

Proposed Amendments to the Poisons Standard

Comment on a proposal to amend the Poisons Standard Schedule 7 entry for nicotine

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Proposed Amendments to the Poisons Standard

Comment on a proposal to amend the Poisons Standard Schedule 7 entry for nicotine

Summary

The signatories above submit this comment in support of the application to amend Schedule 7 of the Poisons Standard to exempt nicotine in preparations with concentrations under 3.6 percent, the levels typically used in electronic nicotine delivery systems (ENDS). The comment is organised under the six headings covering matters the Minister should take into account when considering an application to amend Schedule 7.

(a) the risks and benefits of the use of a substance

The exemption would beneficially mitigate two important risks. Firstly, it would allow many more of Australia's 2.8 million smokers to legitimately switch from cigarettes to ENDS use ('vaping') and so substantially reduce their health risks. The Royal College of Physicians (London) recently stated that the risk of vaping is unlikely exceed 5 percent of the risk of smoking and may be substantially lower than that. However, the Poisons Standard creates a *de facto* prohibition on smokers adopting this option in Australia. Secondly, it would mean that Australians could purchase regulated nicotine liquids for vaping legitimately from Australian business and so avoid risks associated with a grey or black market supply chain and risks associated with handling and mixing of higher strength liquids.

(b) the purposes for which a substance is to be used and the extent of use of a substance

Nicotine liquids are used for the purpose of "tobacco harm reduction" – an approach that is proving popular and successful with smokers in the Europe and the United States without any major adverse consequences. Use of these products is making substantial inroads into the cigarette market and adult and adolescent smoking trends are consistent with ENDS use displacing smoking.

(c) the toxicity of a substance

The toxicity of nicotine liquids at the low concentrations proposed presents no significant risks beyond those already widely present in the home, for example from medicines or cleaning products, and these can be mitigated through straightforward packaging and labelling obligations.

(d) the dosage, formulation, labelling, packaging and presentation of a substance

An amendment to the schedule should include some supporting safeguards and standards that would be based on consumer protection concepts, such as clear labelling, accurate description of contents and secure packaging. Australia has the opportunity to assume leadership in regulation of nicotine products to optimise their potential for public health.

(e) the potential for abuse of a substance

Nicotine use through cigarette smoking can cause dependence. Nicotine liquids would be primarily used to reduce harm to smokers who cannot easily quit nicotine use or choose not to. If the harms associated with ENDS use are much lower, then the negative consequences of any residual nicotine dependence are greatly reduced.

(f) any other matters that the Secretary considers necessary to protect public health

There is a strong public health, ethical and pragmatic case to amend the schedule and to allow Australians access to much less risky ways to consume nicotine than smoking. The case for a *de facto* prohibition and denying Australians this option is very weak.

Proposed Amendments to the Poisons Standard

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Introduction

This is a comment on the proposal to amend Schedule 7 of the Poisons Standard¹ to exempt nicotine in preparations for use as a substitute for tobacco in concentrations up to 3.6 percent - the concentrations commonly used in personal vaporisers or e-cigarettes.

We strongly support an amendment to exempt nicotine in low-concentrations for use in Electronic Nicotine Delivery Systems (ENDS) from Schedule 7 of the Poisons Standard.

Under Section 52E of the Therapeutic Goods Act, in exercising the power to amend Schedule 7, the Secretary (minister for health) must take the following matters into account (where relevant)²:

- (g) the risks and benefits of the use of a substance;*
- (h) the purposes for which a substance is to be used and the extent of use of a substance;*
- (i) the toxicity of a substance;*
- (j) the dosage, formulation, labelling, packaging and presentation of a substance;*
- (k) the potential for abuse of a substance;*
- (l) any other matters that the Secretary considers necessary to protect public health.*

This comment follows the structure of this section of The Act.

