National Health and Medical Research Centre
British Lung Foundation	Australian Dental Association

## Opposing arguments

Below are some of the main concerns raised by opponents of vaping.

### *Precautionary principle*

The precautionary principle cautions policy makers from implementing policies where there is still substantial uncertainty and therefore a potential risk of adverse effects. Vaping has only existed for about 15 years and it is possible that problems unknown at present may appear in the future. Vaping supporters argue that although there are uncertainties about the long-term risk, the risks of smoking are always going to be far greater, given that two out of three long term smokers will die from a smoking related condition.<sup>14</sup>

### *Gateway into smoking*

There is an understandable concern that young people will start vaping and then progress to tobacco smoking. Although teens who try vaping are more likely to later try smoking, there is no compelling evidence available at present that one causes the other.<sup>103</sup> A more likely explanation is ‘common liability’; i.e. young people who are impulsive, rebellious and sensation-seeking are more likely to try both behaviours.<sup>104</sup>

Surveys in several different countries have consistently found that most vaping by teens is experimental and short-lived.<sup>105,106</sup> Frequent vaping is very uncommon among teenagers and is almost exclusively confined to current smokers and ex-smokers. In fact, smoking precedes vaping in most cases.<sup>103</sup> Importantly, most teens do not use nicotine when they vape.<sup>107 66,108</sup>

Where vaping is available, youth smoking rates are continuing to fall, in some cases faster than ever.<sup>109</sup> If there is a gateway effect, it is likely to be very small and is being swamped by other factors.

### *‘Renormalisation’ of smoking*

Vaping critics fear that widespread vaping could make smoking appear more socially acceptable again and undermine decades of successful tobacco control efforts. However, the evidence is that the opposite is occurring.

Smoking rates in countries where vaping is readily available are declining faster than in Australia, in some cases faster than ever.<sup>110</sup> It is likely that vaping and other tobacco control measures work synergistically. According to Zhu, ‘tobacco control campaigns increased smokers’ desire to quit, and e-cigarettes increased the probability of motivated smokers making a quit attempt and staying abstinent’.<sup>80</sup> Other studies suggest that vaping is viewed as sufficiently different from smoking and may ‘de-normalise’ smoking.<sup>111</sup>

### *Unknown long-term effects*

Like all new products, the precise long-term health effects of vaping have yet to be established. For example, most flavouring agents used are safe for ingestion in food but some may be unsafe with long-term inhalation. It is possible

that adverse effects may only emerge after several decades and ongoing monitoring is needed to identify any preventable risks that arise.

However, almost all the harm from cigarettes is due to the combustion of tobacco which does not occur in vaping. The long-term adverse effects of nicotine are likely to be minimal.<sup>5</sup> Based on the known chemicals in the aerosol and their lower concentration compared to smoke, long-term vaping is likely to be far less harmful than smoking. As already noted, the UK Royal College of Physicians estimates vaping is likely to be no more than 5% of the risk of smoking with long-term use.<sup>5</sup>

### *Uptake of vaping by non-smokers*

There is a legitimate concern that non-smoking adults could take up vaping. However, surveys in many countries have found that 'current use' (vaping in the last 30 days) by young adult non-smokers<sup>112,113</sup> and adult non-smokers is rare,<sup>61,64,114-116</sup> usually less than 1%. Daily vaping is even less common and many non-smokers who try vaping do not use nicotine. Although national surveys and rigorous studies consistently find that regular vaping is almost exclusively confined to smokers and former smokers,<sup>61,64,114-116</sup> vaping opponents continue to argue that many vapers have never smoked.

### *The role of 'Big Tobacco'*

There are concerns that vaping is another plot by the tobacco industry to keep people smoking, hook youth or undermine tobacco control. This concern is understandable as a result of the past dishonesty and appalling behaviour of the industry. However, modern vaping was invented by a Chinese pharmacist in 2003 and has been developed by small to medium businesses. Vaping is a disruptive innovation which the tobacco industry later recognised as a major threat to its business model.

Tobacco companies own only a small share of the vaping market globally<sup>117</sup> despite acquiring a 35% share of Juul, the largest brand of vaporisers for US\$12.8 billion in 2018.<sup>118</sup> Tobacco companies sell no e-cigarettes in Australia. After decades of soaring tobacco company stock prices, £100 billion was wiped from global tobacco stocks in 2018.<sup>119</sup> There was a huge rally in the tobacco stock price in September 2018 when the US Federal Drug Administration announced a crackdown on vaping.<sup>120</sup>

It is better for public health if tobacco companies switch to making less harmful alternatives rather than lethal cigarettes. The focus of policy makers should be on reducing smoking-related death and disease, not on destroying the tobacco companies.



