Discussion paper: Options to minimise the risks associated with the marketing and use of electronic nicotine delivery systems [ENDS] in Australia

This Discussion paper was updated by the Commonwealth Department of Health in September 2016, these changes were made after the completion of the expert consultation that is detailed in the associated final report. The version of the Discussion paper that went out for expert consultation was approved by the Department on 01 April 2016 and was prepared by University of Sydney academics and Cancer Council NSW employees.

EXECUTIVE SUMMARY

Electronic nicotine delivery systems [ENDS] are products that heat a solution, typically including nicotine, to form an aerosol, which is then inhaled by the user. For the purposes of this discussion paper we use the term 'ENDS' to mean all products that are designed to generate or release an aerosol or vapour (whether or not containing nicotine) by electronic means for inhalation by its user, unless specified otherwise. For specific reference to non-nicotine containing versions the term 'non-nicotine ENDS' is used.

Australia applies a mixed approach to the regulation of ENDS via existing frameworks for tobacco control, therapeutic goods and consumer goods. Sale of ENDS is not currently permitted in Australia if they contain liquid nicotine and no ENDS have to date been approved by the Therapeutic Goods Administration (TGA) for sale as a therapeutic good. Sale of non-nicotine ENDS is treated differently by jurisdictions.

This discussion paper was prepared to inform a consultation process with technical experts in ENDS, tobacco control or public health. The paper has four key sections: 1) introduction, 2) a literature/evidence review, 3) an analysis of current ENDS policy development, legal issues, and prevention and control activities in Australia and internationally, and 4) possible policy options to minimise risks and harms from ENDS use and marketing.

Prevalence of the use of ENDS in Australia currently appears to be lower than in the US and UK and similar to that in Canada. In Australia, from data collected in 2013, daily smokers were most likely to have used an ENDS in the last 12 months, with 15.3% using. 1.8% of former smokers reported using an ENDS in the last 12 months and use among non-smokers was low, with 0.8% having used an ENDS in the last 12 months. ENDS use among all youth aged 14-17 years was 4.3% in the previous 12 months. While there is limited data available, awareness, trial and regular use of ENDS appears to have increased amongst adult smokers and former smokers between 2010 and 2013.

The global ENDS market was worth US$3 billion in 2013. All major international tobacco companies have invested in the ENDS market. A significant portion of ENDS business is conducted online. The number of ENDS brands and available flavours has substantially increased in recent years.

As these products are relatively new, there are insufficient data available to determine the long-term health effects of ENDS use or of second-hand vapour exposure, in either adults or children. There is substantial variation in the components and operation of different ENDS products. ENDS may contain nicotine; the nicotine content varies considerably, both across different ENDS products and within the same product. Acute nicotine poisoning is possible, particularly if children swallow the liquid. Nicotine may also play a role in tumour promotion and growth and is being investigated as a possible cancer-causing agent. There is inadequate research to determine the safety of inhaling stabilising agents used in ENDS, such as propylene glycol. There is evidence that flavourings used in ENDS may be harmful to users. There are also concerns about particulate matter in ENDS emissions.

Definitive evidence is lacking that ENDS users are more likely than smokers using other methods (including cold turkey) to quit all cigarette use. Outcomes of cessation research are highly mixed, with some studies reporting increased smoking cessation with ENDS use and others reporting less

smoking cessation with ENDS use. The high potential dependence risk associated with the inhalation of nicotine aerosols compared with NRT products is also an important consideration.

Online advertising of ENDS, particularly by vendors, is accessible in Australia. Point-of-sale displays are common in some regions of Australia among the small number of retailers that sell ENDS. ENDS ads can also be found in some Australian print media. ENDS ads often contain potentially misleading information about unproven health benefits. ENDS ads appear to increase the desire to try products and if ads include vaping imagery, they may increase the urge to smoke traditional cigarettes. Further information about claims by ENDS retailer websites can be found in section 2.6 of the Appendix.

In Australia, regulation of ENDS is shared between Commonwealth, and state and territory governments. John Hopkins Bloomberg School of Public Health has summarised ENDS regulation of 123 countries in a comprehensive website. This summary reported that the sale of all types of e-cigarettes is banned in 26 countries, 18 countries regulate ENDS as medicinal products, 26 countries regulate ENDS as tobacco products (or imitation/derivative/substitute products) and four countries regulate ENDS containing nicotine as poisons. Use of e-cigarettes is banned in three countries (Cambodia, Jordan and the United Arab Emirates). As of February 2016, 71 countries have been identified that regulate e-cigarettes.

Seven policy approaches for expert consultation are outlined in Section 4. These policy approaches are not meant to be mutually exclusive.

The seven possible policy approaches are as follows:

Policy approach 1: Maintain the status quo

Policy Approach 2: Increase awareness and enforcement of and compliance with existing legislation

Policy approach 3: Regulate ENDS as medicines

Policy approach 4: Regulate ENDS as tobacco products

Policy approach 5: Regulate ENDS as consumer products

Policy approach 6: Develop an ENDS regulatory framework

Policy approach 7: Adopt measures to ban ENDS

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SECTION 1 INTRODUCTION

1.1 Background and strategic context

This discussion paper was prepared to inform a consultation process with technical experts in electronic nicotine delivery systems (ENDS), tobacco control and public health. This paper has four key sections: 1) an introduction 2) a literature/evidence review; 3) an analysis of current ENDS policy development, legal issues, and prevention and control activities in Australia and internationally; and 4) an outline of possible policy options to minimise risks and harms from ENDS use and marketing. The overarching assumption when outlining the possible policy options for minimising the risk posed by ENDS will be that policies must, as much as is possible to determine, be consistent with the objectives of the *National Tobacco Strategy 2012-2018*.

In October 2014, at the 6th session of the Conference of the Parties (COP) of the World Health Organization [WHO] Framework Convention on Tobacco Control (FCTC), to which Australia is a Party, a decision on ENDS(1) was accepted and endorsed.(2) The COP decision was to invite Parties to consider prohibiting or regulating ENDS, including as tobacco products, medicinal products, consumer products, or other categories, as appropriate, taking into account a high level of protection for human health.

1.2 What are ENDS?

ENDS are products that heat a solution, usually including nicotine but not necessarily, to form an aerosol, which is then inhaled by the user. For the purposes of this report we use the term 'ENDS' to mean all products that are designed to generate or release an aerosol or vapour (whether or not containing nicotine) by electronic means for inhalation by its user unless specified otherwise. For specific reference to non-nicotine versions the term 'non-nicotine ENDS' is used. (See Appendix for additional information.) Where terms such as e-cigarettes or electronic cigarettes have been used in surveys, legislation, or other key sources in this discussion paper, these terms have been retained.

While ENDS are the focus of this discussion paper, the term does not necessarily capture all products which deliver an aerosol and/or vapour via inhalation, including but not limited to the Philip Morris's Marlboro iQOS system (which has tobacco as an ingredient), or British American Tobacco's Voke Inhaler (which does not use electrical power to generate an aerosol). The *Tobacco and Other Smoking Products Act 1998* (Qld) was recently updated to include the term 'personal vaporiser'. ACT legislation also uses the term 'personal vaporiser'. Further information about these products is provided in sections 1.2 and 2.3 in the Appendix, respectively.

1.3 Health claims and health concerns

Three central health benefits claimed for ENDS are that:

1. they are far less hazardous to health than combustible tobacco products;(3-9)
2. they are an effective means of stopping smoking, comparable to or more effective than other smoking cessation strategies;(3, 8, 9) and
3. smokers who also use ENDS ("dual users") reduce the number of cigarettes they smoke and that this is likely to be harm reducing.(8, 9)

Four central health concerns expressed for ENDS are that:

1. smokers who might otherwise have quit smoking, may continue smoking and vaping (dual-using) in the belief that their reduced smoking is significantly harm reducing;(10)
2. non-smokers (especially youth) who may have never used any nicotine product, may take up vaping in the belief that ENDS are risk-free;(11)
3. a proportion of non-smokers may commence smoking in addition to vaping (the so-called gateway effect)(12); and
4. The longer term health effects of use are unknown(13)

SECTION 2 LITERATURE REVIEW

See Appendix for section 2.1 Methods and for the additional, detailed literature review content.

