

Chapter 1

Introduction and overview

Referral and conduct of the inquiry

1.1 On 25 June 2015, the Senate referred an inquiry into personal choice and community impacts to the Senate Economics References Committee (committee) for inquiry and report by 13 June 2016.¹

1.2 The committee's terms of reference require it to report on:

The economic and social impact of legislation, policies or Commonwealth guidelines, with particular reference to:

- a. the sale and use of tobacco, tobacco products, nicotine products, and e-cigarettes, including any impact on the health, enjoyment and finances of users and non-users;
- b. the sale and service of alcohol, including any impact on crime and the health, enjoyment and finances of drinkers and non-drinkers;
- c. the sale and use of marijuana and associated products, including any impact on the health, enjoyment and finances of users and non-users;
- d. bicycle helmet laws, including any impact on the health, enjoyment and finances of cyclists and non-cyclists;
- e. the classification of publications, films and computer games; and
- f. any other measures introduced to restrict personal choice 'for the individual's own good'.

1.3 In accordance with usual process, the committee advertised the inquiry on its website and wrote to relevant persons and organisations inviting submissions to the inquiry.

1.4 To date, the committee has received 485 public submissions and two confidential submissions. The public submissions are available on the committee webpage.

1.5 The committee has held seven public hearings. At its first public hearing, on 11 September 2015 in Canberra, the committee heard evidence on decision making generally. The other public hearings focused on specific matters in relation to the inquiry terms of reference as follows:

- on 3 November 2015, in Parramatta, the committee heard evidence on proposed restrictions on the activities of fans of the Western Sydney Wanderers Football Club;

1 *Journals of the Senate* No. 102, 25 June 2015, p. 2832.

- on 16 November 2015, in Melbourne, the committee heard evidence on mandatory bicycle helmet laws in accordance with inquiry term of reference (d);
- on 20 November 2015, in Sydney, the committee heard evidence relating to inquiry term of reference (b) concerning the sale and service of alcohol with focus on Sydney's lockout laws;
- on 9 March 2016, in Sydney, the committee heard evidence regarding inquiry term of reference (a) concerning tobacco, nicotine and e-cigarettes;
- on 11 March 2016, in Sydney, the committee heard evidence regarding the sale and service of marijuana in accordance with inquiry term of reference (c); and
- on 22 April 2016, in Canberra, the committee heard evidence regarding the classification of publications, films and computer games.

1.6 This report focuses on the evidence in relation to the term of reference (a) concerning the sale and use of tobacco, tobacco products, nicotine products, and e-cigarettes, including any impact on the health, enjoyment and finances of users and non-users.

1.7 The committee thanks all those who have participated in the inquiry so far.

Purpose of the interim report

1.8 The purpose of this interim report is to consider the evidence provided to the committee on the sale and use of tobacco, tobacco products, nicotine products, and e-cigarettes, including any impact on the health, enjoyment and finances of users and non-users.

1.9 While term of reference (a) was designed to broadly address issues relating to tobacco, the majority of submissions received by the committee concerned the sale and use of electronic cigarettes. Additionally, the evidence provided to the committee at its hearing focused predominantly on electronic cigarettes. This report therefore specifically examines this issue.

What are electronic nicotine delivery systems (ENDS)?

1.10 Electronic nicotine delivery systems (ENDS), otherwise known as e-cigarettes, electronic cigarettes or personal vaporisers, are a form of electronic device used to deliver vaporised nicotine or other substances, which simulate the act of smoking cigarettes.² Their primary aim is to deliver nicotine to users without the use of tobacco:

E-cigarettes are devices that deliver nicotine within an inhalable aerosol by heating a solution that typically contains nicotine, propylene glycol and/or glycerol, plus flavours. This aerosol is commonly referred to as vapour and

2 G Griffith, 'E-cigarettes: regulatory and policy options', E-brief, 4, 2015, NSW Parliamentary Research Service, May 2015, p. 1.

