Australian Government

Department of Health

Australian Government Department of Health

Submission to the Select Committee on Tobacco Harm Reduction

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Content

Glossary

Term	Definition
AICIS	Australian Industrial Chemicals Introduction Scheme
AMA	Australian Medical Association
APS	Authorised Prescriber Scheme
CCPSA	*Canada Consumer Product Safety Act*, Canada
CEO	Chief Executive Officer
COP	Conference of the Parties
FCTC	Framework Convention on Tobacco Control
FDA	Food and Drug Administration, United States
ENDS	Electronic Nicotine Delivery Systems
ENNDS	Electronic Non-Nicotine Delivery Systems
EU	European Union
IC Act	*Industrial Chemicals Act 2019*
NCEPH	National Centre for Epidemiology and Population Health
NHMRC	National Health and Medical Research Council
NRT	Nicotine replacement therapy
NZ	New Zealand
Poisons Standard	The Standard for the Uniform Scheduling of Medicines and Poisons
RACGP	Royal Australian College of General Practitioners
RCTs	Randomised Controlled Trials
SAS	Special Access Scheme
SE Act	*Smoke-free Environments Act 1990*, New Zealand
TGA	Therapeutic Goods Administration
TG Act	*Therapeutic Goods Act 1989*
TPD	Tobacco Products Directive, European Union
TSANZ	Thoracic Society of Australia and New Zealand
TVPA	*Tobacco and Vaping Products Act*, Canada
UK	United Kingdom
US	United States
WA	Western Australia
WHO	World Health Organization

Executive Summary

The Australian Government is taking a precautionary approach to e-cigarettes, due to current evidence that raises concerns about direct health harms associated with e-cigarette use, concurrent use of e-cigarettes with tobacco products, and the potential for e-cigarette use to lead to nicotine addiction and tobacco use, particularly among youth.

All smoking cessation products lawfully available for sale in Australia have been evaluated by the Therapeutic Goods Administration (TGA) for safety and efficacy and have been registered with the TGA. There are no restrictions on who might apply to the TGA to market a smoking cessation product in Australia. However, at this time no e-cigarettes have been approved by the TGA for this purpose.

There is no international consensus on the most appropriate regulatory framework for e-cigarettes and there is significant variation in the regulatory treatment of e-cigarettes within, and between, countries. In Australia, the regulatory framework draws on existing laws that may apply to tobacco products, poisons, therapeutic goods, consumer goods and industrial chemicals. However, there remains variation between states and territories in their regulatory approaches to e-cigarettes.

It is important that e-cigarette regulation takes a comprehensive, evidence-based and proportionate approach that can be adapted as new evidence emerges. There is also a need to closely monitor and eliminate marketing strategies employed by the tobacco and e-cigarette industries to circumvent tobacco control efforts. Regulation should aim to protect the Australian community from the potential harms of e-cigarette use and ensure that e-cigarette use does not undermine Australia's achievements in tobacco control and public health.

On 23 September 2020, the TGA announced an interim decision that would clarify the scheduling of nicotine in the Standard for the Uniform Scheduling of Medicines and Poisons (the Poisons Standard).[1] The proposed changes, if made final, would mean that e-cigarette products containing nicotine could only be lawfully supplied with a prescription from an Australian registered medical practitioner in specific circumstances and subject to state and territory legislation. Other affected products would also include heated tobacco products, chewing tobacco, snuff and other novel nicotine products. The proposed changes are consistent with existing state and territory legislation that prohibits the sale of nicotine containing e-cigarettes and nicotine liquids for use in e-cigarettes. Public consultation on the interim decision will be open until 12 November 2020, with a final decision anticipated in mid-December 2020.

Australia continues to invest in tobacco control measures that have resulted in long-standing progress in reducing smoking prevalence. Notably, smoking rates have continued to decline in Australia in recent years without the surge in uptake of e-cigarettes that has been observed in some other countries, particularly among youth.[2, 3, 4]

Ministers in all Australian jurisdictions have agreed that any change to the regulation of e-cigarettes in Australia will have protecting the health of children and young people as its primary focus, as well as protecting the health of existing adult cigarette smokers.[5]

Part one: Australia's policy and regulatory framework for e-cigarettes

1.1 Introduction

Electronic cigarettes, also known as e-cigarettes, are devices for making vapour for inhalation (vaping). Nicotine vaping products comprise components designed to deliver an aerosol via inhalation. Nicotine vaping products:

- may or may not contain tobacco;
- may to a greater or lesser extent resemble tobacco products and/or simulate the act of smoking;
- may or may not use electrical power to generate an aerosol; and
- include, but are not limited to, e-cigarettes.