2.2 Prevalence of ENDS use

Australia

Data from the 2013 National Drug Strategy Household Survey (NDSHS) show that 14.8% of **current smokers** had ever used 'battery-operated electronic cigarettes' or ENDS in the last 12 months.(14) The 2013 survey was the first time that respondents were asked about their use of ENDS. In 2013:

- 1 in 7 (14.8%) smokers aged 14 or older had used ENDS in the last 12 months;
- younger smokers were more likely to have ever used an ENDS in the last 12 months than older smokers: 27% for smokers aged 18–24 compared with 7.2% for those aged 60–69 ;
- daily smokers were most likely to have ever used an ENDS in the last 12 months (15.3%), with only 1.8% of ex-smokers reporting use in the last 12 months;
- male smokers aged 14 or older were generally more likely than females to have ever used ENDS, except among those aged 50–59 where 13.5% of female smokers had used this product compared with 6.7% of male smokers;
- Ever use of ENDS among non-smokers was low, with 0.8% having used an ENDS in the last 12 months, and an additional 0.5% having used an ENDS, but not within the last 12 months;
- Ever having used an ENDS among all youth aged 14-17 years was 4.3% in the last 12 months, and a further 1.7% of youth having ever used an ENDS but not in the last 12 months; and
- ENDS use in the past 12 months was highest in the Northern Territory at 6% and lowest in NSW at 2.8%.

Information regarding ENDS use among vulnerable populations is provided in section 2.2 of the Appendix.

Data from the Cancer Institute NSW's Tobacco Tracking Survey of adult smokers and recent quitters, which included 9% current ENDS users, found that the most common places of purchase of ENDS were the internet (30%) and tobacconists (28%).(15)

Evidence of gateway and renormalisation concerns

Concern has been expressed about whether ENDS use might be a possible gateway into smoking. A 2014 WHO report on ENDS noted that experimentation with ENDS is increasing among adolescents and young adults and is highest among those who also smoke tobacco; this is true both in Australia and internationally.(1) Smoking rates among youth have also declined during these same time periods. The data currently available on youth ENDS use patterns in Australia do not allow

conclusions to be made as to whether youth who try ENDS are more or less likely to go on to use tobacco; if youth who smoke are switching to ENDS; or if youth are experimenting with ENDS in lieu of tobacco. The data show that dual use of tobacco and ENDS is the most likely scenario, as current smokers are also the most likely to be current users of ENDS. As most existing prevalence studies of youth are cross-sectional, it is not possible to determine which users started with cigarettes and which users started with ENDS.(11)

The daily smoking rate among Australian youth aged 12-17 is 3.4% and 13.4% among young adults aged 18-24.(16) ENDS ever use and current use is also low among Australian youth aged 14-17. By contrast, ENDS use has rapidly risen among youth in nations with less stringent ENDS regulations and less comprehensive tobacco control laws,(17) including among adolescent never smokers.(11) Further information regarding ENDS awareness, trial and/or use in Australia when compared to other countries is provided in section 2.2 of the Appendix.

2.3 International ENDS market

Euromonitor estimates that the global ENDS market was worth US$3 billion in 2013.(18) This is a very small market when compared to the global tobacco market; one of the most valuable fast moving consumer goods industries, worth an estimated annual US$800 billion – more than 260 times the size of the ENDS market.(19) This reflects the fact that ENDS use is not as widespread geographically as cigarette use. Euromonitor estimates that the vapour products market could be worth 4% of the total global tobacco market by 2030, for a value of about US$50 billion.

Outside of China, the global tobacco market is dominated and controlled by five major players: Japan Tobacco International (JTI), Imperial Tobacco (IT), British American Tobacco (BAT), Philip Morris International (PMI), and Altria/Philip Morris USA. All of these major global tobacco companies now have a stake in the ENDS market, with most buying up independent ENDS companies.(20)

2.4 Health effects of use and second-hand exposure to ENDS

ENDS have been suggested by some as presenting a significant opportunity to address the burden of tobacco use through harm reduction.(3-6) The current ENDS on the market are relatively new products, so regulators are making decisions on the basis of very limited evidence.

ENDS are often marketed as a less dangerous alternative to smoking and there is evidence that one of the primary reasons for the increasing popularity of ENDS is that users perceive them as being less harmful.(8, 9, 21) The short-term toxicity of ENDS use appears to be comparatively low and, further, ENDS aerosol does not stay in the air for long, reducing the risk of exposure to second-hand vapour by non-users.(10, 22-24) However, while we identified several reviews of the health effects of ENDS, most concluded that there are insufficient data available to determine the long-term health effects of ENDS use or of second-hand exposure, in either adults or children.(5, 10, 13, 22, 23, 25-27) Further, Pisinger and Døssing found that of the 76 articles included in their review many were small, short-term studies with major methodological flaws and authors with significant conflicts of interest, making it difficult to draw firm and reliable conclusions as to the health effects of ENDS.(27)

The lack of product standards and international differences in regulation has meant that there is substantial variation in the components and operation of the different ENDS products and even within the same products.(10, 13, 22, 23, 28) Complicating matters further, recent evidence suggests that differences in the mechanical components, as opposed to the chemical components, of ENDS have implications for potential health effects of ENDS use.(29) It is therefore difficult to determine the health effects of ENDS as a homogenous product class.(30)

ENDS aerosols deliver ultrafine particles. While it is unclear what effect ultrafine particles in ENDS aerosols have on health, frequent, low-level exposure to fine and ultrafine particles from tobacco smoke or air pollution has been shown to contribute to inflammation and increased risk of cardiovascular and respiratory morbidity and mortality.(31)

While ENDS use has not been linked to any serious adverse respiratory events,(30) it may constrict airways, creating a potential risk particularly for those with asthma and other respiratory conditions.(5, 26, 32, 33) There is limited evidence that suggests that ENDS use has no impact on lung function in the short-term but there is also emerging evidence that it may cause pulmonary inflammation.(34) If confirmed, this would have significant implications for public health, particularly in relation to rates of chronic obstructive pulmonary disease (COPD).

ENDS have been linked to occasional explosions, fires, and poisonings.(5, 26) Indeed, the number of ENDS-related reports to poison centres in the USA has been increasing in line with the increasing popularity of ENDS. (13, 25) The potential risk for poisoning is high for liquid nicotine compared with tobacco products and nicotine replacement therapies.(35) The Centers for Disease Control reported that in the United States in the period September 2010 and February 2014 more than half (51%) of the calls to poison centres on ENDS exposures (2,405 calls) related to children aged 0 to 5 years. ENDS poisonings were more likely to be as a result of inhalation, eye and skin contact, and less likely to be as a result of ingestion, compared to conventional cigarettes.(36) Hajek et al. note that such reports remain at lower levels than those related to conventional tobacco products (5) as would be expected given the significantly lower levels of ENDS use.

ENDS contain a number of potentially harmful compounds, albeit at orders of magnitude lower levels than those found in conventional cigarettes.(10) These include both compounds that are purposefully added to ENDS and those that result from the process of using ENDS (i.e. through vaporising or inhalation/exhalation). There is ongoing debate about the absolute toxicity of ENDS relative to tobacco products.(37) There is evidence that nicotine is toxic to the foetus(38) and impacts on the development of the adolescent brain.(39) Further information about the health effects of nicotine, flavourings and other ingredients typically found in ENDS is provided in section 2.4 of the Appendix.

Combes and Balls (2015) state that there is insufficient toxicological data to perform a hazard assessment for electronic cigarettes. They also state that due to the inadequate research, the relative safety of electronic cigarettes has not been scientifically established.(40)

2.5 Risk of dependence, cessation and reducing consumption of conventional tobacco products

Risk of dependence for inhaled nicotine aerosols

The high potential dependence risk associated with the inhalation of nicotine aerosols compared with NRT products is an important issue. Some ENDS have been shown to have a similar nicotine absorption profile to conventional cigarettes (i.e. very rapid absorption and a subsequent rapid fall) in experienced users.(41, 42)

Smoking cessation

A summary of the systematic reviews which were identified in our literature review are provided below. A summary of additional primary studies are provided in Section 2.5 of the Appendix.

