

House of Representatives Standing Committee on Health, Aged Care and Sport

## Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia

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### Associate Professor Colin Mendelsohn

School of Public Health and Community Medicine, University of NSW, Sydney  
Tobacco Treatment Specialist

I have no financial or commercial relationship with any electronic cigarette or tobacco company

E: [REDACTED]

M: [REDACTED]

W: [www.colinmendelsohn.com.au](http://www.colinmendelsohn.com.au)

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## Executive summary

- Adult smoking rates in Australia have stalled over the last 3 years. New and innovative solutions such as e-cigarettes are needed if Australia is to reach its target of 10% smoking by 2018.
- E-cigarettes with nicotine have the potential to save the lives of hundreds of thousands of Australian smokers.
- E-cigarettes are a much safer harm reduction alternative to combustible tobacco for adult smokers who are otherwise unable or unwilling to quit smoking or nicotine.
- E-cigarettes are being used almost exclusively by confirmed smokers who are trying to reduce harm to themselves or others from smoking, or to quit smoking completely.
- Tobacco harm reduction with e-cigarettes can complement traditional tobacco control strategies with no cost to the taxpayer.
- Australia is increasingly out-of-step with other similar countries. E-cigarettes are legally available in the UK, EU and US and are being legalised in Canada and NZ.
- There is no evidence that e-cigarettes are increasing tobacco smoking by renormalising the act of smoking, acting as a gateway to smoking in young people or being used for temporary, not permanent abstinence.
- Good quality, comprehensive reviews of the evidence available to date and large population studies have found that the e-cigarettes help some smokers quit.
- The scientific consensus is that long-term use of e-cigarettes is dramatically less harmful than smoking and probably at least 95% less harmful. Like all new products, the exact long-term risks of vaping are unknown, but are certain to be much less than for smoking.
- As regular e-cigarette use is almost exclusively confined to smokers, any risk should be compared to the risk of continuing to smoke, which kills two out of every three smokers.
- The risk of harm from vapour exposure to bystanders is negligible.
- The first essential step is to exempt low-concentrations of nicotine from Schedule 7 of the Poisons Standard. It is unethical and irrational to ban a less harmful form of nicotine intake (e-cigarettes), while allowing the sales of the most lethal form of nicotine intake (tobacco cigarettes).
- Vaping products should be classified as consumer products, as they are designed to replace an existing, far more harmful, consumer product. They can be effectively managed by existing consumer laws.
- The aim of regulations should be to maximise the substantial benefits to adult smokers who are unable to quit while minimising any small, potential risks to users and the wider community.
- Regulation should be proportionate to the risk of e-cigarettes. Excessive and obstructive regulatory standards will favour the cigarette trade and be detrimental to public health.

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*'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...'.*

UK, Royal College of Physicians, Nicotine without smoke. Tobacco Harm Reduction 2016

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## Background

**In Australia, adult smoking rates have not fallen over the last 3 years for the first time ever in spite of plain packaging and the highest cigarette prices in the world.** (1, 2) Smoking is still the leading preventable cause of death and illness in Australia and kills 15,500 people per year. (3)

The National Drug Strategy target of 10% daily smoking by 2018 is now clearly out of reach. (4) We need new and innovative ideas to help the remaining smokers quit.

Nearly 3 million Australians still smoke (1) and up to 2 in 3 of these will die prematurely from a smoking-related disease. (5) Smokers live on average more than 10 years less than non-smokers. (6) Most of the burden of ill health falls on the most disadvantaged people who have the highest smoking rates and most difficulty quitting. (7)

Smoking is the most powerful addiction of all drugs. Most smokers want to quit, but try and fail repeatedly. 40% try to quit at least once a year. (8) About 40% of smokers are never able to escape the addiction.

According the 2016 National Drug Strategy Household Survey, 1.2% of Australians (18+) are currently vaping. (1) Australians are using e-cigarettes almost exclusively to improve their health. A NSW study found the most common reasons for using e-cigarettes by those over 30 years of age was "to help me quit" (42%) and to "cut down" smoking (35%); for younger adults it was "because they are not as bad for your health as cigarettes" (25%). (9)

## Tobacco Harm Reduction

Complete cessation of all tobacco and nicotine is always the preferred goal. However, a large proportion of smokers are **unable or unwilling to quit and 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 alternative that delivers the nicotine smokers are addicted to, but without smoke.

E-cigarettes meet many of the criteria for an ideal tobacco harm-reduction product. (10) They can replace smoking by delivering high doses of nicotine without the vast majority of harmful constituents of tobacco smoke, and provide the behavioural and sensory aspects of the smoking ritual. A recent Australian review of drugs suitable for long-term maintenance for substance dependence concluded that nicotine meets the criteria for this purpose. (11)

Nicotine has only a minor role in smoking-related disease. (12) It does not cause cancer, lung disease or heart disease. (13, 14) The harm from smoking is caused by burning tobacco, which produces thousands of chemicals, tars, carbon monoxide, other toxic gases and solid fine particles.

Australian tobacco control policy has historically ignored tobacco harm reduction, which is in breach of its international treaty commitments and our own tobacco strategy:

- THR is an integral part of the World Health Organisation's Framework Convention on Tobacco Control (FCTC) treaty, under Articles 1(d) and 1(f). (15) As a signatory of the FCTC Australia is obliged to introduce THR strategies along with other tobacco control measures.
- THR is also one of the objectives of the National Tobacco Strategy 2012-2018, 'reduce harm associated with continuing use of tobacco and nicotine products' (Part 5.2, page 11). THR is complementary to conventional tobacco control strategies. (4)

The concept of harm reduction has been applied with success to several risky human behaviours, such as long-term methadone for heroin users, clean needles and syringes to reduce the risk of HIV/AIDS in drug users and promoting condoms for sex workers.

## **Snus. Proof of concept for Tobacco Harm Reduction**

In Sweden, the long history use of snus confirms the effectiveness and safety of long-term nicotine in humans when used for tobacco harm reduction. Snus is a moist, smokeless, low-nitrosamine tobacco placed in a pouch under the upper lip, which delivers nicotine levels similar to smoking. Snus has been used by Swedish men as a consumer product for over five decades as a non-therapeutic, less harmful alternative to smoking, but is banned in all other EU countries. (16)

A recent review confirmed that snus has both contributed to decreasing initiation of smoking and assisted in smoking cessation. (17) It is the most common smoking cessation aid used by Swedish men. (17) Sweden has a daily smoking prevalence of 5% (the lowest in Europe) (18) and the lowest level of tobacco-related mortality among men in Europe (17).

It has been recently estimated that 355,000 lives **per year** could have been saved in men over 30, if the consumption of snus had been the same in the rest of the EU as in Sweden. (19) Similar benefits would be expected from switching to inhaled nicotine from e-cigarettes.

## **1. Use to assist people to quit smoking (see later for marketing)**

E-cigarettes are an effective aid for helping some smokers quit tobacco. Millions of people have now quit smoking by switching to e-cigarettes. Some continue to vape long-term, others cease both vaping and smoking.