Given that e-cigarettes are likely to be the most common type of nicotine vaping product on the Australian market, the focus of this submission is on e-cigarettes.

Certain e-cigarette products marketed globally are labelled as being nicotine free, even though some have been found to contain nicotine.[6] Some e-cigarette products may also be used to deliver other substances such as cannabis. However, given that the majority of e-cigarette products marketed globally are likely to contain nicotine,[7] the focus of this submission is on e-cigarette products containing nicotine unless stated otherwise.

1.2 Summary of Australian Government Department of Health position on e-cigarettes

All Australian governments are taking a precautionary approach to e-cigarettes. This position is based on the need to consider the overall impacts these products pose to population health, including on non-smokers and smokers. The precautionary approach is consistent with the current regulatory controls governing access to nicotine for use in e-cigarettes in Australia.

The Australian Government Department of Health's (the Department) concerns regarding the marketing and use of e-cigarettes are in the context of the current state of evidence of the risks these products pose to population health. These risks relate to the direct harms e-cigarettes may pose to human health, dual use of e-cigarettes with tobacco products, and the potential for e-cigarette use to lead to nicotine addiction and tobacco use, particularly among youth.[8, 9, 10] At a population level, evidence is not sufficient to support any widespread promotion of e-cigarette use for smoking cessation or harm reduction.[11, 12, 13, 14]

Notably, smoking rates have continued to decline in Australia in recent years without the increase in uptake of e-cigarettes that has been observed in some other countries, particularly among youth.[2, 3, 4]

1.3 Policy context for Australia's approach to e-cigarettes

World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC)

The WHO 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. The WHO FCTC and its guidelines commit nations to implementing a range of demand and supply-side tobacco control measures and to act to protect these measures from commercial and other vested interests of the tobacco industry in accordance with national law. The WHO FCTC also obliges Parties to adopt and implement effective measures to prevent and reduce nicotine addiction.[15]

Australia's policy and regulatory response to e-cigarettes continues to be guided by decisions of the Conference of the Parties (COP) to the WHO FCTC, the governing body of the WHO FCTC. The COP has previously invited Parties to take measures in relation to Electronic Nicotine Delivery Systems (ENDS)/Electronic Non-nicotine Delivery Systems (ENNDS) and to consider prohibiting or otherwise regulating them, including as tobacco products, medicinal products, consumer products, or other categories, as appropriate, taking into account a high level of protection for human health. The COP has also invited Parties to apply regulatory measures to prohibit or restrict the manufacture, importation, distribution, presentation, sale and use of ENDS/ENNDs.[16]

Principles that underpin the current approach to e-cigarettes in Australia

On 28 November 2019, the Ministerial Drug and Alcohol Forum, which comprised Commonwealth, state and territory health and law enforcement Ministers, agreed to updated principles that underpin the current policy and regulatory approach to e-cigarettes in Australia.[5] The updated principles reaffirm the precautionary approach to e-cigarettes being undertaken by all Australian governments. The principles emphasise that any change to the regulation of e-cigarettes in Australia will have protecting the health of children and young people as its primary focus and goal, and that protecting the health of existing adult cigarette smokers is a second key goal.

1.4 Current legislation applicable to e-cigarettes in Australia

E-cigarette regulation is a shared responsibility between the Commonwealth, state and territory governments. The current regulatory framework draws on existing laws that may apply to tobacco products, poisons, therapeutic goods, consumer goods and industrial chemicals. The possession, supply and/or sale of nicotine for use e-cigarettes is currently illegal under state and territory legislation, unless exempt in specific circumstances and when accessed by patients on prescription. The possession of nicotine for use in e-cigarettes without a prescription is illegal in all states and territories except South Australia.

Therapeutic goods

The Commonwealth *Therapeutic Goods Act 1989* (TG Act) and associated regulations provide for the establishment and maintenance of a national system of controls to ensure the quality, safety, efficacy and timely availability of therapeutic goods.[17]

Products claiming to help people quit smoking are therapeutic goods, regardless of whether they contain nicotine. It is illegal to import or sell products in Australia that make therapeutic claims, unless they have received market authorisation by the TGA or they are otherwise exempt or subject to an approval or authority granted by the TGA.