Grana et al's review combined the results of four longitudinal and one cross-sectional study in a random-effects meta-analysis and concluded "that ENDS use in the real world is associated with significantly lower odds of quitting smoking cigarettes."(26) While Grana et al describe these studies as longitudinal, the Cochrane review (see below) notes that, for the purposes of evaluating efficacy of ENDS, two of these were not longitudinal studies: one was essentially a cross-sectional design (because participants were only asked about ENDS use at follow up) and one was a retrospective survey 7 months after enrolment into a quitline service. Herzig, in a critique of Grana et al.'s review, notes that a limitation of this review is that some of the included studies did not control for level of nicotine dependence. (43) This may have adversely impacted the results because it may be that more heavily addicted smokers who are less likely to succeed in quitting are more likely to use ENDS as a cessation aid. In their reply to Herzig, Grana et al noted that an additional two studies had been published since their original review, both of which supported their conclusion that "ENDS use is associated on balance with less cigarette smoking cessation" than among smokers not using ENDS.(44)

The Cochrane Collaboration published a review that considered both cessation and smoking reduction in 2014.(45) Based principally on the only two randomised controlled trials, the review found that participants using ENDS were more likely to have abstained from smoking for at least six months compared with participants using a placebo. One study compared ENDS to nicotine patches and found no significant difference in six-month abstinence rates. The review also included a further 10 prospective cohort studies. The reviewers deemed that all these cohort studies were at high risk of bias. The review authors noted that the overall quality of the evidence included in their review was weak to very weak due to the small number of trials. Consequently their confidence in the estimates of effects was low.

Rahman et al meta-analysed results from six studies on cessation and reduction and concluded that ENDS containing nicotine were more effective for cessation than those without nicotine.(46) The analysis also reported that use of ENDS was associated with a reduction in use of conventional cigarettes. However, the authors noted the heterogeneity of the studies they pooled for their analysis. In particular, one of the included studies was highlighted as having significant problems for generalizability of findings because the study participants were recruited only from notices in community newspapers. Further, the authors noted that they were unable to assess the efficacy of ENDS compared to other cessation interventions due to a lack of evidence.

A **2016 review and meta analysis** assessed the association between e-cigarette use and cigarette smoking cessation among adult cigarette smokers, irrespective of their motivation for using e-cigarettes and found that e-cigarettes, as currently being used, are associated with significantly less quitting among smokers.(47)

In addition to the systematic reviews highlighted above, we identified four significant primary studies. A summary of the findings from these studies is provided in Section 2.5 of the Appendix.

Reducing consumption of conventional tobacco products

The previously noted Cochrane review found that a greater proportion of ENDS users were able to reduce cigarette consumption by at least half, compared with both those using a placebo and those using nicotine patches.(45) As with cessation, these findings are weakened by the overall poor quality of the available evidence. Further, the authors noted that unlike smoking cessation outcomes reduction results were not biochemically verified.

In addition, large declines in daily consumption of conventional cigarettes in ENDS users have been noted in some primary studies. (48, 49) However, available evidence suggests that the health benefits of reducing consumption of conventional tobacco products are minimal at best. For instance, a 2007 systematic review of the evidence on the health impact of smoking reduction noted that most studies available for review were small and had limited follow-up. (50) It found that while there may be a small health benefit in substantially reducing consumption, more studies were needed.

Since that review, three papers involving four cohorts – two being very large – have been published that substantially increase evidence about the health implications of smoking reduction. Note that these studies report mortality but not morbidity and that the use of ENDS was absent or negligible at the time these studies were conducted. A Norwegian cohort of 51,210 people followed from the 1970s until 2003 found no evidence that smokers who reduced their consumption by 50% or more reduced their risk of premature death significantly. (51) Similarly, a Scottish study of two cohorts followed from the 1970s to 2010 found no evidence of reduced mortality in smokers who reduced their consumption.(52) The largest study, from Korea and involving 479,156 men followed for 11 years, found an association between smoking reduction and a significant decrease in risk of lung cancer, but with the size of risk reduction "disproportionately smaller than expected".(53) Moreover, there was no association between smoking reduction and a decline in all-cancer risk.

The Korean study authors were painstaking in noting any limitations in their own research. The study did not include a biological validation of self-reported smoking status; data on smoking status at multiple time points up to the time of cancer occurrence were not available which the authors state leaves a possibility of underestimating the effect of smoking reduction on lung cancer risk.(53)

2.6 Marketing

Australia has one of the most comprehensive bans on tobacco advertising in the world, being the only country to have thus far enacted standardised, plain packaging laws. (Point of sale tobacco advertising laws differ by jurisdiction.) Equally, advertising of over-the-counter medicines and prescription drugs is tightly regulated. In contrast, marketing of ENDS is not as tightly regulated and ENDS marketing is occurring in Australian social media, email promotions, online group purchasing coupons, television, print media and at retail point-of-sale.

There is limited published evidence on the availability and promotions of ENDS in Australia. It is likely that there is wide variety across states given the differing regulatory environments. A study on the availability and promotion of ENDS undertaken by the Cancer Council NSW in 2014 found that in an audit of 1519 tobacco retail outlets across 85 postcodes in NSW(54):

- ENDS were observed for sale in 5.1% (n=77) of outlets sampled;
- Of the 5.1% of outlets where ENDS were observed for sale: Availability of ENDS varied by outlet type, with ENDS most often observed by auditors in tobacconists (45.5%), convenience stores (33.8%) and petrol stations (1.7%). No ENDS were observed in supermarkets or newsagents;
- Auditors in Sydney and suburbs observed ENDS in outlets more often (7.7%) than auditors in other areas of NSW (1.5%); ENDS display boxes were observed in most outlets (81.8%) where ENDS were sold; and ENDS promotional posters were observed in only a few outlets (5.2%) where ENDS were sold.

It is noted that this study was undertaken before the commencement of bans on the display and advertising of e-cigarettes and accessories in retail outlets in NSW on 1 December 2016.

Photographs of the ENDS displays taken during the audit show: the use of packaging colours, emphasis on flavours, and the positioning of products next to confectionery items (Figure 1).

Figure 1 Sample images of ENDS displays collected in NSW tobacco retail outlet audit

One systematic content analysis of ENDS website marketing reported numerous misleading claims.(55) Additionally, some evidence suggests that the widespread promotion of ENDS may increase the urge to smoke among existing smokers, and may reduce former smokers' confidence in their ability to refrain from smoking.(56) There is also evidence that young non-smokers may be more interested in trying ENDS after exposure to ENDS advertisements.(57) Further information on the marketing of ENDS is provided in Section 2.6 of the Appendix.

SECTION 3 SITUATION ANALYSIS

ENDS policy development, legal issues, and prevention and control activities

3.1 ENDS policy - situation analysis for Australia

With the exception of Queensland, NSW and ACT, there are no laws specifically addressing the regulation of ENDS in Australia. Instead, poisons, therapeutic goods, consumer law and tobacco control/product laws apply to ENDS.(58)

The regulatory arrangements applicable to ENDS are shared between the Commonwealth and the states and territories. Broadly, the Commonwealth has responsibility for approving the marketing

and supply of therapeutic goods and requiring suppliers to ensure that consumer products are safe and fit for purpose and that all representations or claims made in relation to the supply of products are truthful. States and territories have responsibility for restrictions on the sale and supply of nicotine, and may also be able to place restrictions on the sale and supply of ENDS devices and on their use in smoke free areas.

The following sections outline the current laws that apply to ENDS sales and possession. Following a description of the existing laws, we outline potential regulatory impacts and effects.

Australia – Existing Regulation Frameworks

Consumer law

Under the Commonwealth *Competition and Consumer Act 2010* (CCA), suppliers of consumer goods such as ENDS are responsible for ensuring the products they supply are safe, fit for purpose and comply with all applicable legal requirements. Potential suppliers of ENDS should ensure that ENDS, as well as the chemicals that their users are exposed to, are safe before they market the product. The CCA also requires that all representations or claims made in relation to the supply of consumer goods are truthful. Further, the Australian Competition and Consumer Commission (ACCC) advises consumers that the quality and safety of electronic cigarettes is not known.