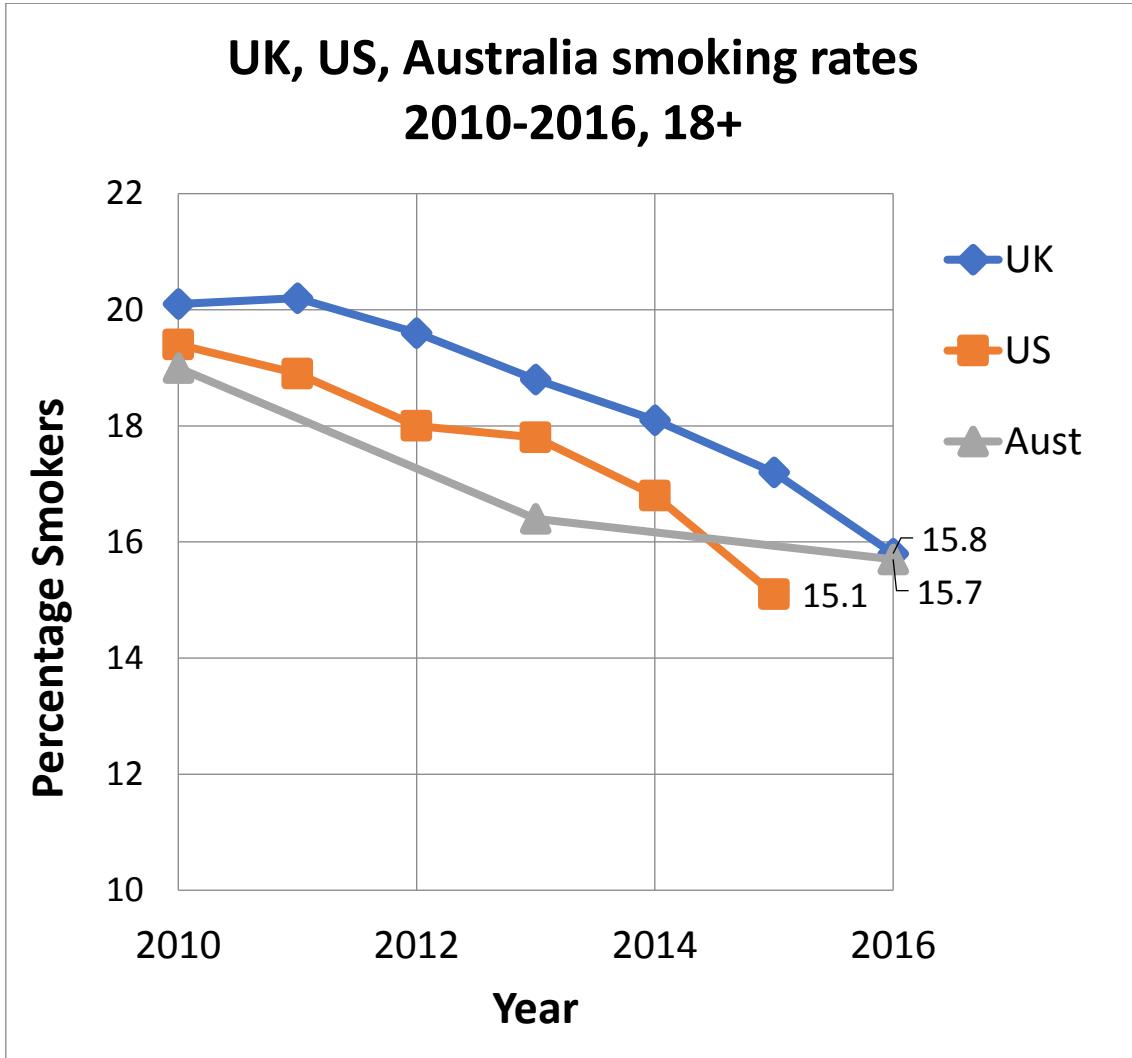
### **Population studies**

The best evidence for the effectiveness of e-cigarettes for smoking cessation is in real-world population studies. For example, in the European Union over 6 million smokers reported having quit using an e-cigarette in 2014. (20) In the UK, 1.5 million former smokers are now vaping. (21) Another 650,000 ex-smokers have quit smoking and vaping altogether. ([ONS 2016](#))

### **Effect on smoking prevalence**

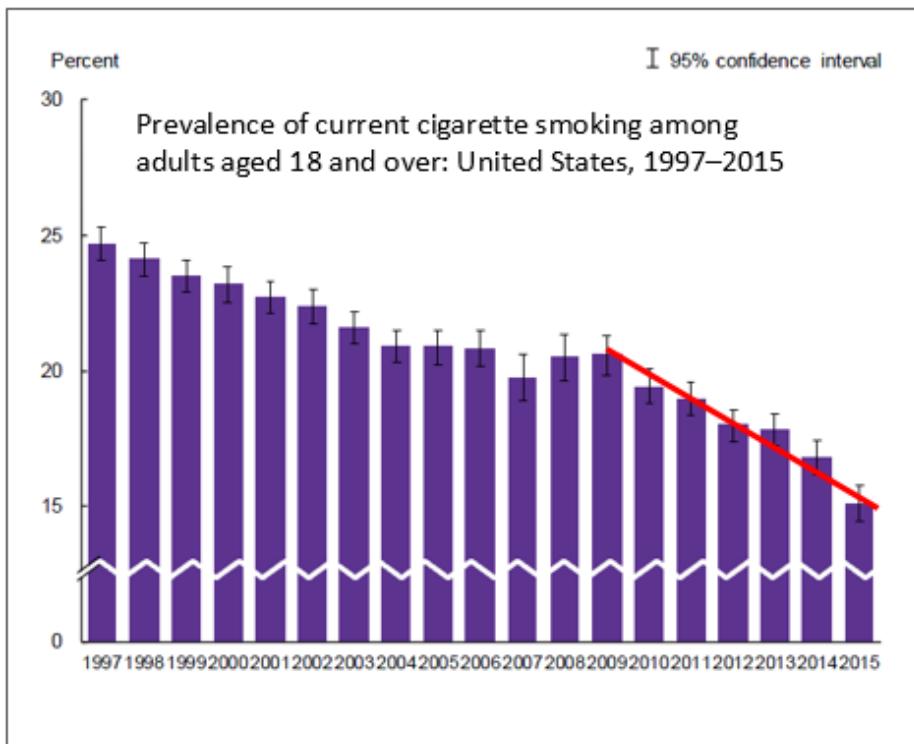
Smoking rates in countries where e-cigarettes are widely available are falling faster than in Australia, as the following graph shows. It is very likely that e-cigarettes are a contributing factor to this rapid decline although it is not possible to prove cause and effect. Certainly, there is no evidence that e-cigarettes are undermining tobacco control or leading to the renormalisation of smoking as some suggest. In fact, the very opposite is occurring.

Based on national surveys of adults 18+, smoking rates in the US and UK are now similar to or lower than Australia, which has historically had significantly lower smoking rates until now.



(Data: UK. Annual Population Survey, Office of National Statistics; US. National Health Interview Survey, CDC National Centre for Statistics; Australia. National Drug Strategy Household Survey, Australian Institute of Health and Welfare)

Smoking prevalence is declining faster than ever in the United States since e-cigarettes became popular around 2010, according to National Health Interview Survey data from the CDC. [[link](#)] Previous to that, smoking rates had flat-lined for 6 years.



(Data from US. National Health Interview Survey, CDC National Centre for Statistic. [[Link](#) p55])

## Randomised controlled clinical trials

Randomised clinical trials (RCTs) are often not suited to public health research on complex consumer behaviours and are often misleading. (22) It is impossible to control an e-cigarette trial as there are many factors independent of the device. (23) Uptake depends on personal preferences, support provided from vape shops or peers, cost, risk perceptions, regulatory issues, accessibility and other factors.

The process of finding a suitable e-cigarette and e-liquid by a smoker is not linear and not easily randomisable. There is an unlimited range of choices and most users experiment with different models, e-liquid strengths and flavours before finding the right one. The typical binary choice of a RCT is not suited to this type of decision making.

Trials are brief. The process of transitioning to vaping often takes months or years, typically with a period of dual use. In a short clinical trial, successes will be missed. More information is available [here](#).

It is important to note that early trials used now-obsolete first generation e-cigarettes with low nicotine delivery and technical flaws. However, the results were comparable with those from NRT products. (24) More advanced devices which deliver higher nicotine levels are more effective. (25, 26)

## Other research

Evidence from a large (n=5,863), real world observational study in England found that smokers using an e-cigarette in a quit attempt were 60% more likely to be abstinent compared to NRT bought over-the-counter or quitting unaided, after adjusting for a wide range of confounders. (27)

One study so far has found significantly higher quit rates when e-cigarettes are combined with counselling by a health professional and other stop-smoking medication. (28) Preliminary data from the UK NHS Stop Smoking Service supports this finding.

Vape shops provide valuable advice and support for smokers wanting to switch and can help smokers achieve high success rates. (95-97)

Anecdotal reports are not strong scientific evidence. However, the large number of individuals who have had positive experiences cannot be ignored. In my own medical practice, I regularly see smokers cease smoking with an e-cigarette after all other methods have failed.

## Reviews of the evidence

Good quality, comprehensive reviews of the evidence available to date have found that the e-cigarettes help some smokers quit. However, further large, high-quality studies are needed.