## *Dual use*

A temporary period of smoking and vaping (dual use) is common as smokers transition to quitting and studies have found that dual users are more likely to quit smoking than other smokers.<sup>121</sup> Research suggests that at any one time, about half of the people currently vaping are smoking as well as vaping.<sup>122</sup>

Completely giving up smoking is always the ideal goal. There is a potential risk that vapers may continue to smoke as well and that this may prevent quitting by other methods. However, there is no evidence to show this is happening. Dual users who substantially reduce their cigarette intake significantly reduce their intake of toxins and carcinogens as well.<sup>97,123</sup> However, the benefit is less for those who reduce their smoking to less or not at all.<sup>98,124</sup>

## 3. Introducing tobacco harm reduction in Australia

### Potential to improve public health

Greater access to vaping for smokers is likely to lead to substantial public health benefits. Every effort should be made to avoid the promotion of vaping products to non-smokers or children.

A study based on the US population estimated that if most smokers switched to vaping over a 10-year period (with a residual 5% smoking rate) there would be up to 6.6 million fewer premature deaths with 86.7 million fewer life-years lost due to smoking.<sup>89</sup>

According to the Chairman of the Federal Parliamentary Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia in 2018:<sup>125</sup>

‘while e-cigarettes could be harmful, they are a better option than smoking and their use could save many thousands of lives’

The UK Royal College of Physicians report concluded:<sup>5</sup>

‘in the interests of public health, it is important to promote the use of e-cigarettes ... as widely as possible as a substitute for smoking’

### The vaping industry

By 2021, it is estimated that the global vaping industry will have an annual turnover of USD \$18 billion.<sup>57</sup>

However, Australia’s share of the global market is disproportionately small due to Australia’s restrictive regulatory environment and low vaping rates. Australian vaping companies are prohibited from producing e-liquids containing nicotine even if those e-liquids are exclusively intended for export.

Markets with more liberal vaping regulations are experiencing explosive growth. According to news reports, many Australian companies have relocated to New Zealand which has a less restrictive regulatory environment and are exporting their products back to Australia.

There is potential for substantial growth in the Australian vaping industry if nicotine is legalised

## Regulation of vaping

### *Legalisation of nicotine*

The first essential step is to make nicotine e-liquid legal to possess and use in low concentrations for tobacco harm reduction. This requires the Commonwealth Government to exempt low concentrations of nicotine from the Poisons Standard so that it may be available for vaping.<sup>70</sup> Clean nicotine decoupled from cigarette smoke is a relatively benign drug without significant adverse effects and is no more toxic than caffeine according to the Royal Society for Public Health.<sup>126</sup> Currently nicotine is exempt only if prepared in nicotine replacement products such as nicotine patches and gums and in tobacco prepared and packed for smoking.

### *Classification as consumer and therapeutic products*

Internationally, vaping products with nicotine are classified as general consumer, therapeutic or tobacco products. The ideal approach is a dual (consumer and therapeutic) pathway as used in the UK, Canada and New Zealand.

- Consumer products

Vaping products are essentially consumer goods designed to compete with and replace an existing, far more harmful, consumer product. As such, they can be effectively managed under existing consumer law which would regulate quality and safety, advertising, display, sales to minors and restrictions on use.

- Therapeutic goods

Manufacturers who wish to make therapeutic claims can apply to the medicines regulator, the Therapeutic Goods Administration (TGA), for approval as therapeutic products. This process would require higher standards of quality and testing and would enable these products to be available on prescription by medical practitioners. TGA approval involves a costly and onerous application process and is not feasible for any but the very largest manufacturers, particularly tobacco companies. TGA regulation would also reduce innovation as every application would involve substantial expense and delays to market. In this fast-evolving field, devices are being rapidly replaced by newer models. At present, no product in any country has been approved by a national regulator and subsequently come to market.

There are many reasons why vaping should be treated very differently from smoking. Vaping products do not contain tobacco and do not combust or generate smoke. Although they are not risk-free, they carry only a small fraction of the risk of combustible tobacco products. Classification of vaping devices as tobacco products would lead to stringent regulation and send a misleading message to smokers that vaping is just as harmful as smoking.

## Regulatory guidelines

Nicotine vaporisers need to be regulated to maximise the benefit for adult smokers while reducing any potential risks to users and harm to the wider population, especially young people who have never smoked. In our view, regulations should:

- Ensure that vaping remains attractive and affordable in order to incentivise smokers to switch
- Not impede product development and use with onerous and expensive requirements
- Be proportionate to risk and based on the risk continuum
- Discourage ‘never-smokers’ and youths from using them.