All smoking cessation therapy products (such as nicotine replacement therapies) entered on the Australian Register of Therapeutic Goods are lawfully available for commercial sale in Australia and have been evaluated by the TGA for quality, safety and efficacy. To date, the TGA has not approved any e-cigarettes for smoking cessation.

If e-cigarettes (and/or their components including the liquids used in e-cigarettes) are detected at the border and appear to make a therapeutic claim, such as for smoking cessation (regardless of nicotine content), the goods may be referred by the Australian Border Force to the TGA. The TGA would advise whether the goods are unlawful therapeutic goods, and whether they are appropriately dealt with under the *Customs Act 1901* including being detained, seized and possibly destroyed.

At present, the importation of e-cigarettes and/or their components that do not make claims of therapeutic use as an aid for smoking cessation, do not constitute therapeutic goods and therefore do not come within the TGA's regulatory remit, regardless of their nicotine content.

In some circumstances, it may be lawful for people to import and possess nicotine for use in e-cigarettes for up to three months of personal therapeutic use under the TGA's Personal Importation Scheme. Under the scheme, an importer must hold a written authority issued by an Australian registered medical practitioner and the possession and use of nicotine for this purpose must also be legal within the importer's state or territory.

There are also other avenues that are available for an individual to be supplied with unapproved therapeutic goods, including the Special Access Scheme (SAS) and Authorised Prescriber Scheme (APS). Under these schemes, medical practitioners are required to apply to access the unapproved therapeutic good on behalf of their patient, and they are required to formally prescribe them to the patient.

While the SAS and APS may be used to supply unapproved therapeutic goods in Australia, they are intended to enable access to products in cases when suitable TGA-approved alternatives that achieve the same therapeutic purpose are not available on the Australian market. Unapproved goods have not been evaluated in Australia by the TGA and therefore there are no guarantees about their quality, safety or efficacy.[18]

Medicines, Chemicals and the Poisons Standard

The Poisons Standard is a legislative instrument made under the TG Act which supports a national classification system that controls how 'poisons' (medicines and chemicals) are made available to the public. Medicines and chemicals are classified into Schedules in the Poisons Standard according to the risk of harm and the level of access control required to protect public health and safety. Substances or groups of substances may be considered for potential scheduling (or rescheduling) on the basis there might be a public health benefit if they were down-scheduled or up-scheduled. Decisions regarding the scheduling of substances for inclusion in the Poisons Standard are made by the Secretary of the Department. In practice, decisions for medicines scheduling are made by their delegate who is a senior medical officer in the Department. Anyone can lodge an application to the TGA to amend the Poisons Standard.

The Poisons Standard is implemented and enforced by the state and territories, through relevant drugs, poisons and controlled substances legislation. Each state and territory has its own laws that determine the availability of a particular medicine or poison, and how it is to be packaged and labelled. However, state and territory governments classify the majority of medicines and poisons (such as nicotine) in accordance with the Poisons Standard to achieve a uniform national approach to the scheduling of substances and uniform labelling and packaging requirements.

The impact of the scheduling of nicotine under the Poisons Standard would be that it is unlawful to import nicotine for use in e-cigarettes for smoking cessation without a doctor's prescription. *For further information on the scheduling of nicotine, see Section 1.5.*

Chemical safety and the Australian Industrial Chemicals Introduction Scheme (AICIS)

A range of Australian and state and territory government agencies share regulatory responsibility for chemical safety, with each chemical being regulated according to its use, whether as a therapeutic good, veterinary medicine, pesticide, food additive or industrial

chemical (which includes any chemical with a use not falling into one of the other categories). A chemical with a therapeutic use, such as a chemical that aids in the cessation of cigarette smoking by influencing, inhibiting or modifying a physiological process, is regulated under the TG Act.

AICIS is a statutory scheme established by the Commonwealth *Industrial Chemicals Act 2019* (IC Act) that is administered by the Department. The IC Act regulates the introduction into Australia of individual chemicals (whether alone or contained in a mixture). AICIS does not register products or articles and registration obligations under the IC Act do not require importers or manufacturers to advise the types of imported or manufactured products that contain industrial chemicals.

Under AICIS, introducers must categorise their chemical introduction against objective criteria. Chemical introductions categorised as medium to high risk to human health or the environment are required to have a pre-market risk assessment before they can be introduced into Australia. Following a pre-market assessment on the introduction and intended use of industrial chemicals, recommendations are made to relevant risk management bodies who regulate and enforce appropriate chemical use. The regulatory requirements under the IC Act also apply to industrial chemicals in e-cigarettes.