- **Centre for Addictions Research of British Columbia, Canada.** ‘Overall, there is encouraging evidence that vapour devices can be at least as effective as other nicotine replacements as aids to help tobacco smokers quit’. (29)
- **UK Royal College of Physicians.** ‘E-cigarettes appear to be effective when used by smokers as an aid to quitting smoking’. (10)
- **Public Health England.** ‘Recent studies support the Cochrane Review findings that EC can help people to quit smoking and reduce their cigarette consumption’. (30)
- **Cochrane Review, 2016.** There is evidence from two trials that ECs help smokers to stop smoking in the long term compared with placebo ECs. However, the small number of trials, low event rates and wide confidence intervals around the estimates mean that our confidence in the result is rated ‘low’ by GRADE standards. (24)
- **The Schroeder Institute for Tobacco Research and Policy Studies at Truth Initiative, US.** ‘Four RCTs show that ENDS are effective in helping some adult smokers to quit or to reduce their cigarette consumption. In the studies that assessed smoking cessation, rates of cessation in the ENDS study groups were similar to or higher than rates of cessation seen in previous clinical trials of nicotine-replacement therapy (NRT)’. (31)

## Poor quality reviews

Many studies and reviews have poor methodology and should be treated with caution. According to The Schroeder Institute for Tobacco Research and Policy Studies at the Truth Initiative, ‘The conclusions from the longitudinal and cross-sectional studies reporting **negative correlations** between those who tried ENDS and smoking cessation have serious limitations, including selection bias (e.g., smokers who quit by using ENDS were excluded from the sample); inadequate measures of exposure (e.g., ever use in one’s lifetime) to test for a cessation indication; and confounders (e.g., smokers who have repeatedly failed to quit are more likely to try ENDS). (31)

The widely cited Kalkhoran review is of particular concern. (32) This review suggests that e-cigarettes reduce quitting and has been widely criticised for its poor methodology. The analysis included heterogeneous studies that were too different in design to be directly compared, didn’t include adequate measures of use (eg a single puff or heavy daily use) or cessation, did not consider the differences in the types of e-cigarettes used, selective inclusion of studies and selective reporting of studies that were included, did not consider whether or not smokers were using e-cigarettes to quit, limitations that the authors acknowledge in the text but ignore in the conclusions. (33, 34) See also [here](#).

## Popularity of e-cigarettes

In the US (35) and UK (2), e-cigarettes are the most popular quitting aid. Because they are popular with smokers, **they are likely to have a wide reach and a greater public health effect**.

In 2016, 1.2% of Australians (18+) are currently vaping. (1) This is considerably less than 5.6% in the UK in 2017 (36), 5.5% in the US in 2014(37), 6% in France (38) and 1.8% in the European Union (20), where e-cigarettes are legal and widely available. Removal of Australia's strict regulatory approach will allow greater uptake of e-cigarettes and improvements in public health.

## Dual use

Dual use (using an e-cigarette while still smoking) is often raised as a criticism of vaping by critics who do not understand the complex process of quitting. Dual use is often part of a long transition to quitting smoking and dual users often progress to exclusive vaping or complete cessation of vaping and smoking. Dual use is a diverse category from smoking as usual and vaping once a week to those who have reduced their cigarette consumption by 90% and vape daily.

Forty-five per cent of current e-cigarette users in the UK (21) and 70% in the US (37) also smoke.

One reason for continuing dual use is that the currently available e-cigarettes are not yet good enough to allow some smokers to quit smoking entirely.

- **Dual users have health benefits**

Clinical studies have shown that compared to exclusive-smokers dual users have improved COPD (39), blood pressure (40) and asthma and lung function (41). 'Biomarker' studies have found significantly lower levels of carcinogens and other toxins in smokers who dual use compared to exclusive-smokers. (42-44)

Most studies have shown that dual users substantially reduce their cigarette intake. (45) Dual users smoke less intensely from cigarettes because they are already receiving nicotine (compensatory smoking) and extract less smoke and other toxins. (46) This is quite different to cutting down without an alternative source of nicotine, as smokers unconsciously smoke more intensely to maintain their nicotine levels, resulting in little benefit to health.(47)

- **Dual use rates are falling**

In the UK in 2014, nearly two thirds of e-cigarette users were also smoking ([ASH UK](#)). In 2017, the dual use rate had fallen to 45%.

- **Dual users are more likely to quit**

According to the Royal College of Physicians review, dual users are more likely to make an attempt to stop smoking than exclusive-smokers. (10) Most studies have found that dual users who vape daily are more likely to quit than exclusive smokers (48, 49), although one study did not. (50) Smokers who also use NRT (known as 'dual users') are approximately twice as likely in the following months to make a quit attempt, and to quit smoking, than those who do not. (51)

- **Dual use is a normal part of quitting**

Dual use rates with e-cigarettes are similar to those with NRT. Data from the Smoking Toolkit Study shows that approximately 50-60% of NRT users are also smoking. (2) Smoking cessation typically includes a period of dual use as smokers adjust to medication. A period of dual use is recommended for nicotine patches, varenicline and bupropion.

## Use by youth

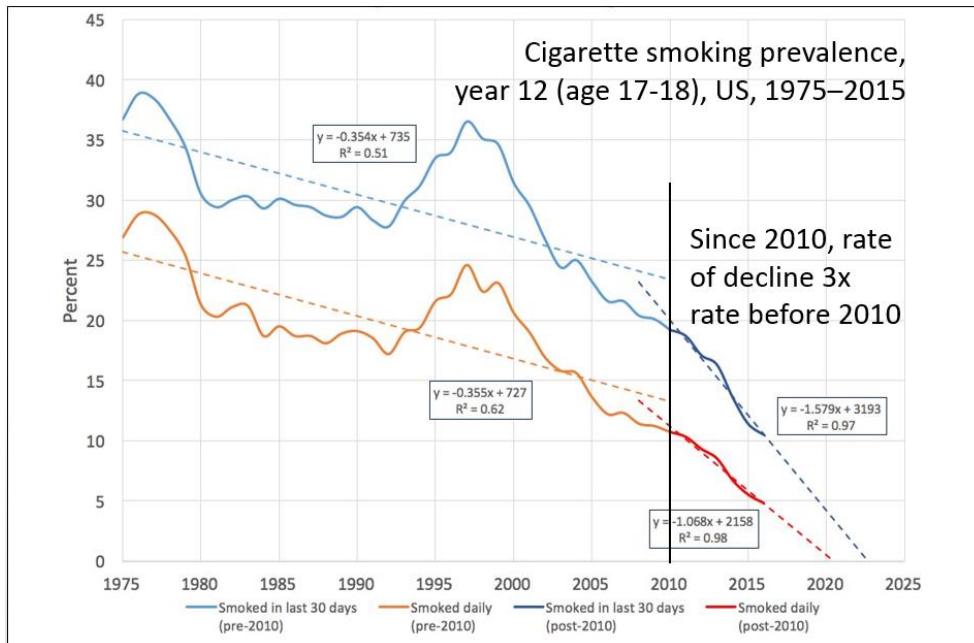
It would be a serious concern if vaping was leading more young people to smoke. Many studies have shown that kids who try vaping are more likely to try smoking, but there is no evidence of cause and effect. It is more likely a case of 'common liability' ie that young people who are more attracted to experimentation are more likely to try both products. (52)

### 1. *Decline in smoking rates*

As vaping rates have been increasing, smoking rates are declining rapidly in young people and are at record low levels in countries where e-cigarettes are readily available. The evidence suggests that vaping is

replacing—rather than encouraging—smoking of tobacco cigarettes among young people and reducing smoking uptake. (29)

In the US, analysis of data from the Monitoring the Future study by the National Institute of Drug Abuse [[link](#)] found that the rate of **decline in cigarette smoking in 12th grade high school students has been three times faster since 2010 when e-cigarettes first became widely available**, than the long-running trend over the preceding 35 years. These findings are incompatible with the claims that e-cigarettes' increase smoking among teens.

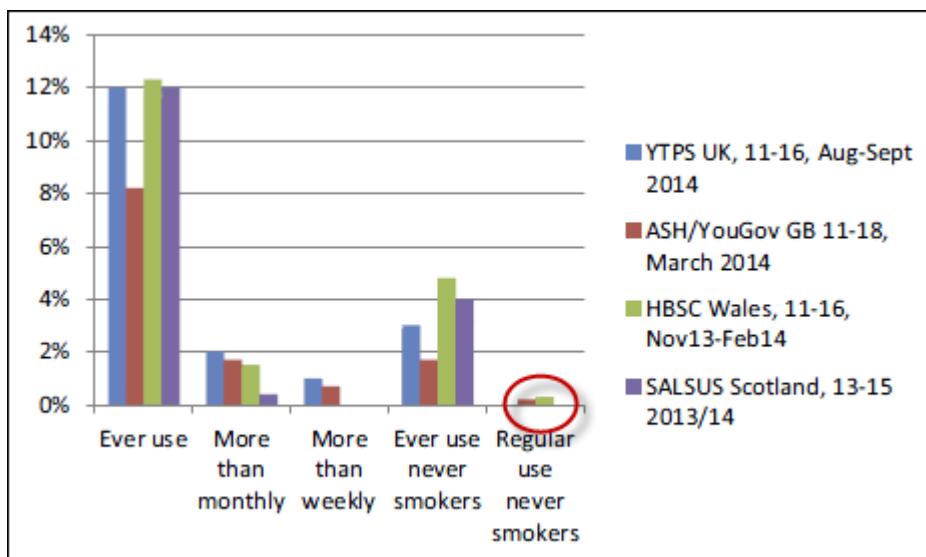


(Data from *Monitoring the Future survey 2015*, National institute on Drug Abuse, 2016 [[link](#)])

## 2. Vaping almost exclusively confined to smokers

Many studies have found that regular vaping among teens is almost exclusively confined to those who already smoke. Regular vaping among non-smokers is rare. Teens are curious, vaping is a fun thing to do and kids try it for a while and then stop.