(a) The risks and benefits of the use of nicotine

a.1 Benefit of clean nicotine availability: mitigation of smoking-related risks

In 2014-15, 16 percent of Australian adults aged 18 years and over, 2.84 million people, were current smokers³. These are people using the mildly psychoactive drug nicotine via its most harmful and its least regulated and controllable delivery system – that is by inhaling tobacco smoke, mainly from cigarettes. The harms associated with nicotine use are overwhelmingly caused by its delivery to the lungs via toxic particles and gases that contain products of combustion of tobacco leaf, not the nicotine itself. The harms are significant and well documented⁴ – smoking is a major cause of cancer, cardiovascular disease and respiratory illness, as well as degraded welfare and wellbeing. Each year, smoking kills an estimated 15,000 Australians and costs Australia \$31.5 billion in social (including health) and economic costs⁵.

In addition to the harms caused directly by smoking, there are additional harms to continuing smokers arising from the *policy response* that aims reduce smoking – for example through high and regressive tobacco taxation or the stigma or alienation that many smokers feel through the public

¹ Government of Australia, Therapeutic Goods Administration, The Poisons Standard July 2016. Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) [\[link\]](#) made under 52D(2)(b) of the *Therapeutic Goods Act 1989* [\[link\]](#)

² Therapeutic Goods Act, 1989 section 52E [\[link\]](#)

³ Australian Bureau of Statistics, National Health Survey: First Results, 2014–15 — Australia. Table 9. [\[link\]](#)

⁴ Surgeon General of the United States. The Health Consequences of Smoking—50 Years of Progress. Centers for Disease Control and Prevention (US) 2014. [\[link\]](#)

⁵ Australian Government, Department of Health, Tobacco Control key facts and figures, accessed 16 August 2016 [\[link\]](#)

health strategy of 'denormalising' smoking. While these policy impacts may be considered a price worth paying to reduce smoking, they are nevertheless a significant detriment to those who continue to smoke.

While nicotine is not entirely benign, it accounts for a very small fraction of the direct harm caused by smoking. Studies of the health effects of prolonged NRT use and smokeless tobacco have allowed the nicotine health effect to be isolated from the overall smoking health effect. The Royal College of Physicians (2016) describe the effects of nicotine alone as follows⁶:

As use of nicotine alone in the doses used by smokers represents little if any hazard to the user, complete substitution of smoking with conventional NRT products is, for practical purposes, the equivalent of complete cessation in almost all areas of harm to the user. [Section 8.4.1 p125]

Nicotine is the main reason why people smoke, but not the direct cause of harm. To summarise⁷:

People smoke for the nicotine but die from the tar

In its extensive April 2016 report⁸, the Royal College of Physicians (London) characterised the relative risk of smoking and e-cigarette use as follows:

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.

At present, Australia's legal recreational nicotine market is dominated by cigarettes. There is no justification for purposefully denying smokers access to products that are a much safer way of using nicotine than smoking. The proposed amendment allows for significant individual and population *risk reduction* that is currently blocked by the Poisons Standard.

a.2 Benefit of clean nicotine availability: mitigation of supply chain risks

Australia's *de facto* prohibition of nicotine liquids for harm reduction does not mean there is no use for this purpose in Australia. In fact, there is a thriving, though unquantified, consumer base of people who are using these products to mitigate their smoking-related risks and to take control of their health outcomes. In doing so, they are forced to circumvent the restrictions of the Therapeutic Goods Act and to purchase internationally from many legitimate websites that cater for this trade or through an unregulated black market.

The economics of the international trade incentivises users to purchase nicotine at higher concentrations (as high as 99 percent), and higher than they would generally use (typically up to 3.6 percent) and then handle, mix and dilute the high strength liquids down to their preferred mix with obvious handling risks. Purchases can be made from many high quality web sites, with prices in multiple currencies, secure payments systems, reputable couriers and paperwork and certification, yet with uncertain quality, ingredients and safety⁹. The example below is a marketing email from a Chinese supplier provided for illustrative purposes.

⁶ Royal College of Physicians (London) Nicotine without smoke: tobacco harm reduction 28 April 2016 [\[link\]](#)

⁷ Russell MJ. Low-tar medium nicotine cigarettes: a new approach to safer smoking. *BMJ* 1976;1:1430-3. [\[link\]](#)

⁸ Royal College of Physicians (London) Nicotine without smoke: tobacco harm reduction 28 April 2016 [\[link\]](#) Section 5.5.