Therapeutic goods regulation

The Commonwealth *Therapeutic Goods Act 1989* and associated regulations establish a uniform, national system of regulatory controls to ensure the quality, safety, efficacy and timely availability of therapeutic goods for human use. Responsibility for these regulatory controls lies with the Therapeutic Goods Administration (TGA) as the national regulatory authority for therapeutic goods.

Under the *Therapeutic Goods Act 1989*, "therapeutic goods" are defined as goods which are:

- represented in any way to be, or because of the way in which they are presented or for any other reason, are likely to be taken to be, for therapeutic use; or
- in a class of goods, the sole or principal use is, or ordinarily is, a therapeutic use.

One important outcome of the *Therapeutic Goods Act 1989* is that most therapeutic goods are required to be approved and included on the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in Australia unless there is an exemption. The legislation provides a number of mechanisms for exemption which allows access to therapeutic goods that have not been approved and included on the ARTG. Among other mechanisms, limited access to therapeutic goods that are not on the ARTG can occur under specific circumstances via the TGA's personal importation scheme (PIS). Further information regarding the PIS is provided below.

No ENDS products have, to date, been approved as a therapeutic good by the TGA.(58) The commercial importation and supply of ENDS (with or without nicotine) that make therapeutic claims is illegal in Australia unless authorised by the TGA. The Commonwealth *Standard for the Uniform*

Scheduling of Medicines and Poisons (SUSMP) is made under the *Therapeutic Goods Act 1989*. Among other purposes, the SUSMP classifies poisons into schedules, as recommendations to Australian states and territories. The scheduling classification sets the level of control on the availability of poisons which are implemented under state and territory poisons legislation. The SUSMP classifies nicotine as a schedule 7 poison that can only be included in products for therapeutic use or in tobacco products.(59) Nicotine for human consumption is then also listed as a schedule 4, prescription-only medicine, with exceptions given for approved therapeutic nicotine replacement products [NRT] that are absorbed through the skin or lining of the mouth. These approved NRT products are unscheduled and can be sold at retail outlets.(60)

As no ENDS have been approved by the TGA to date, the commercial supply (including sale) of nicotine for use in ENDS is currently illegal in Australia under state and territory poisons legislation. In specific circumstances, it may be lawful for individuals to import ENDS and/or liquid nicotine for personal therapeutic use via the PIS. Where ENDS users want to import liquid nicotine for this purpose, the importer must comply with the requirements of the PIS. This includes having a prescription from a medical practitioner registered in Australia, and ensuring that the nicotine when used for this specific purpose is legal under state or territory law. While the PIS may be used to import unapproved therapeutic goods into Australia, the TGA advises that these goods may not be approved for supply in Australia and therefore there are no guarantees about their safety or quality. Further information about the PIS is available at: https://www.tga.gov.au/personal-importation-scheme.

Australia – State and Territory Laws that apply to ENDS

ENDS devices are subject to different regulations across Australian States and Territories.

State and Territory laws that specify personal vaporisers/ENDS

Queensland

As of 1 January 2015, laws took effect in Queensland that specify that ENDS, referred to as, “personal vaporisers” are included in existing tobacco control laws as smoking products. This means that in Queensland, ENDS are:

- prohibited from being sold to minors;
- restricted from advertising, promotion or display at retail outlets;
- prohibited from use in smoke-free areas including indoor and outdoor smoke-free public places and in vehicles with children under 16 present; and
- prohibited from sale in vending machines.

NSW

On 24 June 2015, a Bill to amend the *Public Health (Tobacco) Act 2008* was passed in the Upper House, placing restrictions on the sale to minors, display and advertising of electronic cigarettes and accessories. The key points in this legislation are:

- it is an offence to sell electronic cigarettes and accessories to minors;
- it is an offence for adults to buy electronic cigarettes and accessories on behalf of minors;
- it is an offence to use electronic cigarettes in cars with children under 16 present;
- police have the power to seize an electronic cigarette that is in the possession of a person under the age of 18;
- new restrictions apply to the display and advertising of electronic cigarettes and accessories;
- a person is not able to operate or use a vending machine that dispenses electronic cigarettes and/or accessories on behalf of a minor;
- Electronic cigarette vending machines are only able to be located in areas restricted to adults over 18, such as licensed premises; and
- the sale of electronic cigarettes and accessories to a minor is subject to the same maximum penalty as the sale of a tobacco product to a minor in NSW - that is, $11,000 for an individual or $55,000 for a corporation and, for repeat offenders, $55,000 for an individual and $110,000 for a corporation.

The Act was implemented in two stages; the restrictions relating to sales to and on behalf of a minor commenced on the 1 September 2015, the remaining provisions relating to the display and advertising of products and the use of electronic cigarettes in cars with children under 16 present commenced on 1 December 2015.

Products are defined in NSW legislation as 'e-cigarettes and e-cigarette accessories' whether or not they have nicotine, and where they do contain nicotine, further offences may arise under the *Poisons and Therapeutic Goods Act 1966*. The Public Health (Tobacco) Amendment (E-cigarettes) Regulation 2015 excludes therapeutic goods ("authorised products") that are approved by the Therapeutic Goods Administration from the requirements of the Act relating to e-cigarettes.

ACT

On 5 April 2016 the ACT Legislative Assembly passed the *Smoke-Free Legislation Amendment Bill 2016* (the Bill) to restrict the sale, promotion and use of ENDS, referred to as "personal vaporisers". When the legislation tales effect in the latter half of 2016, it will amend the *Tobacco Act 1927*, *Smoke-Free Public Places Act 2003* and *Smoking in Cars with Children (Prohibition Act) 2011* to include ENDS as smoking products. The legislation will:

- prohibit sales to minors;
- ban sales by vending machine;
- restrict in-store and point-of-sale advertisements and displays;
- ban promotions, inclusion in customer reward schemes, sponsorships and product; giveaways; and
- prohibit use in smoke-free areas.

This approach follows a discussion paper in late 2014 that outlined policy options to protect the community from potential harms associated with personal vaporisers. The purpose of the discussion paper was to seek views on the range of options under consideration, including feedback on the associated costs and benefits. A summary of outcomes from the consultation has been published on the ACT Health website (www.health.act.gov.au). All non-confidential submissions to the consultation have also been made available on the site.

Tasmania

In June 2015, the Tasmanian Government issued a discussion paper outlining options for a public health response to electronic cigarettes. The consultation process closed on 24 July 2015 and information gathered will contribute to the Tasmanian Government decision-making process. The policy options included in the discussion paper were:

Options to prevent uptake:

1. continue with the status quo
2. public education;
3. part-regulation – restrictions on sale and advertising;
4. part-regulation - sale to people under 18 years of age;
5. part-regulation – sale of flavoured e-liquids; or
6. full-regulation of electronic cigarettes in the same way as tobacco.

Options to prevent renormalisation of smoking and protection from second-hand vapour:

1. continue with the status quo
2. prohibit use of electronic cigarettes in existing smoke free public places

South Australia

In June 2015 the South Australian House of Assembly established a Select Committee to investigate and report on e-cigarettes and any legislative and regulatory controls that should be applied to the advertising, sale and use of personal vaporisers. The South Australian Select Committee invited and received public submissions from July to August 2015 addressing the terms of reference. The final report of the Select Committee was tabled in Parliament on 24 February 2016 and contains 20 recommendations across the following seven areas:

- Sale
- Use
- Promotion
- Product safety and quality control
- Enforcement
- Research
- Taxation

The final report of the Select Committee on e-cigarettes is available from the Parliament of South Australian website - www.parliament.sa.gov.au.