- UK. Four studies from the UK show that regular use (ie monthly or more) in young people who have not previously smoked is rare - about 0.2% or 2 in 1,000 young people, and there is no evidence of progression to smoking. (53)



(Source: Bauld L. E-Cigarette Uptake Amongst UK Youth Experimentation, but Little or No Regular Use in Nonsmokers. Nicotine Tob Res 2016)

- US. National Youth Tobacco Survey, 2014 (CDC). ‘It was rare that tobacco naïve youth reported using e-cigarettes and if they did, rarer still to finding them using them frequently (ie, fewer than 0.1% used on 10 or more days per month)’. (54)
- US. Monitoring the Future survey, 2014 (NIDA). ‘Conclusions: Non-smoking high school students are highly unlikely to use e-cigarettes; among those who do, most used them only on 1–2 of the past 30 days’.
- France. 20014 Health Barometer national telephone survey. ‘Fewer than 1 % of 15–24-year-old vaped and had never smoked’. (38)

### 3. Most young people do not use nicotine

An argument claiming to support the ‘gateway theory’ is that adolescents who would never have smoked, will become addicted to nicotine from e-cigarettes and then progress to cigarettes. However, **the great majority of adolescent e-cigarette users do not use nicotine**. The National Institute of Drug Abuse’s annual Monitoring the Future survey in 2015 reported that only about 20% of 12th grade and 13% of 8th grade students who had vaped, used nicotine. (55)

### 4. Use for quitting

Some young people are using e-cigarettes to quit smoking or reduce cigarette use. (38, 56, 57)

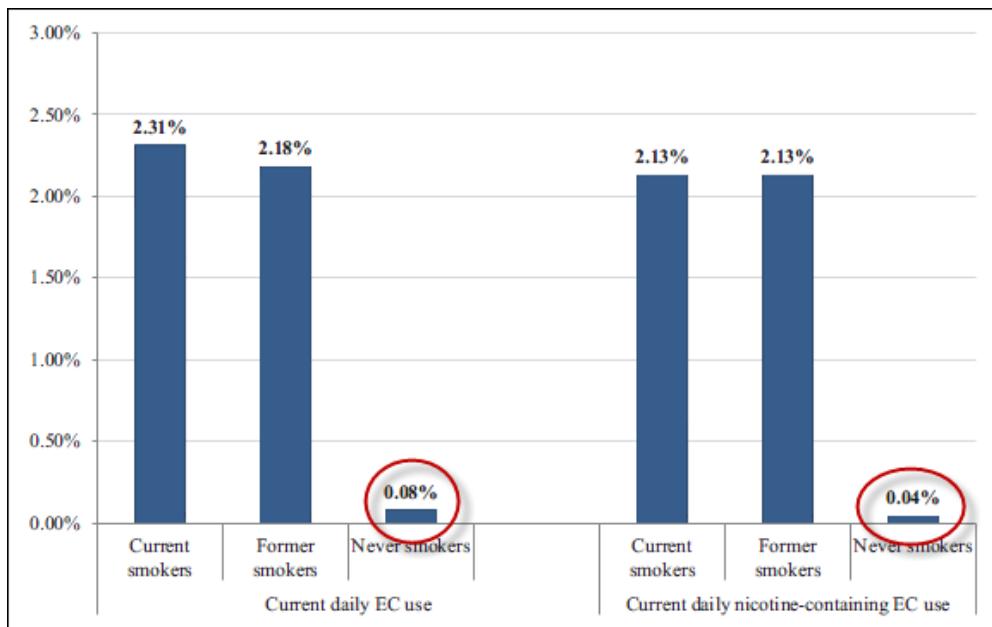
### 5. Banning vaping in young people increases smoking rates

Two large studies from the US have found that the introduction of bans of e-cigarette sales to young people in two states was associated with a significant increase in adolescent smoking compared to states without bans, most likely due to removing a much less harmful and more enjoyable alternative. (58, 59)

### Risk to non-smoking adults

Numerous studies have found that the use of e-cigarettes by adult smokers who have never smoked is rare.

- European Union. Farsalinos found that ‘daily EC use is predominantly observed in current and former smokers but is very rare among never smokers’. Only 0.08% of never smokers (8 in 10,000) used an e-cigarette daily and only 0.04% used a nicotine-containing e-cigarette daily (60).



(Source: Farsalinos KE et al. Prevalence and correlates of current daily use of electronic cigarettes in the European Union: analysis of the 2014 Eurobarometer survey. Internal and emergency medicine. 2017)

- US. National Health Interview Survey 2014. 'Current e-cigarette use is extremely low among never cigarette smokers (0.4%)'. 'Extremely low e-cigarette use among never-smokers and longer term former smokers suggest that e-cigarettes neither promote widespread initiation nor relapse among adults'. (61)
- UK. Office of National Statistics, 2015. 'The use of e-cigarettes by never-smokers in the UK is very low (0.2 percent of never smokers use e-cigarettes)'. (62)
- Germany, 2016. 'only 0.1% of never smokers, used e-cigarettes at the time of the survey'. 'According to our investigation, e-cigarettes are used on a regular basis almost exclusively by smokers and ex-smokers'.

## 2. Health impact of the use of e-cigarettes and personal vaporisers

### Overall harm of e-cigarettes

The scientific consensus is that e-cigarettes are dramatically less harmful than smoking.

Almost all the harm from smoking is from the tars, carbon monoxide and other toxic chemicals caused by combustion of tobacco leaf. On the other hand, e-cigarettes heat a liquid into a vapour without combustion and are certain to be orders of magnitude safer. Comprehensive reviews by The Royal College of Physicians and Public Health England (10, 30) have estimated that they are 95% less harmful. Not everyone agrees with the exact figure, but even the harshest critics accept they are substantially safer than smoking.

According to Public Health England (30) 'The estimate that e-cigarette use is around 95% less harmful than smoking is based on the facts that:

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

The Royal College of Physicians (10) concluded:

- ‘Although it is not possible to precisely quantify the long-term health risks associated with e-cigarettes, 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’.

There is no evidence of serious harm from short-term use. According to the Cochrane review, ‘none of the included studies (short- to mid-term, up to two years) detected serious adverse events considered possibly related to EC use. The most commonly reported adverse effects were irritation of the mouth and throat.’ (24)

E-cigarettes are not completely safe. Nothing ever is. However, e-cigarettes are **used almost exclusively by smokers, so any risk needs to be compared to the substantial risk from smoking** which kills up to two in three long-term users. (5)

## Secondhand exposure

‘The risk of harm from vapour exposure to bystanders is negligible’. (10)

The source of environmental tobacco smoke is mainly due to the emission of tobacco smoke between puffs. With e-cigarettes, there is no emission between puffs. Furthermore, the half-life of e-cigarette emissions is only 11 seconds compared with 20 minutes for cigarette smoke, contributing to reduced risk.