⁹ See test purchase experience: Bates C. Regulators and the compliance fallacy - buying 99% nicotine e-liquid from China, *The Counterfactual* [\[link\]](#)

Example of unsolicited promotional email for Chinese-supplied e-liquids

We are specializing in 99.95% pure nicotine, PG VG based nicotine liquid from 36mg/ml-600mg/ml and about 500 kinds flavors in China.

About Product details:

Pure nicotine is 99.95% USP grad, 1000mg/ml.

Price is : USD \$196/1.15L

500ml is \$100 (20ml sample for free test)

Flavor is USP grade, pure concentrate liquid.

Flavor Price: Tobacco series & Mint series USD \$75 per liter, 500ml is \$38

Fruit series & Herb & Flowers USD \$62 per liter, 500ml is \$31

Flavor sample: 125ml sample is \$10 per one.

Certificate: COA and MSDS.

Packing: Fluorinated bottle and aluminum foil bag.

Delivery: We always send by FedEx, DHL, TNT, UPS.

The offer of 500ml of 99.95% e-liquid for US\$100 makes this purchasing option *extremely* cost effective. Assuming 99.95% is equivalent to pure nicotine in the calculation below:

- ~100% nicotine liquid = 1000mg/ml
- Half litre = 500ml = 500,000mg nicotine
- Typical daily vaper nicotine consumption = 36mg nicotine¹⁰
- 500,000 mg = 13,889 day supply = 38 years supply or one-year supply for 38 people
- Cost = \$2.60 per person-year

We believe that a regulated domestic market for these liquids would be a preferable way to meet the rational and legitimate expectations of Australians to be able to use products that can dramatically reduce their risks. These products are widely available in Europe and the United States with no material harms arising. The proposed amendment would extend a safe supply to Australians: nicotine liquids could be prepared by local manufacturers and made available locally.

(b) The purposes for which nicotine is to be used and extent of use of nicotine

The primary purpose of the amendment would be to allow Australian smokers to use nicotine through technologies that cause much lower risk to health than through smoking, for example through use of e-cigarettes or personal vaporisers – so called Electronic Delivery Systems (ENDS). These technologies rely on electricity to heat a liquid to create an inhalable aerosol rather than combustion of tobacco to create smoke. These technologies have grown rapidly over the last five years primarily because advances in battery technology have allowed for small devices with sufficient power and battery life to make viable consumer alternatives to cigarettes. Experience from other countries suggests that the products in their current state of advancement can reach many smokers – and given continuing innovation will reach many more in future if the regulation and risk communications are fair and proportionate.

¹⁰ Farsalinos KE, Romagna G, Tsiapras D, *et al.* Characteristics, Perceived Side Effects and Benefits of Electronic Cigarette Use: A Worldwide Survey of More than 19,000 Consumers. *Int J Environ Res Public Health* 2014;**11**:4356–73. Table 2 [\[link\]](#)

b.1 United Kingdom experience

We do not have recent detailed data for e-cigarette use in Australia. In 2013, an international survey found that among Australian smokers 9 percent were current users and 24 percent had tried e-cigarettes¹¹. In the United Kingdom where ENDS are widely available, the use of these alternatives is now at a material scale relative to smoking. The Office of National Statistics reported data for 2015¹²

Smoking and e-cigarette users 2015	British adults
Current smokers	8,843,000
Current e-cigarette users	2,201,000
Of the current e-cigarette users:	
Current smokers	1,297,000
Ex-smokers	849,000
Never smokers	56,000
Ex-smokers and ex-e-cigarette users	717,000

Figures rounded to nearest 1,000

The use of ENDS by never-smokers in the UK is very low (0.2 percent of never smokers use e-cigarettes) and even among this group, 39% said they had used e-cigarettes to help them quit smoking. This means the appropriate comparator is with the risks to nicotine users who are smoking. Many of those who are both smoking and using e-cigarettes may be on a path to eventual exclusive use and some evidence suggests that these ‘dual users’ are more likely to go on to quit¹³. The 849,000 current ENDS users and 717,000 former ENDS users who have stopped smoking represent a substantial inroad into the smoking population, though it is not possible to attribute their smoking cessation directly to ENDS use. However, the trend in smoking prevalence is also encouraging. The 8.8m current smokers represents current *record low* adult smoking prevalence of 17.5 percent¹⁴. After stalling in the late-2000s smoking prevalence has been falling rapidly as e-cigarette use has increased from negligible levels in 2011. Throughout this period of widespread ENDS use there have been no major health problems or any other problems – though many ENDS users are now no longer smoking and will be gaining significant benefit from smoking cessation.