Victoria

In November and December 2015, as part of a broader Review of the *Tobacco Act 1987*, targeted consultation was undertaken with key stakeholders on regulating electronic cigarettes. . On 24 May 2016, the Tobacco Amendment Bill 2016 was introduced into the Victorian Parliament. The Bill proposes to regulate electronic cigarettes in the same manner as tobacco products and is available at: http://www.parliament.vic.gov.au/static/www.legislation.vic.gov.au-bills.html.

Sale of ENDS

Currently, in Queensland, South Australia, Western Australia, and New South Wales, tobacco control laws prevent the sale of products that "resemble tobacco products". In NSW however these laws apply to toys and food products. Queensland specifically exempts "personal vaporisers" (ENDS) from the ban on sales of goods that resemble tobacco products.

In WA, a vendor of non-nicotine e-cigarettes was charged with being in breach of section 106(a) of the *Tobacco Products Control Act 2006* (WA), which states that "a person must not sell any food, toy or other product that is not a tobacco product but is (a) designed to resemble a tobacco product." Initially, the Defendant was acquitted but this was overturned on appeal in the WA Supreme Court.

The Defendant subsequently made application to the Full Court of the Supreme Court to appeal the decision. The matter was heard by the WA Supreme Court on 23 November 2015 and the appeal was unanimously dismissed in a decision handed down on 10 March 2016.

Under the South Australian *Tobacco Products Regulation Act 1997*, 'A person must not sell by retail any product (other than a tobacco product) that is designed to resemble a tobacco product'. This carries a maximum penalty of $5,000. Enforcement action in South Australia related to this provision has been based largely on the appearance of the e-cigarette being comparable to a normal cigarette or other tobacco product.

In Victoria, there are provisions in the *Tobacco Act 1997* to ban products that resemble a tobacco product, but no such ban order on ENDS has been issued. In the ACT and Tasmania, laws prevent the sale of a 'toy or food' that resemble, or is intended to represent, a tobacco product. Similarly in the Northern Territory, the law prevents the sale of 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.(60) To date, these laws have not been applied to ENDs.

Potential regulatory impacts under current regulatory framework

Australia's regulatory framework

Overall Australia's existing regulatory framework appears to have limited the marketing and prevalence of use of ENDS compared to countries with more liberal regulatory frameworks such as the USA and the UK. However, there is some evidence that the rate of increase of use of ENDS in Australia may be comparable to the UK over the period 2010-2013.(61)

However, there is not currently a consistent approach to ENDS regulation across Australia, which may be serving as a source of confusion to users, retailers, employers and the general public. Of particular note, are differences as to whether ENDS/personal vaporisers are included under laws that ban the sale of products that resemble tobacco products and how such laws are applied.

ENDS containing nicotine

Although it is illegal to sell ENDS containing nicotine in every Australian jurisdiction, testing of products available at retail outlets reveals that many do in fact contain nicotine and are mislabelled and being sold in direct violation of existing laws. In NSW for example, tests of e-liquid samples collected by NSW Health in 2013 showed that 70 per cent of the samples contained high levels of nicotine even though the label did not state nicotine as an ingredient.(62) ENDS product testing in Tasmania found similar results.(63) If consumers are unaware of the contents, mislabelling has additional impacts, such as increasing exposure to an addictive substance and increasing the risk of inadvertent poisoning.

Medical prescription

While the TGA has clarified that a medical prescription is considered a valid authority to import ENDS containing nicotine for personal therapeutic use, it may be unclear for consumers whether some state and territory poisons legislation allows the lawful possession of liquid nicotine (being a Schedule 4 poison) for therapeutic use in ENDS when obtained via the TGA's personal importation scheme. Requiring a medical prescription may pose a practical barrier for people who wish to legally purchase ENDS containing nicotine online for smoking cessation, as some medical practitioners may be unwilling or unable to provide a prescription for a product that has not been approved by the TGA. Additionally, ENDS users may be uninclined to obtain a valid prescription given how readily available products are both online and in local retail outlets. Additionally, it is currently unknown how many, if any, Australian doctors are providing prescriptions.

Labelling and packaging

Unlike for tobacco products and for therapeutic goods, Australia has not adopted any standardised labelling, packaging, or health warnings for ENDS. E-liquid bottles are often not labelled correctly. Even if a bottle says it does not contain nicotine it may still contain nicotine. Also, the risk of poisoning among children can increase if e-liquid bottles do not have child resistant packaging.

Standards

An unknown number of ENDS users are purchasing their supplies from the internet and overseas markets, despite poor controls on quality, nicotine content, and consistency of nicotine dose. The TGA advises that goods imported via the PIS may not be approved for supply in Australia and therefore there are no guarantees about their safety or quality.

While ENDS that make therapeutic claims, and/or are supplied with nicotine require approval from the TGA prior to marketing in Australia, those controls do not currently apply to non-nicotine containing devices if no therapeutic claims are made. This may impact on consumer safety. Finally, there is also some uncertainty regarding the nature and extent of standards that should be in place due to the limited state of the evidence.

Flavours

Again, unlike for traditional cigarettes, where fruit or confectionery flavours that may have increased appeal to children are banned in most Australian states and territories, ENDS are sold in a multitude of flavours, including many which may be appealing to young consumers. There are potential

inhalation risks related to flavourings used in ENDS. Further information about the health effects of flavourings in ENDS can be found in section 2.4 of the Appendix.

Advertising

ENDS advertising modalities include print media, television, social media, and at retail point-of-sale. As a result, responsibility for the marketing of ENDS is shared between the Commonwealth and states and territories. The following legislation may apply: the *Therapeutic Goods Act 1989*, the *Competition and Consumer Act 2010*, the *Tobacco Advertising Prohibition Act 1992*, and relevant state and territory tobacco regulations. Overall, controls on advertising of ENDS are limited and laws banning therapeutic claims are ambiguous. ENDS displays at retail outlets that sell these products are common and may appeal to young people. Additionally, ENDS print ads have appeared in magazines and free entertainment newspapers that, again, have high youth appeal. While current laws ban ENDS ads from making therapeutic claims or promoting tobacco use, people continue nonetheless to be exposed to these promotions.

In June 2016, the ACCC commenced separate proceedings in the Federal Court against two e-cigarette online retailers alleging that they made false or misleading representations and engaged in misleading conduct by making statements on their websites that their e-cigarette products did not contain toxic chemicals. The ACCC alleges that the two companies in question breached the Australian Consumer Law (ACL) by making representations on their websites that the e-cigarette products being sold did not contain carcinogens or toxic chemicals, and did not contain any of the chemicals found in conventional cigarettes. Further information is available at: https://www.accc.gov.au/media-release/accc-takes-action-against-e-cigarette-suppliers-for-alleged-misleading-%E2%80%9Cno-toxic-chemicals%E2%80%9D-claims

Smoke-free laws

It is possible that employees and non-users could be exposed to potentially harmful particulates and constituents in second-hand vapour from ENDS, especially in enclosed areas, should ENDS users congregate in large numbers as well as from nearby co-workers if ENDS are used in a workplace. Additionally, as some ENDS look very similar to traditional cigarettes and emit a vapour that may appear to be second-hand smoke, using these devices in smoke-free areas may cause confusion and conflict unless laws are clarified. As of June 2016, Queensland is the only state that includes ENDS under smoke-free environment laws (ACT will include ENDS under smoke-free environment laws in the latter half of 2016). Individual workplaces and companies have also adopted policies banning ENDS use. Qantas Airlines, for example, does not allow the use of ENDS while on board, but does permit them to be transported in carry-on luggage, but not in checked bags.(64)

3.2 ENDS policy - situation analysis for other jurisdictions

WHO Survey of ENDS regulation in Member States

In 2014, the WHO conducted a tobacco products survey on ENDS, as well as smokeless tobacco, reduced ignition propensity cigarettes, and novel tobacco products. (1) A total of 90 WHO Member States responded to the survey.

The survey found that the sale of ENDS with nicotine is banned in 13 of the 59 countries that regulate them. The majority of these 13 countries report that ENDS are still available to the public, either through illicit trade or cross-border Internet sales. Comprehensive advertising, promotion and

sponsorship bans on ENDS are in place in 39 countries, use of ENDS in enclosed public places is banned in 30 countries, premarket review is required by 19 countries, vendor licences are required by nine countries, and sales to minors laws were in place in 29 countries.