Chemicals used in e-cigarette liquids are a specified class of introduction, under the definition 'introductions of an industrial chemical for an end use in a personal vaporiser'. Additional, or different, requirements relating to hazard information, reporting or record keeping apply to specified classes of introductions. This is due to an increased level of concern for these introductions because of greater potential for particular hazards or high levels of human or environmental exposure. The requirements for chemicals in e-cigarette liquids are specified by the Industrial Chemicals (General) Rules 2019 and associated Industrial Chemicals Categorisation Guidelines.[19] Industrial chemicals specifically for use in e-cigarettes have not been assessed under the IC Act (that commenced in July 2020) or its predecessor, the Industrial Chemicals Notification and Assessment Act 1989.

Additional state and territory laws applicable to e-cigarettes

All state and territory governments have tobacco control laws with provisions that relate to e-cigarettes. Seven state and territory jurisdictions[i] have amended their tobacco control laws to treat the advertising and sale of e-cigarettes in a similar manner to conventional tobacco products in their respective jurisdictions. These jurisdictions have also prohibited the use of e-cigarettes in legislated smoke-free areas.

In Western Australia (WA), it is an offence under the WA *Tobacco Products Control Act 2006* to sell products that resemble tobacco products, regardless of whether they contain nicotine or not.[20] In a Supreme Court of Western Australia decision, e-cigarettes were found to resemble a tobacco product.[21]

The possession, supply and/or sale of nicotine for use in e-cigarettes is currently illegal under state and territory legislation, unless exempt in specific circumstances and when accessed by patients on prescription. The possession of nicotine for use in e-cigarettes without a prescription is illegal in all states and territories except South Australia.

[i] South Australia, Queensland, New South Wales, the Australian Capital Territory, the Northern Territory, Tasmania and Victoria.

1.5 Future policy and regulatory directions for e-cigarettes in Australia

General considerations

The Department considers that the evidence base supports maintaining and, where appropriate, strengthening the current controls that apply to the marketing and use of e-cigarettes in Australia. To this end, evidence from tobacco control shows that comprehensive public health strategies focussing on both the supply and demand of e-cigarettes are needed to protect the Australian community from risks associated with the marketing and use of e-cigarettes in Australia.

TGA interim decision for the scheduling of nicotine

On 23 September 2020, the TGA announced an interim decision that, if made final, would clarify the scheduling of nicotine in the Poisons Standard.[1] The proposed changes would mean that e-cigarettes containing nicotine, and nicotine fluids for vaping, could only be supplied with a doctor's prescription. The interim decision will be open for public consultation until 12 November 2020, with a final decision expected in mid-December 2020. Decisions related to medicines under the Poisons Standard are made by a senior medical officer in the TGA and independently of elected government.

Proposal to prohibit the importation of nicotine containing e-cigarettes

The Australian Government has deferred its decision to ask the Governor-General in Council to make regulations from 1 January 2021 prohibiting the importation of e-cigarettes containing vaporiser nicotine (nicotine liquids and salts) and nicotine containing e-cigarette refills unless on prescription from a doctor.[22] To proceed, at the present time, with such an amendment would unnecessarily pre-empt any further deliberations of the scheduling Delegate to reach a final decision for the scheduling of nicotine in the Poisons Standard, in accordance with the therapeutic goods regulatory scheme. The Government will also monitor the impacts of any changes to the Poisons Standard, if the delegate’s final decision confirms the interim decision.

Part two: Tobacco control, smoking and e-cigarette use in Australia

2.1 Tobacco control in Australia

Costs of tobacco use to the Australian community

Tobacco use remains a leading cause of preventable death and disability in Australia and was estimated to kill almost 21,000 Australians in 2015.[23] Tobacco use compounds health and social inequalities and is a major contributor to poorer health status in socioeconomically disadvantaged populations.