b.2 United States experience

Similar patterns are seen in the United States. The National Health Interview Survey¹⁵ shows that U.S. adult smoking prevalence (18 years and over) has fallen from 18.9 percent in 2011 to a record low of 15.1 percent in 2015 – below that of Australia – with an especially sharp decline between 2014 and 2015 – see figure below. As with Britain, the impact of ENDS on the cigarette trade is substantial: in 2015, there were approximately 37.5m smokers, but there were 8.3m e-cigarette users of whom 2.5m were ex-smokers¹⁶.

¹¹ Gravely S, Fong G, Cummings K, *et al.* Awareness, Trial, and Current Use of Electronic Cigarettes in 10 Countries: Findings from the ITC Project. *Int J Environ Res Public Health* 2014;**11**:11691–704. [\[link\]](#)

¹² Office of National Statistics (UK), E-cigarette use in Great Britain, 2015 Dataset. 18 February 2016 [\[link\]](#) Table 2a.

¹³ Manzoli L, Flacco ME, Ferrante M, Vecchia CL, Siliquini R, Ricciardi W, *et al.* *Cohort study of electronic cigarette use: effectiveness and safety at 24 months.* *Tobacco Control.* 2016 [\[link\]](#)

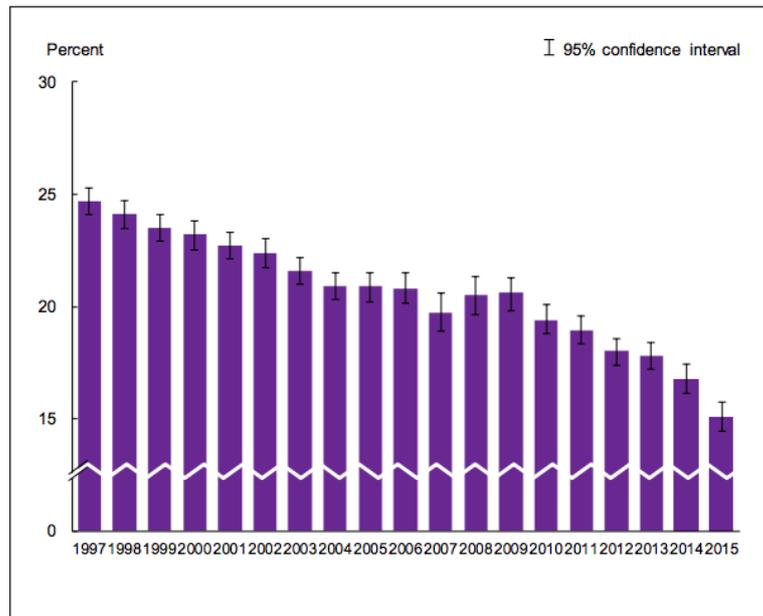
¹⁴ Office of National Statistics (UK), Adult Smoking Habits in Great Britain 1974-2014. 18 February 2016 [\[link\]](#) Table 1.

¹⁵ National Center for Health Statistics, *National Health Interview Survey, 1997–2015*, Sample Adult Core component. Figure 8.1. Prevalence of current cigarette smoking among adults aged 18 and over: United States, 1997–2015. [\[link\]](#)

¹⁶ CDC, *National Health Interview Survey, 2015 Data Release* [\[link\]](#); Cited in Rodu B. *How Many Americans Vape? CDC Data Show Fewer Vapers & Smokers in 2015*, *Tobacco Truth* 17 July 2016 [\[link\]](#)

Current smoking

Figure 8.1. Prevalence of current cigarette smoking among adults aged 18 and over: United States, 1997–2015



Source: National Center for Health Statistics, *National Health Interview Survey, 1997–2015*

b.3 Adolescent ENDS use

There have been concerns expressed that adolescent uptake of ENDS may be ‘addicting future generations’. However, the data suggest a different pattern. Most use is by teenage smokers and data is consistent with ENDS use displacing smoking.