According to the UK Royal College of Physicians <sup>5</sup>

‘There is a need for regulation to reduce direct and indirect adverse effects of e-cigarette use, but this regulation should not be allowed significantly to inhibit the development and use of harm-reduction products by smokers.’

Regulation would make vaping more accessible to Australian smokers. It would improve the quality and safety of legitimate nicotine vaping products and substantially reduce the black market vaping supplies. A proposed risk-proportionate regulatory framework is described in the table:

<b>Sales</b>	Allow sale and supply of nicotine containing vaping devices to people 18 years and over.
<b>Advertising</b>	Responsible advertising and promotion permitted to inform addicted smokers of the benefits of vaping and to encourage uptake as a safer alternative. Some constraints are appropriate to protect youth and non-smokers such as restricting the timing, placement and subject matter of advertising – as with alcohol advertising.
<b>Quality and safety standards</b>	Mandatory national product manufacturing standards for vaping products and e-liquids should be required, including: manufacturing standards for devices and components; e-liquid standards; emissions standards; refill bottle design; child resistant containers; labelling; packaging standards; and electrical safety.
<b>Display</b>	Vape shops should be able to display products and discuss them with customers.
<b>Use in public and smoke-free areas</b>	Unlike second-hand tobacco smoke, there is no evidence that passive exposure causes significant harm to health. However restrictions are justified in some circumstances for the amenity and comfort of others.

<b><i>Vaping in motor vehicles with children &lt;16 years</i></b>	Restrict vaping in the confined space of a motor vehicle when children are present.
<b><i>Licensing of retailers</i></b>	Registration to allow monitoring, education and supervision.
<b><i>Post-marketing surveillance</i></b>	Post-marketing surveillance will be required to evaluate the effects of legislation. Product notification and recall pathways are required as well as enforcement procedures, such as for sales to youth, and continuing research.
<b><i>Flavours</i></b>	As the long-term risk of inhaling flavour chemicals is unknown, flavours should be monitored for adverse outcomes. Certain potentially harmful flavours should be banned (see above)

## Taxation of vaping

There is no case for excessive taxes on vaping products on public health grounds as this will lead to less vaping and increased smoking. A significant tax differential between smoking and vaping would encourage smokers to switch to the less costly and safer alternative.<sup>127</sup>

Studies have found that a lower price increases the demand for vaping products over smoking.<sup>128,129</sup> A significant increase in the tax on nicotine e-liquid in Italy in 2015 led to a substantial reduction in vaping and a return to smoking.<sup>130</sup> The tax was later reduced.

In our view, the tax on vaping products should be kept as low as possible in accordance with the level of risk and the potential benefit of vaping to public health.



## Conclusion

The growing weight of evidence from research and overseas experience suggests that legalising and regulating vaping in Australia would improve public health. Although more research is needed, we now have enough information to be sufficiently confident that vaping nicotine is likely to be far less harmful than smoking over the long term and could help many Australian smokers quit.

Tobacco harm reduction through vaping is the missing ingredient in Australia's tobacco control plan. Despite being enshrined in Australia's National Tobacco Strategy and mandated by Australia's international treaty commitments, it is not recognised in practice.

Australia's policy is increasingly out of step with the countries Australia usually compares itself with such as New Zealand, the United Kingdom, members of the European Union, Canada and the United States.

Although the complete cessation of smoking and nicotine is the ideal goal, tobacco harm reduction through vaping is a pragmatic solution which can complement traditional tobacco control strategies. Vaping can provide an exit strategy for the many smokers for whom traditional treatments are not effective.

There are potential risks which need to be acknowledged and monitored such as uptake by young people, unknown long-term harm and possible renormalisation of smoking. Policy changes should be regularly reviewed for unintended consequences. However, the potential risks from vaping are far outweighed by the harms of continuing to smoke as two out of three long-term smokers are killed by smoking.

Reducing the barriers to switching from smoking to vaping would be of particular benefit to low-income and disadvantaged populations and would reduce economic and health inequities. It would also reduce health care costs at a time when the ageing of the population and the increasing cost of new pharmaceuticals add to the strain of national spending on health.

Appropriate regulation would maximise the potential benefits of vaping for addicted smokers while minimising the risks to young people, non-smokers and the community at large. Good quality modelling studies with realistic assumptions suggest that the net benefit would be very positive.

Vaping has the potential to speed up the demise of smoking and the massive health, social and financial harms it causes to the Australian community. This is a huge public health opportunity which should not be delayed.





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