Table 1 WHO Survey ENDS regulation

Type of ENDS	ENDS regulated as					Not regulated or unknown
	consumer product	therapeutic product	tobacco product	other	total	
With nicotine	14 (27%)*	12 (6%)	22 (10%)	11 (6%)	59 (49%)	135 (51%)
Without nicotine	23 (35%)	0 (0%)	18 (7%)	12 (2%)	53 (44%)	141 (56%)

* The figure in parentheses after the number of countries indicates the percentage of the world population living in these countries

Source: Electronic nicotine delivery systems. Report by WHO.(1)

John Hopkins Bloomberg School of Public Health has summarised ENDS regulation of 123 countries in a comprehensive website.(65) Eighteen countries regulate ENDS as medicinal products, 26 countries regulate ENDS as tobacco products (or imitation/derivative/substitute products) and four countries regulate nicotine-containing ENDS as poisons.(65) Sale of all types of e-cigarettes is banned in 26 countries and three countries ban the use of e-cigarettes (Cambodia, Jordan and the United Arab Emirates).

Togo taxes ENDS at a ceiling of 45% and South Korea applies a special tax to ENDS.

The John Hopkins Bloomberg School of Public Health also reported that use of ENDS is banned in enclosed public spaces, including bars, restaurants and other workplaces in: Bahrain, Belgium, Colombia, Croatia, Ecuador, Greece, Honduras, Malta, Nepal, Nicaragua, Panama, Philippines, Serbia, South Korea and Turkey.

A selection of country case study regulations is outlined in the Appendix. This literature review found little in the way of regulatory evaluation of these policies and any impact they have on population-level smoking rates.

SECTION 4 POLICY APPROACHES

Noting the evidence presented in the literature summary (section 2) and the regulatory review (section 3) of this document, this section sets out for consideration possible policy approaches to minimise the risks associated with the marketing and use of ENDS in Australia.

4.1 WHO FCTC and international guidance on ENDS policy objectives

The World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC), to which Australia is a Party, aims to advance international cooperation to protect present and future generations from the preventable and devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke. Further information about

the WHO FCTC is available at:
http://www.who.int/fctc/WHO_FCTC_summary_January2015_EN.pdf?ua=1.

In mid-October 2014, the sixth session of the Conference of the Parties (COP 6) to the WHO FCTC discussed the WHO Report on ENDS. The report states that there is limited evidence on the health risks of ENDS to users and non-users; the efficacy of ENDS in helping smokers to quit smoking; and the effect of widespread ENDS use on nicotine dependence. The report, in items 12 through to 17, identifies a number of health risks of ENDS to users and non-users. The report identifies a number of regulatory objectives to minimise the risks related to ENDS and outlines a range of specific regulatory options for consideration. These options include addressing health claims, the use of ENDS in public places, advertising promotion and sponsorship, protection from vested commercial interests, product design and information, health warnings, surveillance and monitoring and sale to minors. The WHO report on ENDS also states that *'…Parties will need to consider the available national regulatory frameworks that could best provide solid regulatory grounds. Nevertheless, it is likely that a two-pronged regulatory strategy – regulating ENDS as both a tobacco product, in accordance with the provisions of the WHO FCTC, and as a medical product – would be necessary.'*

Noting the findings of the WHO Report on ENDS, Parties agreed to a decision pertaining to ENDS/ENNDS.(2) The decision invites Parties to consider a range of measures to address the challenges posed by ENDS/ENNDS, including prohibition or regulation '*as tobacco products, medicinal products, consumer products, or other categories, as appropriate, taking into account a high level of protection for human health*'. The decision also invites Parties to *'protect tobacco-control activities from all commercial and other vested interests related to ENDS/ENNDS, including interests of the tobacco industry'.*

4.2 National guidance on tobacco control and ENDS policy objectives

All policy approaches canvassed in this section should be seen within the overarching strategic context of *harm minimisation* as defined in the Australian National Drug Strategy 2010–2015.(66) This encompasses the three pillars of *demand reduction, supply reduction and harm reduction* being applied together in a balanced way. From a tobacco control perspective, demand reduction means strategies and actions that prevent the uptake and reduce the use of tobacco and support people to quit smoking. Supply reduction means strategies and actions that control, manage and/or regulate the availability of tobacco. Harm reduction means strategies and actions that primarily reduce the adverse health consequences of tobacco use.

The overarching assumption when outlining the possible policy approaches for minimising the risk posed by ENDS will be that policies must, as much as is possible to determine, be consistent with the objectives of the *National Tobacco Strategy 2012-2018*. These are to:

- prevent uptake of smoking;
- encourage and assist as many smokers as possible to quit as soon as possible, and prevent relapse;
- reduce smoking among Aboriginal and Torres Strait Islander people, groups at higher risk from smoking, and other populations with a high prevalence of smoking;

- eliminate harmful exposure to tobacco smoke among non-smokers reduce harm associated with continuing use of tobacco and nicotine products;
- ensure that tobacco control in Australia is supported by focused research and evaluation; and
- ensure that all of the above contribute to the continued denormalisation of smoking.

In March 2015, the Australian National Health and Medical Research Council [NHMRC] issued a statement on e-cigarettes citing that there is insufficient evidence to conclude whether e-cigarettes can benefit smokers in quitting, or about the extent of their potential harms.(67) The NHMRC recommended that health authorities act to minimise harm until evidence of safety, quality and efficacy can be produced.

A detailed policy situation analysis for Australia is set out earlier (refer to section 3.1). Key summary points of the status quo are provided here for ease of reference.

Current nicotine regulation

- Except when used in approved therapeutic preparations, or where it is present in tobacco prepared and packed for smoking, nicotine is a schedule 7 poison and cannot be manufactured, sold, or supplied without a valid licence;
- The TGA permits ENDS users in Australia who wish to legally use nicotine in their vaping devices, for therapeutic purposes such as quitting smoking, to obtain a valid prescription from a medical practitioner. However, the nicotine for use in ENDS must also be legal under state or territory law, the medical practitioner must be willing to prescribe it and the importer must comply with the conditions of the TGA PIS;
- Where therapeutic claims are made in relation to nicotine free ENDS, importers must comply with the conditions of the TGA PIS;
- It is legal to possess an ENDS that is nicotine-free in all states and territories; and
- Regulation of the sale of ENDS that are free of nicotine and do not make therapeutic claims varies across Australian states and territories.

Some potential ENDS regulation impacts from the current regulatory framework

- Australia regulatory framework for ENDS appears to have helped to limit the marketing and prevalence of use of ENDS;
- ENDS containing nicotine are available and may be mislabelled as nicotine-free at some Australian retail outlets;
- People under age 18 can legally purchase ENDS in all states except WA, Queensland, NSW, and, in the latter half of 2016, ACT, and given the practices of some ENDS suppliers, it seems likely they are purchasing products containing nicotine;
- ENDS containing fruit or confectionery flavours may have added appeal to young people and further be encouraging purchase and use;
- There may be harms from active and passive exposure to the use of ENDS that contain flavourings, nicotine or other chemicals in ENDS;
- Although requiring a medical prescription to import ENDS containing nicotine for therapeutic use may minimise any harmful effects from the use of ENDS, it may be a barrier for those wishing to use ENDS as an aid in quitting smoking;
- ENDS with or without nicotine are not held to any manufacturing standard and may be mislabelled;

- Some manufacturers and retailers may use general health claims to undermine prohibitions on therapeutic claims or false or misleading statements. General statements that imply a reduced level of harm, or an increased level of health or safety may not amount to therapeutic claims under the *Therapeutic Goods Act 1989,* or false and misleading statements under the *Competition and Consumer Act 2010*;
- Lack of product labelling standards, no requirements for child resistant packaging, no standards to minimise risk of explosions and fires caused by poor quality products, and no mandated health warnings may risk exposing consumers to harm;
- Allowing ENDS to be advertised may act as another enticement for people, particularly youth, to purchase ENDS;
- It is unclear if smokefree environment laws that do not include ENDS are offering adequate protection to employees and the public from the potentially harmful particulates and constituents in ENDS vapour, or protect against renormalisation of smoking behaviours.