In the UK, use of ENDS among adolescents is low and confined mainly to young smokers. A March 2015 survey found 2.4 percent of 11-18 year olds had used e-cigarettes in the last month, and these were mainly smokers¹⁷.

In the United States, almost all adolescent users of ENDS are former or current smokers, and therefore ENDS represents a *change* in the way nicotine is used for most. Analysis of CDC 2014 data shows that 90 percent of the 1.96m current e-cigarette high school users are current or former users of other tobacco products¹⁸. Some of the remaining 10 percent may have become smokers in the absence of e-cigarettes. There is no evidence supporting a gateway from ENDS to smoking¹⁹.

In fact, smoking among American adolescents has been falling rapidly. The National Youth Tobacco Survey (CDC)²⁰ shows that between 2011 and 2015, current use of cigarettes by high school students fell from 15.8 percent to 9.3 percent, and use of cigars and pipes also fell. The data are consistent with a decline in smoking partly due to displacement by much lower risk ENDS (an ‘exit gateway’), though it is not possible to attribute causation from this type of survey.

¹⁷ YouGov for Action on Smoking and Health (UK) Smokefree GB Youth Survey. Published in ASH Fact sheet [\[link\]](#)

¹⁸ Rodu, B. Analysis of CDC National Youth Tobacco Survey 2014, The CDC Buries the Lead: Teen E-cigarette Use Rises as More Dangerous Cigarette Use Plummet, 13 October 2015 [\[link\]](#)

¹⁹ McNeill A, Brose LS, Calder R, *et al.* E-cigarettes: An Evidence Update. A Report Commissioned by Public Health England. London: 2015. [\[link\]](#) Section 4 *Gateway* page 37

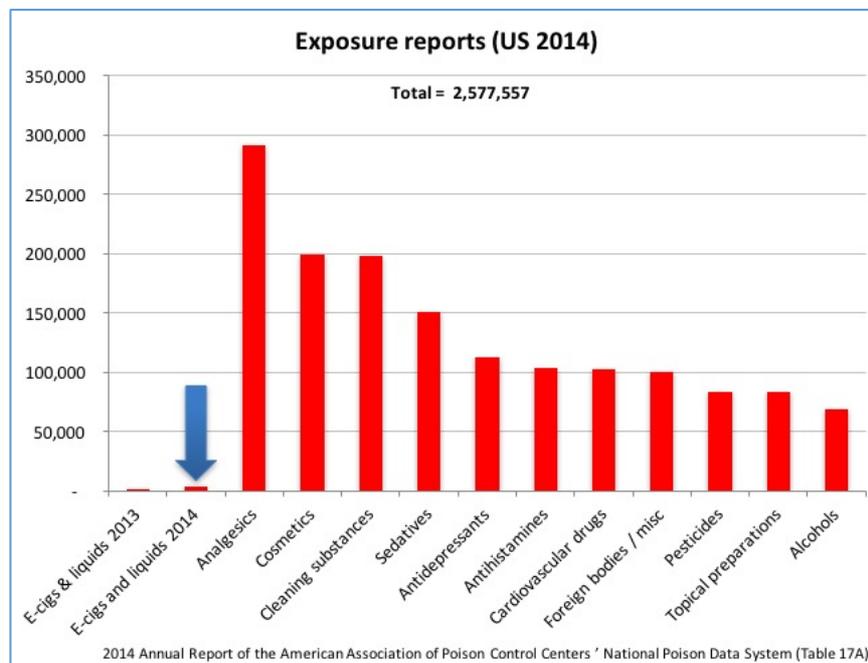
²⁰ Singh T, Arrazola RA, Corey CG, *et al.* *Tobacco Use Among Middle and High School Students — United States, 2011–2015.* MMWR Morb Mortal Wkly Rep 2016;65:361–367. [\[link\]](#)

(c) The toxicity of nicotine

Public Health England’s expert review addressed the toxicity risks of nicotine liquids used for personal vaporisers²¹. The review noted that:

- fatal nicotine poisoning is extremely rare
- conventional estimates of LD₅₀ for humans (30-60mg ingestion) are grounded in ‘dubious’ 19th Century experiments and the likely lethal dose is much higher²²
- that individuals attempting suicide with nicotine have survived very high doses
- nicotine inhalation is self-regulating as users become nauseous
- that nicotine is an emetic and swallowing a significant dose ends in vomiting.