so the use of an e-cigarette is described as vaping. Unlike cigarettes, there is no combustion (burning) involved, such as tar and carbon monoxide.³

1.11 The devices are frequently designed to look like traditional tobacco cigarettes or everyday items such as pens or USB sticks.⁴ The technical design of ENDS often varies considerably in regards to battery voltage, unit circuitry and resulting emissions. Some devices allow for user modification, which use accessorial parts in order to change the delivery of the vapour (for example, the potency of the vapour or flavour of the vapour).⁵

1.12 There is currently debate in the medical community regarding the safety of ENDS and their suitability as a therapeutic aid to assist those seeking to quit smoking tobacco cigarettes. The area of debate that is most contentious is the lack of evidence regarding the long-term health impacts of ENDS, and whether this should be overlooked in order to allow tobacco cigarette smokers to use ENDS. This debate will be further discussed in Chapter 2.

Personal choice and ENDS

1.13 The key argument raised by submitters in favour of allowing individuals to use ENDS was that the illegal status of ENDS has resulted in cigarette smokers being unable to use the devices in order to help them quit smoking tobacco cigarettes. This, it was argued, results in further harm, illness and death being caused to smokers wishing to quit.

1.14 Those arguing for the right to use ENDS argued that current research on the devices suggests that they are significantly less harmful than tobacco cigarettes, resulting in less harm to users and providing an alternative method of quitting smoking cigarettes.⁶ Numerous users also told the committee that their personal experiences in using ENDS had helped them quit tobacco cigarette smoking and greatly improved their health (see Chapter 2).

1.15 A number of individuals who gave evidence to the committee noted that, due to the laws regarding ENDS, people who use the devices are labelled criminals.⁷ As

3 Andy McEwan and Hayden McRobbie, *Electronic Cigarettes: A briefing for stop smoking services*, document tabled at a public hearing held in Sydney on 9 March 2016, p. 5.

4 World Health Organisation, *Electronic nicotine delivery systems*, 1 September 2014, http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10Rev1-en.pdf?ua=1 (accessed 15 March 2016) p. 2.

5 World Health Organisation, *Electronic nicotine delivery systems*, 1 September 2014, http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10Rev1-en.pdf?ua=1 (accessed 15 March 2016) p. 2; Mrs Judith Wolters, *Committee Hansard*, 9 March 2016, p. 8.

6 New Nicotine Alliance Australia, *Submission 200*, [p. 2]; Dr Attila Danko, New Nicotine Alliance Australia, *Committee Hansard*, 9 March 2016, pp 1-2; Mr Clive Bates, Director, Counterfactual, *Committee Hansard*, 9 March 2016, p. 18.

7 See, for example: Dr Attila Danko, New Nicotine Alliance Australia, *Committee Hansard*, 9 March 2016, p. 1; Ms Angela Gordon, *Committee Hansard*, 9 March 2016, p. 3, Ms Jennifer Stone, *Committee Hansard*, 9 March 2016, p. 5.

nicotine is listed as a Schedule 7 Poison under the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), its use is highly controlled under federal, state and territory law, preventing the usage of ENDS for therapeutic or personal use. Submitters to the committee indicated that this has resulted in many people illegally procuring liquid nicotine in order to quit smoking, causing them to feel that they are being criminalised for giving up smoking 'the wrong way'.⁸

1.16 Dr Attila Danko of the New Nicotine Alliance Australia stated:

We stand here today as a group of people representing many thousands of Australians who have only managed to give up smoking by breaking the law. I myself smoked daily from the age of 11 and was unable to give up smoking any other way except by using nicotine electronic cigarettes. I am a criminal, because Australia treats the nicotine I use in my e-cigarettes under schedule 7 poisons laws as a dangerous poison with hefty penalties for possession.⁹