The most recent available estimates of the overall social (including health) costs of tobacco use in Australia were $137 billion in 2015-16. This included $19.2 billion in tangible costs and $117.7 billion in intangible costs.[24]

Tangible costs included health care costs ($6.8 billion), workplace costs ($5 billion), costs related to premature deaths ($1.8 billion) and other costs primarily associated with fires, litter and expenditure on tobacco by dependent smokers ($5.7 billion). In addition to the tangible costs of smoking, there are substantial intangible costs (e.g. the value of life lost, pain and suffering), both from premature mortality ($92.1 billion) and from the lost quality of life of those experiencing smoking attributable ill-health ($25.6 billion).[24]

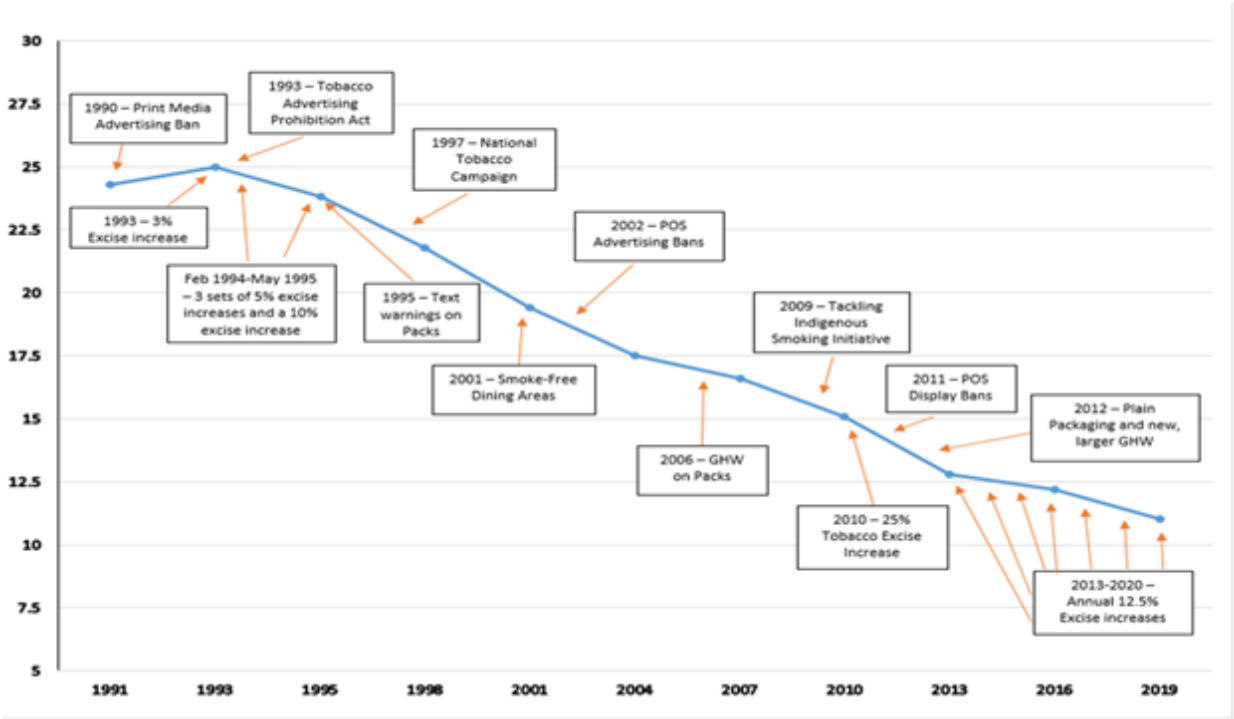
Summary of Australia's approach to tobacco control

Tobacco control is a shared responsibility between the Commonwealth and state and territory governments. At the national level, the Australian Government continues to implement a range of tobacco control measures to reduce smoking prevalence. These measures include increased tobacco excise and excise-equivalent customs duty; education programs and campaigns; plain packaging of tobacco products; labelling tobacco products with graphic health warnings; prohibiting tobacco advertising and promotion; providing support for smokers to quit; and measures to minimise the illicit tobacco trade.

State and territory governments have also implemented a broad range of measures, such as restrictions on the advertising, promotion and sponsorship of tobacco products, measures to reduce exceptions to smoke-free workplaces, public places and other settings, education programs and campaigns, and measures to support smokers to quit.

Figure 1 illustrates that the comprehensive range of measures progressively implemented by all Australian governments has been instrumental in ensuring the long-term decline in smoking prevalence, even when compared to most other developed countries.[25]

Figure 1: Tobacco control measures and daily smoking prevalence in Australia, people aged 14 and over, 1991-2019