American activists have publicised rapidly rising calls to poison centers as though it a proxy for poisoning risks²³. However, these calls are from a low base, rise in line with growth in the product from 2011 and refer to ‘exposures’ (any contact) rather than poisoning or harm. E-liquid or e-cigarette related calls to poison centers rose from 271 in 2011 to 3,783 in 2014, though have been declining since²⁴. However, these figures are small compared to other normal household risks²⁵.



Data source: American Association of Poison Control Centers 2014 Annual Report

The approach to poisoning risks with nicotine liquids should be as with other moderate household hazards: child-resistant containers, labelling, and advice on what to do in the event of contact. This can be specified through ordinary consumer regulation, and is done for a large number of consumer products.

²¹ McNeill A, Brose LS, Calder R, *et al.* E-cigarettes: An Evidence Update. A Report Commissioned by Public Health England. London: 2015. [\[link\]](#) Section 9 page 63-67

²² Mayer B. How much nicotine kills a human? Tracing back the generally accepted lethal dose to dubious self-experiments in the nineteenth century. *Arch Toxicol* 2014;**88**:5–7. doi:10.1007/s00204-013-1127-0 [\[link\]](#)

²³ Campaign for Tobacco Free Kids, Poisoning Cases Related to E-Cigarettes Keep Spiraling Upward, September 2014 [\[link\]](#)

²⁴ American Association of Poison Control Centers, E-Cigarettes and Liquid Nicotine, viewed 21 August 2106 [\[link\]](#)

²⁵ Mowry JB, Spyker DA, Brooks DE, *et al.* 2014 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 32nd Annual Report. *Clin Toxicol* 2015;**53**:962–1147.(Table 17A) [\[link\]](#)

(d) The dosage, formulation, labelling, packaging and presentation of nicotine

We support the proposal to exempt nicotine preparations up to 3.6 percent nicotine from schedule 7 of the Poisons Standard for use in ENDS for harm reduction. Given that nicotine “*in tobacco prepared and packed for smoking*” is exempted from Schedule 7, it is discriminatory and ‘anti-proportionate’ to continue to include the much lower-risk commercial alternative.

d.1 Standards to build into the Schedule 7 exemption

Exempting these nicotine liquids from Schedule 7 would approximately recreate the regulatory regime that has worked well in Europe and the United States prior to introduction of the European Union Tobacco Products Directive on 20 May 2016 and FDA Deeming Regulation on 8 August 2016 respectively. Though specifying the exemption provides the TGA with opportunities to specify some conditions regarding the packaging:

- Intended for recreational use in electronic cigarettes, personal vaporizers or other nicotine delivery systems that do not include tobacco prepared and packed for smoking.
- Where no therapeutic claim is made by the manufacturer
- That do not exceed 3.6 percent nicotine concentration (by mass)
- In a child resistant container specified to ISO standard 8317²⁶
- Accurately labelled with nicotine content usually specified as mg/ml
- List of ingredients
- Appropriate warnings regarding children

The threshold of 3.6 percent is sensible and cautious. Though the large majority (>90 percent) of consumers are likely to use liquids under 2.0 percent²⁷, the stronger liquids are important for the more highly dependent nicotine users (and hence more at-risk smokers); for novice users while they learn to use the products; and to support future innovations.

d.2 Towards a world-leading regulatory regime for ENDS

An amendment as proposed also gives Australia an opportunity to define a world-leading proportionate public-health orientated regulatory framework for ENDS. The regime defined in the United States is built on legislation designed for tobacco products before ENDS existed. The European Union Tobacco Products Directive is based on pre-2012 understanding of the risks and potential benefits. Neither provides a model for Australia, or anywhere.

Such an approach would be based on industry-wide standards for ENDS and e-liquids – and could be variations on those developed by British Standards Institute (BSI)²⁸ and in France under the equivalent body, AFNOR²⁹, or a forthcoming European CEN standard.