1.17 Dr Danko cited data from the Australian Cancer Council stating that, as of late 2014, close to 15 per cent of smokers and recent ex-smokers in Australia (almost half a million people) regularly used e-cigarettes despite the restrictions prohibiting their use.¹⁰

Regulation of ENDS

1.18 In Australia, ENDS are regulated under a complex combination of Commonwealth and state laws. While no laws are yet directed specifically at the regulation of ENDS, laws regulating poisons, therapeutic goods and tobacco control affect the legal status of the devices.¹¹

1.19 At all levels of regulation, the status of ENDS' legality is dependent on:

- (a) whether the ENDS contain liquid nicotine;
- (b) whether the ENDS is sold commercially or are owned solely for personal use; and
- (c) whether the ENDS claims to be of therapeutic value.

1.20 The laws at both the Commonwealth and state/territory level are set out below.

8 Dr Attila Danko, New Nicotine Alliance Australia, *Committee Hansard*, 9 March 2016, p. 5.

9 Dr Attila Danko, New Nicotine Alliance Australia, *Committee Hansard*, 9 March 2016, p. 1.

10 Dr Attila Danko, New Nicotine Alliance Australia, *Committee Hansard*, 9 March 2016, p. 2.

11 Quit Victoria, *Legal status of electronic cigarettes in Australia*, September 2015, <http://www.quit.org.au/downloads/resource/policy-advocacy/policy/legal-status-electronic-cigarettes-australia.pdf> (accessed 18 February 2016).

Commonwealth regulation

1.21 ENDS are regulated under two main Commonwealth Acts in Australia:

- The SUSMP, which consists of 'decisions regarding the classification of medicines and poisons into Schedules for inclusion in the relevant legislation of the States and Territories';¹² and
- The *Therapeutic Goods Act 1989* (TG Act), which currently does not list ENDS as a therapeutic good.

1.22 Additionally, Australia is bound to the World Health Organisation Framework Convention on Tobacco Control (FCTC), which first came into force on 27 February 2005. According to the Department of Health (department), parties to the treaty:

recognise that it is their responsibility to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption, in order to reduce the prevalence of tobacco use and exposure to tobacco smoke.¹³

1.23 Nicotine can be used for human consumption as a prescription-only medicine under schedule 4 (S4) classification of the SUSMP. It is also listed as a poison under schedule 7 (S7) classification of the SUSMP, with the exception of preparations for human therapeutic use or in tobacco prepared and packed for smoking. If not classified as a therapeutic good, ENDS fall into the S7 classification.¹⁴ It is also illegal to manufacture, sell or supply nicotine to another person without proper licencing and authorisation, which prohibits the sale of liquid nicotine in retail stores.¹⁵

1.24 While there are no explicit restrictions on the importation of liquid nicotine, it can be an offence to possess or use imported nicotine liquid, depending on the relevant state and territory laws where jurisdiction applies.¹⁶ However, a patient wishing to obtain liquid nicotine for the purposes of quitting tobacco smoking can import a three-month supply of liquid nicotine with the prescription of an Australian registered medical practitioner.¹⁷ An importer cannot import more than 15 months' supply of liquid nicotine in a 12 month period.¹⁸ However, the committee heard

12 Therapeutic Goods Administration, *The Poisons Standard (the SUSMP)*, 11 March 2016, <http://www.tga.gov.au/publication/poisons-standard-susmp> (accessed 15 March 2016).

13 Department of Health, *Supplementary Submission 444.1*, p. 4.

14 Heather Douglas, Wayne Hall and Coral Gartner, 'E-cigarettes and the law in Australia', *Australian Family Physician*, vol. 44, no. 6, p. 416.

15 Heather Douglas, Wayne Hall and Coral Gartner, 'E-cigarettes and the law in Australia', *Australian Family Physician*, vol. 44, no. 6, p. 416.

16 Heather Douglas, Wayne Hall and Coral Gartner, 'E-cigarettes and the law in Australia', *Australian Family Physician*, vol. 44, no. 6, p. 416.