4.3 Possible policy approaches to minimise the risks associated with the marketing and use of ENDS

Seven possible, high-level, policy approaches are proposed for consultation. It is **HIGHLY** recommended that readers consider all approaches prior to forming opinions on which policy approach is most suitable. The preceding document and appendix is also highly recommended as essential reading prior to assessing the policy approaches.

In brief, the seven policy approaches are as follows:

Policy approach 1: Maintain the status quo
Policy Approach 2: Increase awareness and enforcement of and compliance with existing legislation
Policy approach 3: Regulate ENDS as medicines
Policy approach 4: Regulate ENDS as tobacco products
Policy approach 5: Regulate ENDS as consumer products
Policy approach 6: Develop an ENDS regulatory framework
Policy approach 7: Adopt measures to ban ENDS

The policy approaches are fully outlined in table 2 below. The policy approaches should be considered in the context that Australia currently applies a mixed approach to the regulation of ENDS via existing frameworks for tobacco control, therapeutic goods and consumer goods. The policy approaches are not meant to be mutually exclusive. For example, some stakeholders may prefer ENDS to be regulated as medicines, but also to include ENDs in tobacco control regulations that prohibit use in smokefree areas.

For the purposes of clarity **only brief points are made in table 2**, it is essential to review the text in the policy situation analysis and the preceding section on the policy discussion for full details on the context and possible impacts.

Analysis of ENDS policy concerns

Below is a high-level summary of some of the priority concerns when considering ENDS policy approaches.

Nicotine regulation

Article 5.2(b) of the WHO Framework Convention commits Parties not only to preventing and reducing tobacco consumption and exposure to tobacco smoke but also to preventing and reducing nicotine addiction independently from its source. Therefore, while medicinal use of nicotine is a public health option under the treaty, recreational use is not. WHO has also recommended that ENDS only be made available to existing smokers.(1)

In Australia, no ENDS products have been subject to a transparent regulatory process or safety standard. Additionally, importing products from overseas and online outlets compromises the accuracy of product labelling and what can be known about the actual ingredients contained within the products.

There are strict controls regarding the commercial supply (including sale) of nicotine. However, it may be unclear for consumers whether state and territory poisons legislation precludes the lawful possession of liquid nicotine (i.e as a Schedule 4 poison) for therapeutic use in ENDS when imported via the TGA's personal importation scheme. The avenue for obtaining liquid nicotine under this specific circumstance may warrant further clarification/agreement by the states and territories.

Overall, Canada's and Australia's existing regulatory framework appears to have helped to limit the marketing and prevalence of use of ENDS compared to countries with more liberal regulatory frameworks such as the USA and the UK.

There is not currently a consistent approach to ENDS regulation across Australia, which may be serving as a source of confusion to users, retailers, employers and the general public.

Significant risks associated with liberalising the supply of nicotine include that:

- Prevalence of the use of ENDS containing nicotine is likely to increase at a point in time when the overall benefits/harms of market proliferation are not known.
- If governments are required to provide resources to implement and support options to allow ENDS containing nicotine on the market while regulating to minimise their risks, it weakens arguments that ENDS are solely a market-based solution to reducing the harms from smoking related disease. These concerns are especially important given that the benefits of ENDS are not agreed and there are concerns they may be harmful.

Sales to young people

Our literature review suggests there is little debate or controversy in banning the sale of ENDS to young people and such a policy would be consistent with norms in other jurisdictions. Evidence regarding the prevalence of ENDS use amongst young people aged 14 – 17 years is of concern (4.3% having used ENDS in the last 12 months) and provides support for the need to ensure that young people do not have access to such products. There are concerns about the potential influence of ENDS use on tobacco use. Maintaining the low rates of smoking amongst young people is paramount.

Equally, this policy measure should not be considered a comprehensive approach to ENDS, but just one possible measure within a suite of measures. Similar laws have long been in place for the sale of tobacco products and it is well recognised that they form only a part of a comprehensive approach to tobacco control regulation. Tobacco retailers are already well versed in and equipped for restrictions of sales to minors and including ENDS in such laws is unlikely to incur additional costs on tobacco retailers.

Smoking cessation and health claims

The review of the evidence has shown that, while the short-term health effects of ENDS use appear to be minimal, there is insufficient evidence available to determine the long-term health effects of ENDS. Additionally, available evidence is equivocal as to the usefulness and effectiveness of ENDS as a smoking cessation aid. Therefore, there is sufficient cause for concern that allowing manufacturers to make therapeutic claims without TGA approval would be inappropriate at this time. Current regulations allow general health related claims, such as claiming ENDS are a "less harmful alternative" and allow users to "regulate your nicotine intake." Such claims have been widely documented in Australian ENDS promotions. ENDS making specific therapeutic claims are not permitted for sale under existing Australian regulations and any ENDS that do make such claims are to be referred to the TGA.

ENDS use in smoke-free areas

There is limited evidence available to determine whether exposure to second-hand vapour has meaningful health effects, in either the short- or long-term. However, the WHO report on ENDS states that "smoke free policies are designed not only to protect non-smokers from second hand smoke, but also to provide incentives to quit smoking and to denormalize smoking as adolescents are particularly vulnerable to visual cues and social norms."(1) Smoke-free laws as applied to conventional tobacco products are well received, readily enforced, and common in Australia. These laws are primarily the responsibility of individual states and territories.

Advertising of ENDS

The evidence that advertising increases ENDS use, particularly among young people, is cause for concern. Given the propensity for nicotine addiction and other possible health harms, advertising such products may be counter to public health goals. Tobacco retailers are already well versed in and equipped for point-of-sale display restrictions and including ENDS in such laws is unlikely to incur additional costs on businesses.

Any ENDS advertising must however comply with the Commonwealth *Tobacco Advertising Prohibition Act (1992)* and not be deemed to promote smoking or tobacco products in any way. Additionally, advertisements for ENDS must not make, or imply, therapeutic claims unless the product has been approved by the Therapeutic Goods Administration (TGA) as a therapeutic good for supply in Australia.

Personal importation of ENDS

The personal importation of ENDS is an aspect of the status quo. None of the policy approaches address the quality, safety, and efficacy of products imported directly by the consumer.

Additional and emerging products

It is important to note that the priority concerns noted above focus on ENDS (with or without nicotine). However, when considering these concerns, Australian governments may also wish to assess their relevance to a broader range of products available which deliver an aerosol and/or

vapour via inhalation. The *Tobacco and Other Smoking Products Act 1998* (Qld) was recently updated to include the term 'personal vaporiser'; and ACT legislation will soon be updated to include this term. Examples of these products have been provided in sections 1.2 and 2.3 in the Appendix, respectively.

Table 2 Policy approaches to minimise the risks associated with the marketing and use of ENDS in Australia

Policy Approach and Description	How the approach addresses the problem	Potential positives of the approach	Potential drawbacks of the approach
1. Maintain the status quo • Continues with a mixed approach to the regulation of ENDS via existing frameworks for tobacco control, therapeutic goods and consumer goods. • Refer to section 3.1 for a description of the status quo.	• Affirms and assures that should an ENDS product be developed that has provable therapeutic benefits there is a regulatory mechanism to bring such a product to the Australian market.	• Requires no additional government action or investment.	• There is a risk that consumers will be misled as to the benefits and risks of ENDS use by the generalised health- or cessation-related claims that are currently permitted under existing regulations. • Does not provide for consistent protection across Australia, as there are some differences in regulations across states/territories.
2. Increase awareness and enforcement of and compliance with existing regulations • Improve compliance with existing regulations by implementing retailer education, compliance and enforcement strategies.	• Educating retailers about, and increasing enforcement of and compliance with, existing regulations pertaining to the sale of ENDS could reduce the sale of mislabelled products and the sale of illegal products containing nicotine.	• Does not require the development of additional regulations and so can be implemented relatively quickly • May improve stakeholders' understanding of some of the existing regulations that apply to ENDS and some of the risks that ENDS may pose.	• Reaching all ENDS vendors is likely to be difficult given they are not required to be registered or licensed. • Funding for education, enforcement and compliance activities would be necessary. • There are ambiguities in the existing regulatory framework that may impede the effectiveness of education, compliance and enforcement activities if this approach was implemented in isolation. For example, it is unlikely to reduce confusion among stakeholders regarding which devices should