²⁶ ISO 8317 Child resistant packaging [\[link\]](#)[\[guide\]](#)

²⁷ Action on Smoking and Health, Fact sheet: ASH Fact Sheet on the use of electronic cigarettes among adults in Great Britain [\[link\]](#)

²⁸ BSI PAS 54115:2015 Vaping products, including electronic cigarettes, e-liquids, e-shisha and directly-related products - Manufacture, importation, testing and labelling - Guide [\[link\]](#) July 2015

²⁹ AFNOR (France) Electronic cigarettes and e-liquids Part 1: Requirements and test methods for e-cigarettes XP D90-300-1 March 2015 [\[link\]](#) and Part 2: Requirements and test methods for e-cigarette liquid XP D90-300-2 [\[link\]](#) March 2015

(e) The potential for abuse of nicotine

e.1 Psychoactive properties of nicotine

Nicotine is a mildly psychoactive drug with few side effects or direct harms, and, unlike alcohol, it does not cause intoxication and resulting accidents, violence and vulnerability. According to Benowitz³⁰.

Nicotine induces pleasure and reduces stress and anxiety. Smokers use it to modulate levels of arousal and to control mood. Smoking improves concentration, reaction time, and performance of certain tasks. Relief from withdrawal symptoms is probably the primary reason for this enhanced performance and heightened mood

It may be that these benefits are in fact manifestations of relief from withdrawal or craving – i.e. there are no additional benefits compared to being a non-user. However, this interpretation is controversial and for those already dependent on nicotine it is of academic interest only – these are rewards that are experienced directly and contribute to continued use.

e.2 Dependence on smoking

Nicotine is dependence-forming when smoked on account of its activation of reward systems in the brain; the speed with which a peak nicotine blood concentration is reached through lung delivery; the presence of other substances in tobacco smoke (for example, monoamine oxidase inhibitors) that contribute to dependence; sensory effects such as ‘throat hit’; conditioning behaviours and cues that trigger craving.

e.3 Dependence on ENDS

The use of nicotine liquids has been overwhelmingly concentrated in current or former smokers who are already exposed to nicotine and may be dependent on nicotine through smoking. It is likely that nicotine delivered through electronic delivery systems (ENDS) is less dependence-forming than through smoking: there are other agents present in cigarette smoke that contribute to dependence and the pharmacokinetics of nicotine delivery by ENDS is ‘slower’. However, that is not a reliable assumption for the longer term – the success of ENDS as a public health intervention depends on replacing the experience of smoking with a satisfying way to take nicotine that is less harmful.

(f) Any other matters necessary to protect public health

f.1 The value of lifting Australia’s *de facto* prohibition on e-liquids

Policymakers must base decisions with real-world life-or-death consequences on a dispassionate view of the evidence, and the scientific evidence now suggests that electronic nicotine delivery systems (ENDS) could be a benefit to millions of smokers.

- Smokers who switch to ENDS are likely to avoid at least 95% of the major smoking-related risks for cancer, heart disease and respiratory illness. They will also experience significant short-term gains in health and wellbeing and, in high tobacco tax jurisdictions like Australia they are likely to be financially better off. No government should deliberately try to deny smokers this option – now adopted by millions of smokers world-wide.

³⁰ Benowitz NL. Nicotine addiction. *N Engl J Med* 2010;**362**:2295–303. [\[link\]](#)

- It is unethical to deny a smoker access to products that are much safer than the dominant product on the market, cigarettes³¹. Outside the field of tobacco and illicit drugs, there are no precedents for banning safer alternatives to widely used products.
- The availability of ENDS is not an alternative to conventional anti-smoking policy but complementary. By providing smokers with an easier way of responding to the pressures of high taxes and other measures, the overall tobacco control policy will become both more responsive and more humane.
- There is no credible evidence to suggest that ENDS undermine tobacco control, induce young people to smoke, or reduce the rate that adults quit smoking. The evidence, when examined dispassionately, shows what a neutral observer would expect unless presented with evidence to the contrary: people use much safer products to reduce their health risks or quit smoking.
- ENDS are an effective tool for switching from smoking at no cost to the public purse – the individual smokers bear the costs.
- A widespread switch to ENDS would reduce exposure to second-hand tobacco smoke. E-cigarettes pose no material risk to bystanders³².
- The quality of products available from reputable manufacturers is now very high and they are on widespread sale in the European Union, North America and throughout Asia without any major problems.
- There is a growing international experience with the regulation of ENDS as consumer products, and, by changing its approach, Australia has the opportunity to take a leadership role in these developments.
- It would be better for Australia to have its own legitimate and properly regulated supply chain and to have responsible producers contributing corporate and sales taxes as appropriate, and less international internet trade in high strength liquids.
- There is no reason to protect the cigarette trade in Australia from competition from superior low-risk products or erect regulatory barriers to entry that are so severe that only tobacco companies have the resources to enter the market, if any company does.