17 Heather Douglas, Wayne Hall and Coral Gartner, 'E-cigarettes and the law in Australia', *Australian Family Physician*, vol. 44, no. 6, p. 416.

18 Quit Victoria, *Legal status of electronic cigarettes in Australia*, September 2015, <http://www.quit.org.au/downloads/resource/policy-advocacy/policy/legal-status-electronic-cigarettes-australia.pdf> (accessed 18 February 2016) p. 3.

evidence that this method is infrequently used as many medical practitioners are wary as it is an 'irregular' practice.¹⁹

1.25 The TG Act currently does not list any form of ENDS as a therapeutic good. Any product claiming a therapeutic benefit would be referred to the Therapeutic Goods Administration for scrutiny.²⁰

State regulation

1.26 The laws relating to ENDS can differ radically depending on the state or territory a user resides in. The inconsistency in legislation was noted in evidence to the committee. See Table 1 for an overview of the relevant legislation applicable in each state and territory.

1.27 The sale of products resembling a tobacco product is prohibited in South Australia, Western Australia, New South Wales (NSW) and Queensland.²¹ In 2014, Queensland further restricted ENDS use by including 'personal vaporisers' in its definition of a 'smoking product', which applies laws regarding tobacco cigarettes to ENDS as well. For example, while it is not illegal to possess an ENDS that does not contain nicotine, it is illegal under the new Queensland legislation to inhale from an ENDS.²²

1.28 Further restrictions have recently been brought into NSW legislation. The Public Health (Tobacco) Amendment (E-cigarettes) Bill 2015 was introduced into the NSW Parliament on 6 May 2015 in order to amend the *Public Health (Tobacco) Act 2008*. It focussed on regulating the sale, advertising, and restrictions to children of ENDS.²³ It also set the penalties for the sale of e-cigarettes and accessories to a minor at \$11,000 for an individual and \$55,000 for a corporation, increasing in severity with subsequent offences. The provisions are now law as of 1 December 2015.

1.29 In the Australian Capital Territory (ACT) and Tasmania, it is prohibited to sell a 'toy or food' which resembles (or is intended to resemble) a tobacco product. It has been noted that 'if it could be proven that e-cigarettes were intentionally marketed to children, it might be possible to argue they were being marketed as a toy and therefore breach the law'.²⁴ These jurisdictions do not currently have specific

19 Dr Attila Danko, New Nicotine Alliance Australia, *Committee Hansard*, 9 March 2016, p. 4.

20 Heather Douglas, Wayne Hall and Coral Gartner, 'E-cigarettes and the law in Australia', *Australian Family Physician*, vol. 44, no. 6, p. 416.

21 Heather Douglas, Wayne Hall and Coral Gartner, 'E-cigarettes and the law in Australia', *Australian Family Physician*, vol. 44, no. 6, p. 416.

22 Heather Douglas, Wayne Hall and Coral Gartner, 'E-cigarettes and the law in Australia', *Australian Family Physician*, vol. 44, no. 6, p. 416.

23 New South Wales Government, *Are electronic cigarettes legal in NSW? Fact Sheet*, 9 September 2015, <http://www.health.nsw.gov.au/tobacco/Factsheets/e-cigs-are-they-legal.pdf> (accessed 23 March 2016), p. 2.

24 Heather Douglas, Wayne Hall and Coral Gartner, 'E-cigarettes and the law in Australia', *Australian Family Physician*, vol. 44, no. 6, p. 416.

regulations regarding ENDS. However, the ACT Government has announced its intention to tighten its regulation of the devices, including placing age limits on their purchase, significantly curtailing advertising, and restricting public use to be consistent with current restrictions for tobacco cigarettes.²⁵

1.30 In the Northern Territory, it is prohibited to sell 'a product designed for consumption by children if it resembles, or is packaged to resemble, a tobacco product; or it has, or is likely to have, the effect of encouraging children to smoke'.²⁶ ENDS are not restricted if they do not make a therapeutic claim and if they do not target children or encourage them to smoke.²⁷

1.31 Several of the states and territories have also held community consultations or inquiries assessing the merits and options regarding ENDS regulation. States holding reviews or inquiries include Tasmania and the ACT. The South Australian Parliament also established the Select Committee on E-cigarettes in June 2015 to consider the legislative response to ENDS.