Policy Approach and Description	How the approach addresses the problem	Potential positives of the approach	Potential drawbacks of the approach
			be treated as therapeutic goods and which devices would not be treated as therapeutic goods.
3. Regulate ENDS as medicines • Declare **all** ENDS (with or without nicotine) as therapeutic goods under the *Therapeutic Goods Act 1989*. • In effect this would require all ENDS suppliers meet safety, quality and efficacy standards in order to commercially supply and market products. • Decision makers would need to consider when to remove ENDS without nicotine from the commercial market given that no ENDS products have been approved by the TGA to date. • Declaring all ENDS as therapeutic goods may not necessarily preclude their lawful importation for personal therapeutic use.	• May address some ambiguity as currently there is confusion among stakeholders regarding which devices should be treated as therapeutic goods and which devices should not be treated as therapeutic goods. • Ensures that prior to being marketed in Australia, all commercially supplied ENDS or refillable liquids: ○ do not contain dangerous chemicals; ○ have adequate premarket research demonstrating their safety and quality – specifically, adequate provision of pharmacological and toxicological data, and clinical efficacy; and ○ have access and advertising restrictions that are proportionate to the level of risk and benefits to individual	• Minimises population health impacts, such as increases in ENDS use by non-smokers, when population health outcomes are unclear. • No new legislative mechanism required and expertise already in place which will minimise government investment. • Responsibility and cost is largely on suppliers. • Consumer access to and marketing of ENDS remains flexible and readily changed in light of new evidence. • Sends a clear message that ENDS should only be available to existing smokers for therapeutic use.	• Does not address all the risks, additional measures may be required from tobacco control laws, such as prohibiting use of ENDS in smokefree areas. • Reduces access to products that some consumers may be using in place of cigarettes. • The TGA's assessment and approval of certain therapeutic goods can be a lengthy process. • The nature and extent of ENDS users that are not using the devices for therapeutic use would need to be further considered.

Policy Approach and Description	How the approach addresses the problem	Potential positives of the approach	Potential drawbacks of the approach
	products. For example, any products demonstrated to be low risk could be sold at retail outlets, high-risk products would require a prescription and be subject to more stringent advertising restrictions.		
4. Regulate ENDS as tobacco products • Apply selective/appropriate tobacco control measures to all ENDS, such as bans on sales to minors, price measures and smokefree environment laws	• A number of tobacco control laws already apply to ENDS across a range of jurisdictions. • Comprehensive tobacco control regulations have been highly successful, especially in preventing young people from taking up smoking, applying the same approaches is likely to result in avoiding increased ENDS uptake among non-smokers • The extent to which tobacco control measures would address issues associated with ENDS would largely depend on the nature and extent of the tobacco control measures applied.	• The general public is highly supportive of tobacco control • Some of these measures may reduce the risk of ENDS serving as a gateway to tobacco use.	• ENDS would remain on the market, and their contents/composition would be largely unregulated. • Tobacco control legislation is guided exclusively by decreasing product use. Assessing if ENDS should be regulated as a tobacco product then depends on whether the regulation of ENDS should also be exclusively guided by minimising use. • Little evidence as yet available on whether applying tobacco control policies to ENDS would encourage or discourage smokers who would have otherwise not quit smoking to switch to exclusive ENDS use.
5. Regulate ENDS as consumer products	• ENDS are already treated as consumer products under	• Potentially minimises some of the known risks of ENDS, such	• Compared to therapeutic goods and tobacco control

Policy Approach and Description	How the approach addresses the problem	Potential positives of the approach	Potential drawbacks of the approach
• Implement standards for ENDS and/or their components under the Commonwealth *Competition and Consumer Act 2010*. This could include but may not be limited to: emissions, ingredients, packaging, marketing etc. • The intention of this approach is to implement standards on any ENDS device and/or component(s) on the market. • Standards implemented under this approach would build on the existing framework that applies to ENDS and nicotine. For instance, they could also apply to any ENDS product (containing nicotine) that had received approval for marketing from the TGA (in addition to therapeutic standards).	Australian Consumer Law. • Additional controls for ENDS implemented under the Commonwealth *Competition and Consumer Act 2010* may potentially reduce the risks associated with the use and/or mishandling of individual products.	as: exposure to toxic flavourings and other harmful contents such as heavy metals, spontaneous fires and explosions and accidental poisonings. • Follows other jurisdictions that have developed product standards for ENDS, such as the revised EU Tobacco Products Directive which covers all consumer ENDS sold in the EU.	approaches, standards implemented through consumer legislation in isolation may create an unwarranted perception of safety.
6. Develop an ENDS regulatory framework • Develop a comprehensive ENDS regulatory framework. • This approach could include but may not be limited to product standards.	• Developing a comprehensive and well-designed regulatory framework that ensures the domestic market is well controlled and continuously monitored could assist in avoiding any unwanted outcomes such as increased	• An ENDS framework could allow users highly controlled, local access to a product that does contain nicotine, but is likely less dangerous than conventional tobacco products. • An ENDS framework could be structured to capture future	• Developing an exclusive ENDS framework could be costly and will likely take time to create and implement. • Developing the standards, including but not limited to: emissions, ingredients, nicotine strength and packaging will

Policy Approach and Description	How the approach addresses the problem	Potential positives of the approach	Potential drawbacks of the approach
	uptake among non-smokers/youth and dual use of ENDS and traditional cigarettes among smokers.	development and innovations in tobacco and tobacco-like products.	require more widespread consultation and additional resources. • Current evidence is not definitive that standards will prevent potential long-term harms associated with the use of ENDS nor guarantee products will not appeal to youth and/or non-smokers.
7. Adopt measures to ban ENDS • Prohibit the commercial importation or commercial supply of **all** ENDS (with or without nicotine).	• Currently, the retail sale of ENDS containing nicotine is banned in all states and territories via their existing medicines and poisons legislation. Additionally, the retail sale of all ENDS (with or without nicotine) is currently banned in effect in Western Australia via the *Tobacco Products Control Act 2006* (WA). • Additional controls to ban ENDS may reinforce and clarify for consumers that ENDS have not been demonstrated to be a safe product (with or without nicotine) and that ENDS containing nicotine are likely to be addictive and as such should not be available for domestic	• Relatively straightforward to legislate.	• Depending on the nature of the ban considered, considerable government resources may be required. • Severely limiting the supply of ENDS may be seen as a contradiction when more harmful conventional cigarettes are still widely available in Australia. • Enforcement may be difficult, and effectively monitoring importation and use of an illegal product is more challenging. • Reduces access to products that some consumers may be using in place of cigarettes.

Policy Approach and Description	How the approach addresses the problem	Potential positives of the approach	Potential drawbacks of the approach
	supply.		

AUTHOR DISCLOSURE STATEMENT

None of the authors have engaged in work including but not exclusive to government relations work or regulatory affairs work for, or associated with, the tobacco industry or the ENDS industry, or intends to do so in the future.

In 2000-1 Chapman was a member of a group of researchers that received research funding from GlaxoSmithKline for researching beliefs about smoking cessation. Australian Smoking Cessation Research Consortium (R Borland, S Chapman, K Jamrozik, L Roberts, C Silagy) 2000-2001. Funding received for: Oakes W, Chapman S, Balmford J, Borland R, Trotter L. "Bulletproof skeptics in life's jungle": which self-exempting beliefs about smoking most predict lack of intention to quit? Prev Med 2004;39:776-82.

None of the other authors have undertaken work for, or has had an association with, pharmaceutical companies that market smoking cessation therapies.

Authors Freeman, Chapman, Bellew and Walsberger have publicly advocated for increased ENDS regulation. Freeman and Chapman have published research and opinion pieces on ENDS and tobacco harm reduction.

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