Misrepresentation of scientific findings by some academics and the media have combined to exaggerate risks but understate the benefits of e-cigarettes. There are no precedents for banning safer products while leaving the most dangerous products widely available. On the contrary, ENDS will *support* a tobacco control agenda by giving smokers options to respond to increasing taxes and other controls on smoking. ENDS offer far safer options to smokers than coping with high taxes by switching to buying cigarettes on the black market.

³¹ Hall W, Gartner C, Forlini C. Ethical issues raised by a ban on the sale of electronic nicotine devices. *Addiction* 2015; **110**:1061–7 [[link](#)]

³² Burstyn I. Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks. *BMC Public Health*, 2014 [[link](#)]

f.2 The experience of users

Ministers, officials and regulators should be mindful of the human consequences of their decisions and avoid dehumanising the 2.8 million Australians who smoke. Vapers in Australia³³, the United Kingdom³⁴ and the United States³⁵ provide moving and inspiring testimony of their experience in using ENDS to quit smoking. Three examples of thousands of user testimonials are included below in their own words:

Example of experience from Australia

“It’s really hard to believe it’s been a year. Never in my wildest dreams did I think that I could really quit smoking and make it last this long. I figured my addiction would kill me one day. Now, I am in great health, have managed to slim down to what I weighed in my 20’s, and am fitter than I have been in years. I’ve tried to convert many people, but so far have only succeeded with one friend. I hope to continue to pay forward the time that the Brisbane lady gave me at the airport one year ago and will chat to anyone in the street about vaping.

Example of experience from the UK

“Vaping has probably saved my wife’s and my own life, I was a smoker for 50 years, nothing I have ever tried has had the impact of vaping, this alone was the only thing that saved me, how can governments legislate against something that is saving so many peoples lives.

Example of experience from the United States

“I had been a pack-and-a-half a day smoker for 25 years, the majority of my life. I had tried to quit for about a third of that, using methods like the gums, but without success—I could only ever quit for a few days at most. In December of 2014 I first tried vaping, exploring a variety of vaporizers and fluids. I cut my smoking down dramatically, and was a dual user for about a month and a half. On my birthday in the following January, I threw my cigarettes away by plan, and have been an EX-smoker for the many months since then.

f.3 The preferences of users

A 2014 survey of Australian vapers³⁶, an important group of notional beneficiaries of Australia’s policy approach, drew the following conclusion about attitudes to regulation:

E-cigarette users in Australia are in favour of e-cigarettes being regulated as long as those regulations do not impede their ability to obtain devices and refill solutions, which they view as important for them to remain smoke free. These views align with some aspects of appropriate policy designed to maximise the public health potential of e-cigarettes in society, but conflict with some of the proposed regulatory models. Governments should consider how future regulation of e-cigarettes will affect current consumers while helping to maximise the number of smokers who switch to e-cigarettes and minimise the possibility of non-smokers becoming addicted to nicotine.

The Secretary should reflect on the justification for state intervention to *prevent* smokers adopting vaping. There is now every reason to encourage rather than discourage these user experiences in Australia. There is no reason for any government to place obstacles in the way of smokers making the life-saving transformations described in the testimonials above and thousands of others.

³³ AussieVapers forum, Your story. [\[link\]](#)

³⁴ Counterfactual. UK vaping testimonies. clivebates.com. [\[link\]](#)

³⁵ Consumer Advocates for Smoke-free Alternatives Association (CASAA), E-cigarette user testimonials. [\[link\]](#)

³⁶ Fraser D, Weier M, Keane H, *et al.* Vapers’ perspectives on electronic cigarette regulation in Australia. *Int J Drug Policy* 2015;**26**:589–94. [\[link\]](#)