Reviews have concluded

- ‘ENDS release negligible levels of nicotine into ambient air with no identified health risks to bystanders’. (30)
- ‘So far, no direct evidence that such passive exposure is likely to cause significant harm.’ (10)
- ‘The potential of any significant adverse effects on bystanders is minimal’. (63)
- ‘Pollutant levels are much lower than from cigarettes and are likely to pose a much lower risk (if any) compared to cigarettes. (64)

## Health improvements after switching

Studies have shown health improvements when smokers switch to e-cigarettes, especially in respiratory and cardiovascular health. Documented improvements include:

- Asthma. Improved objective lung function, reduced asthma symptoms and less need for medication has been demonstrated. (65)
- COPD. Significant reduction in exacerbations, improved symptoms and exercise ability. (39)
- Significant improvements in lung function. (66)
- Respiratory infections. Reduced frequency. (67, 68)
- Pneumonia. Reduced frequency. (68)
- Blood pressure. Reduction in blood pressure in smokers with hypertension. (40, 69)
- Cardiovascular health. ‘If ECs can be substituted completely for conventional cigarettes, the harms from smoking would be substantially reduced and there would likely be a substantial net benefit for cardiovascular health’. (13)

## Chemicals in vapour

Toxicity is determined by the dose of toxins, not their mere presence. A number of potentially harmful constituents are present in vapour but at much lower levels than in cigarette smoke. (10). Goniewicz found that ‘The levels of the toxicants were 9–450 times lower than in cigarette smoke and were, in many cases, comparable with trace amounts found in the reference product’. (70)

These doses are in most cases below levels that have a biological effect or cause harm to human health. For example Burstyn (71) did a comprehensive review of chemicals in vapour and concluded:

- ‘there is no evidence that vaping produces inhalable exposures to contaminants of the aerosol that would warrant health concerns by the standards that are used to ensure safety of workplaces’.

## ‘Biomarkers’

Further confirmation of the reduced harm from e-cigarettes is the **dramatic reduction in exposure to carcinogens and toxins (biomarkers)** measured in e-cigarette users compared to tobacco smokers.

For example, Shahab found that long-term e-cigarette users (>6 months) had substantially reduced levels of selected tobacco-related carcinogens and toxins in the saliva and urine compared to continuing smokers.  
(72) Other studies have found similar results (42-44, 46)

## Effects of nicotine

### *1. Adverse effects*

‘The long-term adverse effects of nicotine are likely to be minimal’ (10), except in pregnancy. Nicotine has relatively minor adverse health effects when decoupled from tobacco. However, nicotine has been associated with the harms from smoking and there is misinformed resistance to using it to treat tobacco dependence.

- Pregnancy. Nicotine from smoking is harmful to the foetal brain and lungs and contributes to low birth weight. There is no evidence that the use of nicotine replacement therapy is harmful to the foetus.
- Respiratory disease. There is no evidence that nicotine causes respiratory disease.
- Cancer. There is no evidence that nicotine causes cancer in humans (14, 73). Laboratory and animal studies have raised some concerns about cancer-promoting effects (74), however this is not corroborated by human data from long-term use of nicotine replacement therapy (75) and snus (oral nicotine product) (76). The Royal College of Physicians concluded that ‘there is no evidence that this theoretical risk, derived from animal studies, translates into an increase in cancer risk or tumour growth in humans’. (10)
- Cardiovascular disease. ‘Nicotine may contribute to cardiovascular disease (CVD), but its impact is much less, compared to tobacco smoke’. (13)
- Adolescence. There is no evidence in humans that nicotine affects brain development, although adverse effects have been found in animal studies. (77) Animal studies often include chronic, high dose exposure to nicotine and don’t approximate the type of nicotine exposure from adolescent smoking. It is unclear how these changes translate to humans.
- Nicotine toxicity. In the low doses used in e-cigarettes, nicotine is not associated with clinically significant toxicity. (12)
- Overdose. Most cases of intentional or accidental nicotine poisoning involving nicotine e-liquid result in prompt vomiting and rarely cause serious harm. (78, 79) According to Public Health England, the risk from ingesting nicotine is comparable to similar potentially poisonous household substances. (30)

### *2. Beneficial effects*

Nicotine also has positive effects on health which can benefit some long-term users.

- Performance. Improved fine motor skills, concentration, short-term memory. (80)
- Short-term alleviation of stress, anxiety and depression. (81)
- Beneficial effects on ADHD (82), Parkinson’s disease (83) and schizophrenia (84).
- Weight control (85). There is some evidence that vapers gain less weight than those quitting with other methods. (86)

## Addiction potential

Dependence on e-cigarettes is significantly less than for combustible cigarettes. (10)

Lower dependence levels have been confirmed by user reports (87), use of a validated Cigarette Dependence Index (88) and Time to First Cigarette of the Day (89). E-cigarettes deliver nicotine more slowly than smoking (90) and do not include other chemicals in tobacco smoke that increase smoking's addictiveness (91). Empirical evidence from adolescent use suggests that, although adolescents experiment with e-cigarettes, few – if any – never-smokers who do so become regular e-cigarette users. (53)

### **Exaggerated perceptions of risk**

There are widespread misperceptions about the risks of nicotine and vaping in general. An Australian study reported that only 35% of Australians believed that e-cigarettes are a lot less harmful than conventional cigarettes. (34) This is partly a result of misinformation from vaping critics, media reports and press releases in which the scientific evidence of absolute harm is highlighted and that of relative harm is overlooked. (92)

### **Unknown long-term health effects**

According to the UK Royal College of Physicians, 'the hazard to health arising from **long-term** vapour inhalation from the e-cigarettes available today is **unlikely to exceed 5% of the harm from smoking tobacco.**' (10) As regular e-cigarette use is almost exclusively confined to smokers, any risk should be compared to the risk of continuing to smoke, which kills two out of every three smokers. (5)

Some people argue that we should ban e-cigarettes until long-term safety data is available. By this impossible standard, no new drug or treatment would ever be allowed until 20 or 30 years of continuous testing. However, after more than ten years of research and international experience, a considerable amount is now known about the science and behaviour of vaping. Given the huge potential to save lives, we should act on what we know now, not be paralysed by unrealistic and over-cautious standards.

Studies of up to two years have not detected any serious health harm. (35)

### **Overall effect on public health**

Two recent studies using very conservative assumptions calculated that between 16,000-22,000 smokers had quit for the long-term in one year in England who would not have quit if e-cigarettes were not available. This equates to 10,000 to 15,000 lives saved each year. (22, 93)

Modelling studies incorporating a range of different assumptions have shown that the overall benefit to public health is positive. For example, Levy found that 'Based on current use patterns and conservative assumptions, we project a reduction of 21% in smoking-attributable deaths and of 20% in life years lost'. (94)

Cherng found that 'the simulated effects of e-cigarettes on smoking cessation generate substantially larger changes to smoking prevalence compared with their effects on smoking initiation'. (95)

Further modelling by Saitta (96) used the Risk Management Plan from the US Department of Health & Human Services to model the impact and probability of risks from e-cigarettes. Most the risks are small and of low potential. Any risk needs to be balanced by the health risks of maintaining the status quo, continued smoking.

After a detailed and comprehensive review, The UK Royal College of Physicians (10) concluded:

- 'for all the potential risks involved, harm reduction has huge potential to prevent death and disability from tobacco use, and to hasten our progress to a tobacco-free society'
- '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...'.

### 3. International approaches to legislating and regulating the use of e-cigarettes and personal vaporisers

#### International database of e-cigarette regulation

There is currently a wide range of regulatory approaches to e-cigarettes. The Johns Hopkins Bloomberg School of Public Health maintains a database of international e-cigarette regulations and policy [[link](#)]. (97) Currently 79 countries are listed.

#### Regulatory mechanisms [[link](#)]

- **Thirty-nine countries have a law/decreed/resolution/circular/notification regarding e-cigarettes**  
Belgium, Brazil, Bulgaria, Cambodia, Chile, Croatia, Cyprus, Czech Republic, England, Estonia, Finland, Gambia, Germany, Italy, Jordan, Kuwait, Latvia, Lebanon, Lithuania, Malta, Nepal, Northern Ireland, Oman, Panama, Philippines, Poland, Portugal, Qatar, Romania, Saudi Arabia, Scotland, Slovakia, Slovenia, Suriname, Togo, Uganda, United Arab Emirates, United States and Wales
- **Eleven countries use existing legislation**  
[Australia](#), Brunei Darussalam, Canada, Iceland, Malaysia, Mauritius, New Zealand, Norway, South Africa, Venezuela and Viet Nam)
- **Six countries use existing bans on imitation products**  
Colombia, Honduras, Mexico, Nicaragua, Seychelles and Singapore
- **Seven countries made amendments to existing legislation**  
Barbados, Fiji, Greece, Hungary, Spain, Turkmenistan and Uruguay.
- **Ten countries used a combination of new and existing regulation**  
Argentina, Bahrain, Costa Rica, Denmark, Ecuador, Ireland, Japan, Netherlands Switzerland and Thailand
- **Four countries use a combination of amended tobacco control legislation and existing legislation to regulate e-cigarettes**  
Jamaica, Republic of Korea, Turkey and Ukraine
- **Two countries use a combination of new, amended and existing regulation**  
Austria and France

#### Product classifications [[link](#)]

Generally, countries regulate e-cigarettes based on their classification as

- Multiple classifications. Sixteen countries classify or regulate e-cigarettes as consumer products, in addition to classifying them as other types of products ([Australia](#))
- E-cigarettes/ENDS. Fifty-five countries refer to e-cigarettes as ENDS/e-cigarettes
- Medicinal. Twenty-two countries regulate e-cigarettes that make a cessation claim and/or contain a specific threshold of nicotine as medicines/drugs/medical devices
- Tobacco. Forty-two countries classify or regulate e-cigarettes as tobacco products
- Poisons. Four countries regulate nicotine as poisons or hazardous substances ([Australia](#))

#### Policy domains include [[link](#)]

- Sale of e-cigarettes
  - Sale of all types of e-cigarettes is banned in 27 countries
  - In thirty-three countries, that permit the sale of e-cigarettes, there are regulations around sale such as marketing authorization requirement, or cross-border sale restrictions/regulations
  - Nine countries prohibit the sale of nicotine-containing e-cigarettes ([Australia](#)).
  - Seven countries do not have regulations on sale beyond age of majority purchase rules
- Minimum age. In twenty-eight countries, the minimum age for e-cigarette purchase mirrors those of traditional cigarettes in the country.