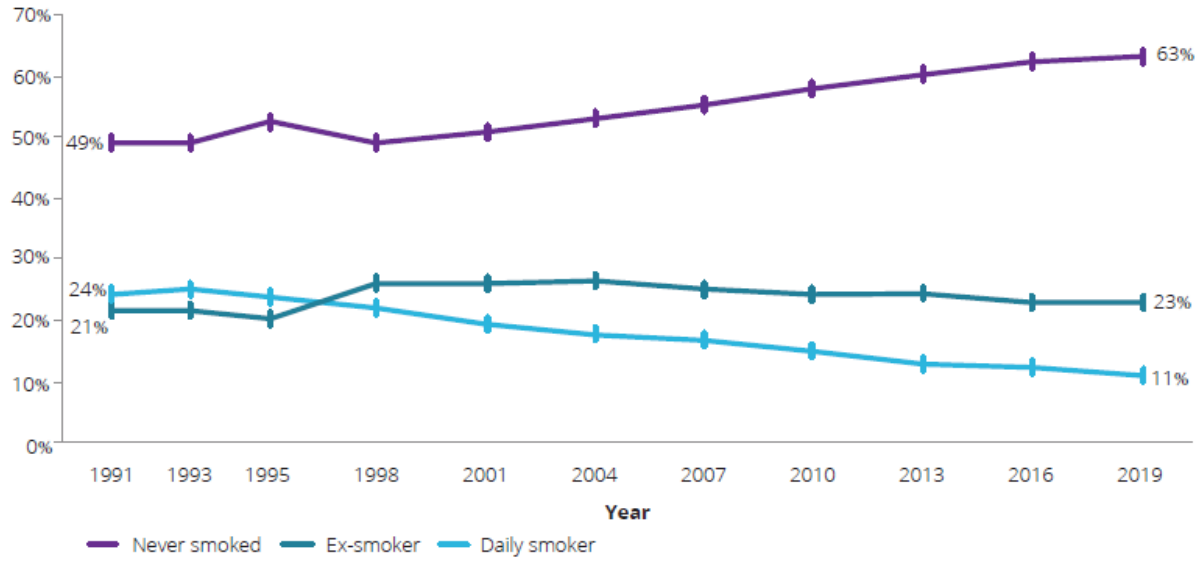
Source: Adapted from the Australian Institute of Health and Welfare. Alcohol, tobacco & other drugs in Australia. Canberra: AIHW; 2020.

2.2 Smoking prevalence

Figure 2 illustrates the long-term decline in smoking prevalence in Australia, as well as Australia's success in reducing the uptake of smoking since 1991.

In 2019, 11.0% of Australians aged 14 years and over smoked daily, down from 24% in 1991. During this period, the proportion of never smokers aged 14 years and over increased from 49% to 63%, while the proportion of ex-smokers remained relatively similar.[2]

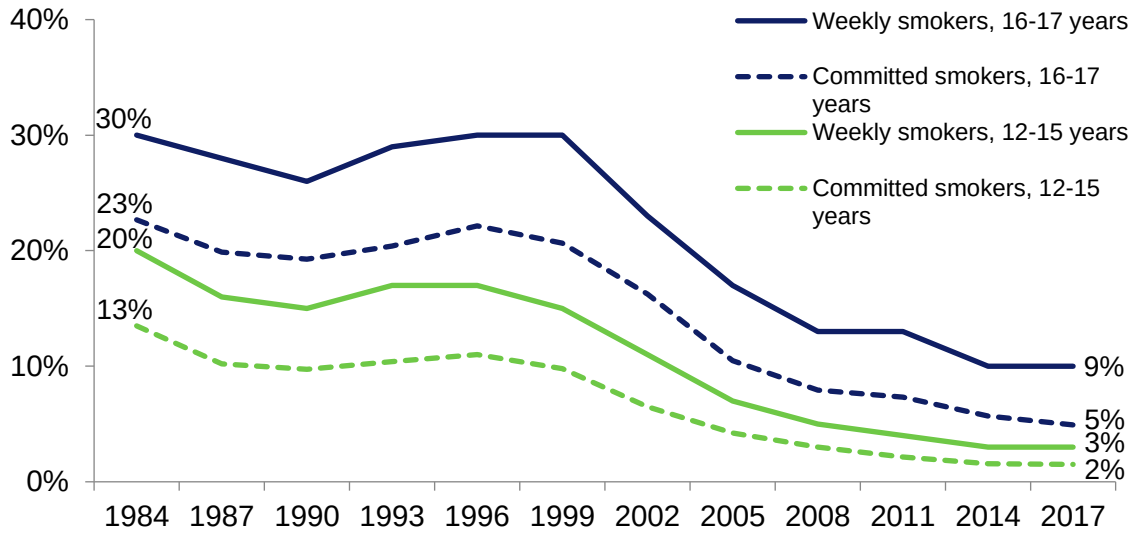
Figure 2: Tobacco smoking status in Australia (including 'never smokers'), people aged 14 and over, 1991-2019



Source: Adapted from the Australian Institute of Health and Welfare. National Drug Strategy Household Survey 2019. Drug statistics series no. 32. Cat. no. PHE 214. Canberra: AIHW; 2020.