1.32 Laws relating to ENDS in Western Australia were recently the subject of legal challenge. This case, *Hawkins v Van Heerden* dealt with charges laid under section 106(a) of the *Tobacco Products Control Act 2006* (WA), which restricts the sale of 'any food, toy or other product that is not a tobacco product but is designed to resemble a tobacco product or a package; or in packaging that is designed to resemble a tobacco product or a package'.²⁸ The defendant was an online ENDS retailer who was found in possession of sixty devices. He claimed that the devices were not 'designed to resemble a tobacco product'.²⁹

1.33 While at first instance Mr Van Heerden was found not guilty, on appeal the Supreme Court of Western Australia overturned the verdict. Justice Pritchard found that the first-instance magistrate had erred in declining to accept evidence of the appearance of an ENDS device during its use, and in not considering the full range of similarities between a traditional cigarette or cigar, and an ENDS device, and that the device was intended to resemble a tobacco product.³⁰ Mr Van Heerden attempted to

25 Henry Belot, 'Electronic cigarette use to be heavily restricted under proposed laws', *The Canberra Times*, 20 October 2015, <http://www.canberratimes.com.au/act-news/electronic-cigarette-use-to-be-heavily-restricted-under-proposed-laws-20151020-gkdlhy.html> (accessed 23 March 2016).

26 Heather Douglas, Wayne Hall and Coral Gartner, 'E-cigarettes and the law in Australia', *Australian Family Physician*, vol. 44, no. 6, p. 416.

27 Heather Douglas, Wayne Hall and Coral Gartner, 'E-cigarettes and the law in Australia', *Australian Family Physician*, vol. 44, no. 6, p. 416.

28 Heather Douglas, Wayne Hall and Coral Gartner, 'E-cigarettes and the law in Australia', *Australian Family Physician*, vol. 44, no. 6, p. 416.

29 Heather Douglas, Wayne Hall and Coral Gartner, 'E-cigarettes and the law in Australia', *Australian Family Physician*, vol. 44, no. 6, p. 416.

30 *Hawkins v Van Heerden* [2014] WASC 127 (10 April 2014).

challenge this verdict in the Court of Appeal, but his case was dismissed on 9 March 2016.³¹

1.34 In NSW, there has also been confusion regarding ENDS and their status in law. In April 2013, a man was charged with smoking a cigarette on a train station platform, a prohibited smoking area. While he later stated that he was smoking an ENDS device, the police officer involved stated that she witnessed him stamping out the cigarette, which would not occur with an ENDS.³² This incident highlights the confusion that can arise regarding the legislation and the challenges that law enforcement face in attempting to maintain ENDS regulation.

Table 1: State and territory legislation applicable to the regulation of ENDS

State	Legislation
NSW	<i>Public Health (Tobacco) Act 2008</i> <i>Poisons List NSW</i> <i>Poisons and Therapeutic Goods Act 1966</i> <i>Poisons and Therapeutic Goods Regulation 2008</i>
QLD	<i>Tobacco and Other Smoking Products Act 1998</i> <i>Health Legislation Amendment Bill 2014 Part 8 Amendment of Tobacco and Other Smoking Products Act 1998</i> <i>Health Act 1937</i> <i>Health (Drugs and Poisons) Regulation 1996</i>
VIC	<i>Tobacco Act 1987</i> <i>Drugs, Poisons and Controlled Substances Act 1981</i> <i>Drugs, Poisons and Controlled Substances Regulations 2006</i>
TAS	<i>Public Health Act 1997</i> <i>Poisons Act 1971</i> <i>Poisons Regulation 2008</i>
SA	<i>Tobacco Products Regulation Act 1997</i>