- Advertising, promotion, sponsorship. Fifty-eight countries prohibit or regulate advertising, promotion, or sponsorship of e-cigarettes (including **Australia**)
- Packaging (child safety packaging, health warning labelling and trademark).
  - Twenty-seven countries have regulations on child safety packaging. Twenty-eight countries mandate the placement of health warnings on e-cigarette packaging
  - Twenty-six countries do not permit the use of ingredients (other than nicotine) that pose a risk to human health in heated or unheated form in nicotine-containing e-liquid
  - Twenty-six countries regulate the quality of nicotine and other ingredients used to manufacture the e-liquid, as well as regulate the flavors that can be used in e-liquids
- Product regulation (nicotine volume/concentration, safety/hygiene, ingredients/flavors). Twenty-six countries regulate the amount (concentration/volume) of nicotine in e-liquids.
- reporting/notification. Twenty-seven countries have regulations that require manufacturers/retailers to notify the competent authority prior to introducing e-cigarettes to the market, as well as submit an annual report of sales and other specified information
- Taxation. Very few countries are applying taxes to e-cigarettes or the liquids.
- Vape-free public places. Thirty-nine countries prohibit or restrict the use of e-cigarettes in public places. Use is prohibited in vehicles with minors in three countries

## Specific countries

### 1. New Zealand

- **Community Consultation Process**, Ministry of Health, 2 August 2016. Policy Options for the Regulation of Electronic Cigarettes [[link](#)] The Ministry of Health's spokesman, Professor Hayden McRobbie, says "Evidence around the risks and benefits of e-cigarettes is not yet conclusive. But it is time now to develop regulations that maximise the potential benefits of e-cigarettes and minimise any risks, not only to smokers but also the wider population."
- **Health Minister announces that the sale of nicotine e-cigarettes and e-liquid will be made legal as a consumer product with appropriate controls**, 29 March 2017. [[link](#)]
- Cabinet agreed to retain the requirement that e-cigarettes making a therapeutic claim (eg, for use as a tool to quit smoking) must have a product approval under the Medicines Act 1981.
- **Consultation on Electronic Cigarettes: Analysis of submissions**, 4 April 2017. 'This Analysis of Submissions describes the key themes which emerged during the consultation process. These submissions were used to inform policy decisions'. [[link](#)]
- Consumer Questions and Answers document [[link](#)].
- **Regulatory Impact Statement**, March 2017. Regulation of e-cigarettes and emerging tobacco and nicotine-delivery products, Ministry of Health. [[link](#)] 'It provides an analysis of options to regulate e-cigarettes and e-liquid as consumer products, as well as an analysis of high-level options for the regulation of emerging tobacco and nicotine-delivery products'. The Ministry's recommendations are to amend the Smoke-free Environments Act 1990 to:
  - legalise the sale and supply of nicotine e-cigarettes and e-liquid as **consumer products**
  - regulate both nicotine and non-nicotine e-cigarettes and e-liquid as consumer products under the Smoke-free Environments Act 1990
  - continue to regulate e-cigarette products that make a **therapeutic claim** under the Medicines Act 1981
  - prohibit the sale, and supply in public areas, of nicotine and non-nicotine e-cigarettes and e-liquid to people **under the age of 18 years**
  - restrict the use of **vending machines** for nicotine and non-nicotine e-cigarettes and e-liquid to R18 settings and require that they be manually operated by a salesperson

- prohibit promotion and advertising of nicotine and non-nicotine e-cigarettes and e-liquid, with exemptions for:
  - point-of-sale display for all retailers
  - in-store display, free samples, rewards (eg, loyalty points), discounts (eg, for old stock), co-packaging, window displays and promotion on the outside of the store where settings are R18, for specialist vape shops
  - enable product safety requirements to be set out in regulations and/or tertiary legislative instruments, such as notices and guidelines.
- **Electronic Cigarette Technical Expert Advisory Group**, 9 June 2017. Announcement of formation. [[link](#)]
- Amendments to the Smokefree Environment's Act 1990 are being prepared.

### **3. Canada**

Legislation is currently before parliament (Bill S-5). The proposed Act amends the Tobacco Act to regulate vaping products as a separate class of products. As such, the Tobacco Act would be renamed the Tobacco and Vaping Products Act and will regulate the manufacture, sale, labelling and promotion of e-cigarettes. This would include

- prohibiting sales to young people
- restricting some forms of advertising
- prohibiting sales in vending machines
- setting standards for product characteristics

Products making a therapeutic claim will continue to be regulated as medicines.

#### **Progress**

- Report of the Standing Committee on Health. Vaping - towards a regulatory framework for e-cigarettes. March 2015 [[link](#)]
- Bill S-5. An Act to amend the Tobacco Act and the Non-smokers' Health Act and to make consequential amendments to other Acts [[link](#)]
  - Passed by the Senate 1 June 2017 [[link](#)]
  - First reading in House of Commons 15 June 2017 [[link](#)]

### **4. United Kingdom**

#### **Revised European Union (EU) Tobacco products Directive (TPD)**

The UK is required to follow the EU TPD which came into effect in May 2017 and sets out new regulations for nicotine e-cigarettes. There are seven requirements of the TPD:

- Restrict e-cigarette tanks to a capacity of no more than 2ml.
- Restrict the maximum volume of e-liquid for sale in one refill container to 10ml.
- Restrict e-liquids to a nicotine strength of no more than 20mg/ml.
- Require nicotine-containing products or their packaging to be child-resistant and tamper evident.
- Ban certain ingredients including colourings, caffeine and taurine.
- Labelling requirements and warnings.
- E-cigarettes and e-liquids to be notified to health regulators 6 months prior to marketing.

#### Other issues

- The use and sale of e-cigarettes with nicotine to adults is legal. It is illegal to sell e-cigarettes or e-liquids to minors (<18 years)
- E-cigarettes which make no therapeutic claims are classified as **consumer products**
- The display of vaping products is not restricted in retail outlets

### ***Vaping in public places***

E-cigarette use is not covered by laws restricting smoking in public places. Public Health England has issued guidance to assist businesses and employers determine their own vaping policies. [\[link\]](#)

### ***Therapeutic products***

EU rules don't apply to therapeutic products, which are regulated under national rules (Medicines and Healthcare Products Regulatory Authority has approved a novel cigarette-like nicotine inhaler called Voke and an e-cigarette called e-voke).

### ***Advertising***

Almost all advertising sponsorship and promotion of e-cigarettes is banned under the TPD. This excessive approach protects the incumbent cigarette trade from a disruptive challenger.