Figure 3 shows that smoking prevalence among Australian children is at historically low levels. Between 1984 and 2017, the proportion of teenagers smoking at least once in the previous week declined from over 30% to 9% among 16-17 year-olds, and from 20% to 3% among 12-15 year-olds.[4]

Figure 3: Prevalence of Australian secondary school students who report smoking in the last week, and smoking at least three days in the last seven, Australia 1984 – 2017, 12-15 year olds and 16-17 year olds

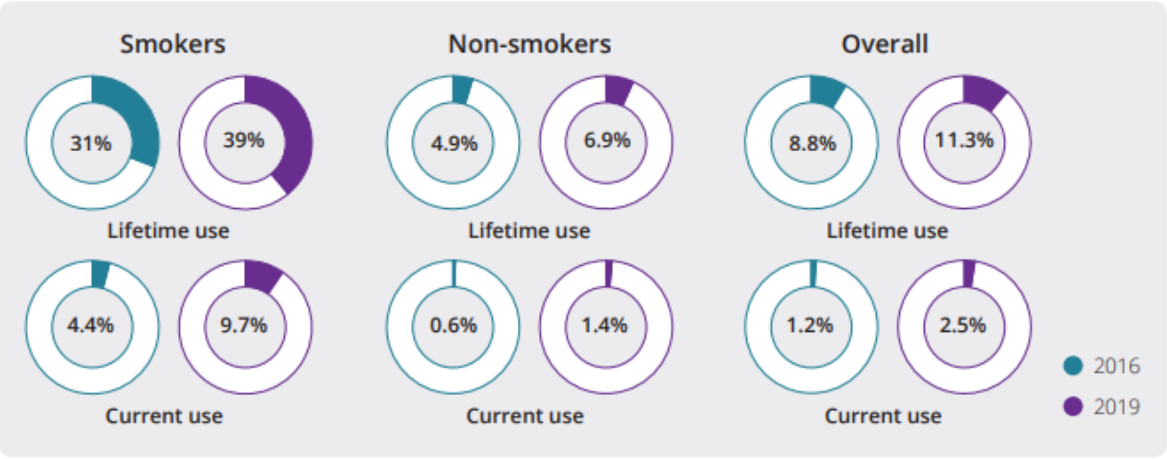


Source: Guerin N and White V. Australian secondary students' use of tobacco, alcohol, over-the-counter drugs, and illicit substances. ASSAD 2017 Statistics & Trends. Melbourne: Cancer Council Victoria; 2018.

2.3 E-cigarette use in Australia

Figure 4 shows that between 2016 and 2019, lifetime and current use (defined as daily, weekly, monthly or less than monthly use) of e-cigarettes increased among smokers and non-smokers in Australia.[2]

Figure 4. Prevalence of lifetime and current e-cigarette use among smokers and non-smokers in 2016 and 2019



Source: Australian Institute of Health and Welfare. National Drug Strategy Household Survey 2019. Drug statistics series no. 32. Cat. no. PHE 214. Canberra: AIHW; 2020.

In addition, increases in the proportion of e-cigarette use between 2016 and 2019 occurred across most age groups in Australia. The increase was particularly marked among young people. During this period, the proportion of respondents aged 18-24 who reported using e-cigarettes, daily, weekly, monthly or less than monthly at the time of being surveyed nearly doubled, from 2.8% in 2016 to 5.3% in 2019.[2] *Note: information on e-cigarettes and their overall impacts on nicotine consumption and smoking prevalence is at Section 6.2 and 6.3.*

While the prevalence of e-cigarette use in Australia has increased in recent years, particularly among young people, it remains relatively low compared to rates observed in some other countries. In the US, which has the largest market for e-cigarettes, 19.6% of high school students and 4.7% of middle school students reported current e-cigarette use[ii] in 2020.[26] In Canada, 20% of students in grades 7 to 12 reported having used an e-cigarette in the past 30 days in 2018-19, an increase from 10% in 2016-17.[4]

[ii] Current e-cigarette use in this report is defined as e-cigarette use in the past 30 days.