31 Alisha O'Flaherty, 'E-cigarette vendor loses fight against conviction for breaching WA tobacco laws', *ABC News*, 10 March 2016, <http://www.abc.net.au/news/2016-03-10/electronic-cigarettes-vendor-vincent-van-heerden-loses-appeal/7236440> (accessed 17 March 2016).

32 Richard Noone, 'Anthony Campo fined \$300 for smoking on Gosford Train Station', *Daily Telegraph*, 23 December 2013, <http://www.dailytelegraph.com.au/newslocal/central-coast/anthony-campo-fined-300-for-smoking-on-gosford-train-station/story-fngr8h0p-1226787202325> (accessed 30 March 2016).

	<i>Controlled Substances Act 1984</i> <i>Controlled Substances (Poisons) Regulations 2011</i>
WA	<i>Tobacco Products Control Act 2006</i> <i>Poisons Act 1964</i>
ACT	<i>Tobacco Act 1927</i> <i>Medicines, Poisons and Therapeutic Goods Act 2008</i>
NT	<i>Tobacco Control Act 2002</i> <i>Medicines Poisons and Therapeutic Goods Act 2012</i>

International trends

1.35 Australia's prohibitive regulation of ENDS was argued by some submitters and witnesses to be out of step compared to responses in international jurisdictions. A 2014 World Health Organisation (WHO) report into ENDS suggested that the devices are available in at least 62 countries, amounting to half of the world's population.³³

1.36 The international market for ENDS is reported to have generated approximately US\$3 billion in sales in 2013.³⁴ While the majority of the market is made up of small independent operators, the WHO reported that many transnational tobacco companies are entering the market and 'aggressively competing with the independent companies to gain market share'.³⁵

1.37 Some submitters and witnesses to the inquiry pointed to the United Kingdom (UK) jurisdiction as an example of the effective regulation of ENDS.³⁶ In both UK and European Union law, ENDS are legally available and regulated under general product safety regulations which do not require product testing before being placed on the market; however, ENDS manufactures can obtain a medicinal licence if their products are for therapeutic use.³⁷

1.38 Additionally, there has been a concerted effort in the UK to ensure that ENDS are available to those wishing to use the devices as a safer alternative to tobacco

33 World Health Organisation, *Electronic nicotine delivery systems*, 1 September 2014, p. 3, http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10Rev1-en.pdf?ua=1 (accessed 15 March 2016).

34 World Health Organisation, *Electronic nicotine delivery systems*, 1 September 2014, p. 2.

35 World Health Organisation, *Electronic nicotine delivery systems*, 1 September 2014, p. 3.

36 See: Professor Gerry Stimson and Mr Clive Bates, *Committee Hansard*, 9 March 2016, pp 15-17.

37 Public Health England, *E-cigarettes: an evidence update*, 19 August 2015, <https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update> (accessed 15 March 2016), p. 20.

cigarettes. As an example, Professor Gerry Stimson informed the committee that guidelines for professionals working in tobacco cessation clinics have been distributed in order to provide the most current evidence and create clear recommendations for those wishing to use the devices.³⁸

1.39 Other jurisdictions have also chosen to regulate ENDS as alternative consumer products to tobacco cigarettes, as opposed to therapeutic goods. The Food and Drug Administration in the United States has proposed a rule to extend the agency's authority to include ENDS, which would subject manufacturers to requirements for registration, reporting, advertising and restrictions on the claims regarding reduced risk.³⁹

38 Professor Gerry Stimson, *Submission 141*, p. 5.

39 Professor Riccardo Polosa, *Submission 92*, p. 2.