- E-cigarette advertising on TV and radio is prohibited under Article 20(5) of the Tobacco Products Directive 2014/40/EU. [\[link\]](#) E-cigarettes and re-fill containers can't be advertised or promoted, directly or indirectly:
  - on TV or on-demand TV
  - on radio
  - through information society services (this includes for example internet advertising and commercial e-mail)
  - in certain printed publications – newspapers, magazines, periodicals and similar publications
- The TPD also requires prohibition of:
  - sponsorship of television and radio programmes which promotes electronic cigarettes
  - product placement of electronic cigarettes
- The following advertising is permitted:
  - Cinema, fax, outdoor posters, billboards, posters on sides of buses, leaflets, and direct hard copy mail
  - Internet. Non-promotional Information on vendor websites

### ***Standards***

A set of voluntary safety and quality standards (PAS 54115:2015) was developed by the British Standards Institution in July 2015 and sponsored by the Electronic Cigarette Industry Trade Association, ECITA (EU) Ltd. It acts as a guide for manufacturers and gives guidance on manufacture, import, labelling, marketing and sale of vaping products. [\[link\]](#)

Similar voluntary standards have been developed in France (AFNOR) [\[link\]](#), consisting of

- XP D90-300-1: Requirements and test methods for electronic cigarettes
- XP D90-300-2: Requirements and test methods for e-liquids
- XP D90-300-3: Requirements and test methods concerning emissions

## **4. The appropriate regulatory framework for e-cigarettes and personal vaporisers in Australia**

Most public health experts and governments agree that e-cigarettes need to be regulated, but less strictly than tobacco products. The ultimate goal of responsible regulation is to maximise the benefit for adult smokers while reducing any potential risks to users and harm to the wider population. Regulation should be proportional to risk, based on the risk continuum of nicotine-containing products.

There would be cause for public health concern if e-cigarettes promote uptake of smoking, delay or deter smoking cessation or encourage relapse among former smokers. On the other hand, if current cigarette

smokers who are otherwise unwilling or unable to quit tobacco use switch completely from cigarette smoking to e-cigarette use, a public health benefit may result. (37)

**Regulations should ensure that less harmful alternatives such as e-cigarettes remain attractive and affordable. Regulation should not impede product improvement and innovation**

## **Legalisation of nicotine**

The first essential step is to exempt low-concentrations of nicotine from Schedule 7 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) so that it may be available for use with an e-cigarette for tobacco harm reduction. (98) It is unethical and irrational to ban a less harmful form of nicotine intake (e-cigarettes), while allowing the sales of the most lethal form of nicotine intake (tobacco cigarettes). Nicotine in 'tobacco prepared and packed for smoking' is specifically exempted from the SUSMP.

A proposal for this change was submitted to the TGA [[link](#)], but was rejected [[link](#)]. The reasoning for decision has been criticised [here](#) and [here](#).

## **Classification as consumer products**

E-cigarettes are classified as general consumer products, tobacco products or medicinal products. Classification as consumer products is most appropriate. (99, 100)

### **1. Consumer product**

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

As consumer products, e-cigarettes are regulated by

- The Commonwealth Competition and Consumer Act 2010 (CCA). Under this law, suppliers of consumer goods are responsible for ensuring their products are safe, fit for purpose and comply with all legal requirements. This could include product standards (safety, performance, ingredients, quality), packaging, marketing etc.
- States and territories. Responsible for regulating the sale and supply of nicotine, the sale of e-cigarettes, minimum age of sale, sale in vending machines, use in smoke-free areas, advertising and display. In most cases, this is currently regulated under existing tobacco control laws.
- Additional regulatory requirements may be needed such as post-market monitoring and surveillance and product recall procedures.

### **2. Tobacco product**

It is inappropriate for e-cigarettes to be classified as tobacco products. E-cigarettes do not contain tobacco and do not combust and carry only a minor degree of the risk to health of tobacco products. A tobacco classification would subject them to restrictions that are excessive for the level of risk involved. Tobacco control legislation aims to reduce product use whereas the evidence supports encouraging increased e-cigarette use to reduce tobacco-related harm.

E-cigarettes contain pharmaceutical grade (usually) nicotine which is usually derived from tobacco. The presence of nicotine does not make them tobacco products, just like nicotine replacement therapies are not tobacco products.

Classification as tobacco products would carry a misleading message to smokers that e-cigarettes are equally harmful as tobacco cigarettes.

### **3. Medicinal product**

E-cigarettes are not used as medicines, but as safer alternatives to tobacco products. Classification as medicinal/therapeutic goods would require onerous and costly applications to the TGA and compliance for each product. This would create substantial barriers to entry. It is likely that only the Tobacco Industry and pharmaceutical companies could comply with these requirements and the majority of the small and medium private business that sell most e-cigarettes would close.

Part of the appeal of e-cigarettes is that they are consumer driven and non-medicalised. The therapeutic pathway would reduce the range of products available, medicalise vaping, require doctor visits, prescriptions, pharmacy charges and increased costs to government. The cost of e-cigarettes would also increase making them a less attractive option for smokers.

Medicinal approval requirements would hinder further development of e-cigarettes, because small improvements would require new licensing applications, dramatically extend the innovation timescale, and make the cost of innovation prohibitive. (100)

As a result, internationally, no products have been licensed as therapeutic products and come to market so far. **Requiring all products to be classified as medicines would have the same result as prohibition.**

Some countries have a dual approach for regulation, for example New Zealand is proposing a consumer regulation with a medicinal pathway for products that wish to make a therapeutic claim. [[link](#)]

### **Regulatory guidelines**

The aim of regulations should be to maximise the substantial benefits to adult smokers who are unable to quit while minimising the small, potential risks to users and the wider community. Regulation should be guided by the best available evidence to minimise potential unintended consequences of ill-informed regulation.

#### **1. Sales**

Restricting sale and supply of nicotine containing e-cigarettes to people under 18 years, the minimum age of legal cigarette purchase, is the most politically acceptable rule. Similarly, vending machines would be restricted to adult environments.

However, two studies from the US found that states that introduced bans of e-cigarette sales to adolescents subsequently had significantly increased adolescent smoking rates. Based on the available evidence it is possible that bans of sales to youth may be counterproductive.(58, 59)

As e-cigarettes are also used by young smokers to quit, an alternative option is to allow youth to purchase e-cigarettes with the explicit permission of a parent, guardian or doctor. (101)

#### **2. Promotion and advertising**

Responsible advertising and promotion are recommended to encourage use by adult smokers. Banning the advertising of low-risk products is disproportionate and is similar to banning anti-smoking advertising.

It is possible to provide protection to young people by restricting the timing, placement and subject matter of advertising – an approach often used to restrict alcohol advertising. While some exposure to young people is unavoidable, the evidence so far shows that e-cigarettes are likely to be reducing youth smoking rates, not increasing them (see above) and there is no significant evidence of harm.

Some restrictions are appropriate to protect youth and non-smokers. For example, UK Code of Non-Broadcast Advertising [[link](#)] outlines a range of sensible rules such as:

- Communications should be socially responsible and not associated with a tobacco brand
- Must not make a health or medicinal claim unless authorised

- Must do nothing to undermine the message that quitting tobacco use is the best option for health
- must state clearly if the product contains nicotine
- Must not encourage non-smokers or non-nicotine-users to use e-cigarettes.
- must not be likely to appeal particularly to people under 18
- People shown using e-cigarettes or playing a significant role must neither be, nor seem to be, under 25.
- communications must not be directed at people under 18 through the selection of media or the context in which they appear.

Promotion and advertising is regulated by the states and territories. Advertisements need to be substantiated, fair, balanced and not misleading.

### ***3. Product quality and standards and safety***

Mandatory product manufacturing standards for e-cigarettes and e-liquids are required. Internationally, a range of standards have been/are being developed:

- The European Union CEN/Technical Committee 437 [[link](#)] and the International Organization for Standardization (ISO) [[link](#)] are together developing standards for thermal, electrical and chemical safety and e-liquids standards, as well as analytical methods for aerosol emissions. Completion is expected in 2019.
- The British Standards Institute has developed a voluntary standard for the manufacture, importation, testing and labelling of vaping products [[link](#)]
- AFNOR, the French national standards body has developed standards [[link](#)]
- American E-liquid Manufacturing Standards Association (AEMSA) have completed standards [[link](#)]
- International electrical safety standards are available, such as: IEC 60335-1 (safety of household appliances); IIEC 60335-2-29 (safety of battery chargers); IEC 62133 (safety of portable batteries); IEC 61558 (safety of AC adaptors); IEC 61000 series; and EN 55022 & EN 55024 (for USB chargers & cables)
- ISO standard for child-resistant packaging: ISO 8317:2015 [[link](#)]

Some considerations include:

- Manufacturing standards for devices and components
- E-liquid standards, such as pharmaceutical grade ingredients; accuracy of contents listed; exclusion of chemicals of concern; purity standards for contaminants
- Emissions standards: analysis of chemicals in vapour
- Refill bottle design: child resistant containers – this may adopt ISO8317 for example; leak-proof
- Labelling: safety warnings; discouragement of use by non-smokers; use-by date; first-aid advice; list of ingredients
- Packaging standards. Standardised packaging is not appropriate for a health promotion product
- Electrical safety. Lithium ion batteries in e-cigarettes rarely overheat and malfunction, as they do in other portable electrical devices, such as mobile phones and laptops. Electrical safety standards and consumer education are required to minimise this risk.

### ***4. Point-of-sale display and taste testing***

#### ***Vape shops***

Vape shops should be able to display products and discuss them with customers. Vape shops provide valuable advice and support for smokers wanting to switch and can help smokers achieve high success rates. (102-104) Staff members (who often vape) help users select the right device from a wide range of choices, teach them to use, clean and maintain them, advise on e-liquid selection and safety issues.

Customers should be able to sample flavours in vape stores as this is an important factor in user satisfaction. (105, 106) Two studies of vape stores have found no evidence of significant exposure to hazardous chemicals among bystanders in this setting. [[link](#)]

### **Tobacconists**

Display of vaping products and information about vaping should be allowed where cigarettes are sold to raise awareness of the safer alternative for tobacco smokers and to encourage switching.

## **5. Vaping in confined smokefree areas**

Allow businesses and local authorities to make their own decisions about whether to allow vaping in their premises. Unlike secondhand tobacco smoke, there is ‘no direct evidence that such passive exposure is likely to cause significant harm.’ (10)

Public Health England (107) and Action on Smoking and Health UK (108) have both produced evidence-based guides to help public places and workplaces make local policy. This approach is also supported in New Zealand. [[link](#)]

The benefits of allowing e-cigarette use in some workplaces and public places outweigh concerns that this might normalise smoking behaviour. (109)

- There is no evidence that e-cigarettes are renormalising tobacco smoking (10)
- Banning e-cigarettes sends the misleading message that they are just as harmful as smoking and could deter switching from smoking to vaping
- Bans may drive vapers out with smokers and encourage them to start smoking
- Indoor vaping bans remove one advantage of vaping relative to smoking and so may discourage switching and encourage relapse

Questions of ‘etiquette’ are relevant as bystanders may find e-cigarette aerosol unpleasant. Some businesses, may choose to limit the use of e-cigarettes not for health and safety reasons but because of concerns that customers or employees will be annoyed by their use. (108) Hospitals, schools and airplanes would be environments suited to a vaping ban.

There is no justification for **outdoor** vaping bans.

## **6. Non-tobacco flavours**

Flavours should be permitted, with the exception of certain flavours associated with potential risk, such as diacetyl and acetyl propionyl (110), benzaldehyde (111) and cinnamaldehyde (112).

Flavours are an important part of the appeal of vaping for adult smokers and make the products attractive as an alternative to smoking, just as flavours are also used to enhance the appeal of nicotine gum. (105, 106) Banning flavours would likely undermine the use of e-cigarettes and the public health benefits.

Potential issues with e-cigarette flavours are that:

- They attract young people to vaping. There is some evidence of appeal of flavours to youth (113) but other evidence suggests that flavours do not attract interest in non-smoking teens who had not used e-cigarettes. (106) Any small, potential risks to teens needs to be balanced against the large benefits to adult smokers who switch to vaping. However, if vaping displaces smoking among young people (as described above) then attractors to vaping may play a positive role in this group.
- There may be long-term health effects from inhalation of flavourings. More research is needed on individual flavours but as regular users are almost exclusively smokers, the relative risk is extremely low compared to inhaling tobacco smoke.

## 7. **Taxation**

High excise taxes on combustible tobacco are justified by the clear evidence that they reduce tobacco use and improve public health. (114) However, there is no such harm from e-cigarettes and e-liquid, which improve health through smoking cessation.

As with nicotine replacement therapies, taxes should be kept to a minimum, to encourage switching from tobacco to the much less harmful alternative. Given the potential public health benefits of e-cigarettes and the economic value of quitting, zero taxation would be appropriate. (115)

E-cigarette sales are responsive to price. E-cigarettes have quite high price elasticities and a positive cross-elasticity with conventional cigarettes. In one study, every 10% increase in e-cigarette prices was associated with a drop in e-cigarette sales of 8%. (116) It follows that high taxes on e-cigarettes will perpetuate smoking. This unfortunate experience has been found in Italy where substantial e-cigarette tax rises dramatically reduced vaping rates. (115)

The taxation of combustible tobacco and e-cigarettes should be proportional to risk. A greater differential would maximize incentive for tobacco users to switch to the much less harmful product and help prevent relapse. (117)

## 8. **Monitoring**

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.

# 5. Other related matters

## **Evidence-based policy**

Policy decisions should be based on evidence, not ideology. The evidence for tobacco harm reduction is substantial and is supported by many international health organisations and national bodies. However, it is opposed by all Australian health departments, Australia's peak medical bodies, public health organisations and medical associations. Much of this resistance is based on an ideology and values such as:

- Entrenched beliefs. The ideological framework of tobacco control for the last 50 years has been the complete elimination of addiction and nicotine. This framework does not include harm reduction.
- Big Tobacco: The tobacco industry has behaved appalling and deceptively in the past. Some believe that 'anything they are involved with must be bad'.
- Core values and beliefs. Some people believe smoking is sinful or abhorrent and harm reduction implies acceptance of what should just be eliminated.
- Nicotine: A belief that it must be harmful because of its association with tobacco and its role in addiction, and should be entirely eliminated.

Some anti-vaping advocates justify their (unconscious) views by citing concerns about vaping being a gateway for youth smoking, the risk of renormalising smoking and undermining tobacco control. However, **these arguments are not supported by the extensive evidence, as cited above**. We need to look objectively and dispassionately at the evidence as the basis for making policy decisions.

## **Financial and social justice considerations**

E-cigarettes could be of special benefit to disadvantaged smokers. They are 95% less harmful than smoking and will help reduce health disparities. They are also about 85% cheaper than smoking and could substantially reduce financial stress and improve quality of life. [[link](#)]

Half of all smokers in Australia are the most socio-economically disadvantaged members of society. (1) Smokers in lower income groups smoke more heavily, belong to networks where smoking is normalised and have greater difficulty quitting and poorer health. (7) Rising tobacco prices have created substantial financial stress and hardship for continuing smokers (118, 119) and leads to compromises in diet, clothing, warmth and other basics. (120) E-cigarettes have the potential to reduce health inequalities.

E-cigarettes also have the potential to generate substantial savings for the Commonwealth, for example:

- No cost to the taxpayer for the products. Consumers purchase and pay for their own supplies
- No costs to Medicare for doctor visits for smoking cessation
- No cost to the PBS for smoking-cessation medications
- Substantial downstream savings in health care from less smoking-related disease in smokers switching to vaping
- Sales generate GST and excise. Currently most users purchase products on the black market or illegally online and potential revenue is lost overseas or in the black economy.
- Employment in the vaping industry and stimulation of the Australian economy
- Improved work productivity and longer working careers

## The Tobacco Industry

The involvement of the tobacco industry is often raised as a reason to block e-cigarettes. However, Big Tobacco has been forced to compete in this market to avoid becoming redundant from this new technology, like Kodak. However, not one e-cigarette sold in Australia is made by a tobacco company.

Philip Morris International and BAT have spent \$3 billion and \$1 billion US respectively on research and development of reduced risk products and have published their research in peer-reviewed journals. Japan Tobacco and Imperial Brands are also investing heavily in reduced risk products.

The stated aims of PMI [[link](#)] and BAT are to ultimately replace combustible products. There is no evidence for the conspiracy theory that the tobacco industry wants people to smoke and vape as claimed by some commentators.

The past behaviour of Big Tobacco has been appalling and their behaviour needs to be closely monitored. However, the priority now is not to destroy the tobacco industry, but rather to save lives and improve public health. **The tobacco industry may be part of the solution if it is encouraged to move out of selling tobacco cigarettes and into less harmful alternatives.** Big Tobacco has the cash flow, research and development resources and marketing network to drive the tobacco harm reduction agenda.

## Why not wait?

Supporters of bans may suggest that bans remain until further long-term studies have been conducted on public health outcomes. Hall et al. provides this response (121)

- First, it will take a decade or more before we know the outcome of this policy. During this time smokers will be denied access to a safer form of nicotine.
- Secondly, we doubt that any epidemiological evidence would be strong enough to change the minds of those who support a ban.
- Thirdly, a ban has not prevented e-cigarette use by smokers in Australia and other countries; it has abdicated responsibility for regulation of e-cigarettes to the black market.

Furthermore, delays will result in continuing preventable death and illness. Quitting smoking is urgent. Every year a smoker continues to smoke after the age of 35 years, 3 months of life expectancy is lost. (6) Delaying an effective public health policy will cost Australian lives.

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