Part three: Regulatory responses to e-cigarettes in other jurisdictions

3.1 Regulatory responses to e-cigarettes in other countries

There is currently no international consensus on the most appropriate policy and regulatory response to e-cigarettes. The regulatory arrangements applicable to e-cigarettes vary considerably within and across countries, ranging from prohibition to minimal or no regulation. Broadly, e-cigarettes may be regulated under various regulatory frameworks that apply to tobacco products, poisons, medicines and consumer products.

Table 1 provides a summary of key measures taken to date for e-cigarettes in Brazil, Canada, New Zealand (NZ), the European Union (EU), the United Kingdom (UK) and the United States (US). *More detailed country specific information is at Appendix A.*

Table 1. Regulatory approaches to e-cigarettes in selected jurisdictions

Regulatory Approach	Brazil	Canada	NZ	EU	UK	US
Restrictions on advertising and promotion	Advertising banned	Advertising restrictions apply	Advertising restrictions apply	Advertising in media banned	Advertising in media banned	FDA has power to regulate advertising
Restrictions on the use of flavours and other ingredients	Sale and distribution banned	Colourings, caffeine, some flavours & other additives banned	General retailers – Only tobacco, mint & menthol flavours from 2021 Specialist vape retailers – Any flavour unless expressly prohibited	Regulated by Member States	Flavours not banned Colourings, caffeine & other additives banned	FDA can enforce actions on unauthorised flavours Flavours also regulated at state level - California has banned flavoured e-cigarettes from 2021
Age restrictions on access by minors	Sale and distribution banned	Must be 18+ to access	Must be 18+ to access	Regulated by Member States	Must be 18+ to access	Must be 18+ to access
Packaging and product information	Sale and distribution banned	Labelling and packaging restrictions apply	Labelling and packaging restrictions apply – To be set in new regulations in 2021	Labelling and packaging restrictions apply	Labelling and packaging restrictions apply	Labelling and packaging restrictions apply
Restrictions on where e-cigarettes are used	Subject to smoke-free prohibitions	Banned in some workplaces & transport	Subject to smoke-free prohibitions	Regulated by Member States	Not covered by smoke-free law – Banned in some settings	Regulated by states
Importation, access and distribution controls	Importation, sale and distribution banned	Importation, sale and distribution restrictions apply	Product must be notified before sale by 2022 – Other restrictions apply	Product must be notified before sale – Other restrictions apply	Product must be notified before sale – Other restrictions apply	Importation restrictions apply, sale restrictions vary across sub-national jurisdictions
Product standards apply	Sale and distribution banned	Nicotine concentration restrictions apply	To be set in new regulations in 2021	Nicotine concentration restriction & refill requirements apply	Nicotine concentration restriction & refill requirements apply	Flow restrictor requirements for cartridges apply
Total ban on e-cigarette sales and distribution	In addition to Brazil, several other jurisdictions including Singapore, Uruguay, Jordan, Oman, Qatar, and India have announced total bans on the sale and distribution of e-cigarettes or intend to introduce legislation which would ban their sale and distribution.					

Note: The information provided in Table 1 provides a broad summary of regulatory approaches to e-cigarettes and does not necessarily reflect regulatory differences between individual states/provinces of each country.

3.2 Patterns of e-cigarette use in other jurisdictions

Globally, e-cigarette use has increased in recent years, particularly among youth.

For example, a recent analysis of US, Canadian and English data found that past 30 day use of e-cigarettes among youth aged 16 to 19 years increased in all three countries between 2017 and 2019. However, the magnitude of these increases were greater in Canada and the US than in England. The analysis also found there to be a year on year increase across all countries in the proportion of never smokers who reported the use of e-cigarettes in the past 30 days over the same period.[27]

Part four: Protecting tobacco control policy from all commercial and other vested interests

4.1 Legal and policy context

Under Article 5.3 of the WHO FCTC, Parties are obliged to act to protect their public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry, in accordance with national law.

Implementation guidelines for Article 5.3 (Article 5.3 Guidelines) were adopted by the COP in 2008 and acknowledge that there is a '*fundamental and irreconcilable conflict between the tobacco industry's interest and public health policy interests*.' The Article 5.3 Guidelines also acknowledge that '*the tobacco industry has operated for years with the express intention of subverting the role of governments and of WHO in implementing public health policies to combat the tobacco epidemic*.'[28]

At COP 6 in 2014, Parties were invited to protect tobacco control activities from all commercial and other vested interests related to ENDS/ENNDS.[29] A similar decision was also agreed to by Parties at COP 8 in 2018 which invited Parties *'to protect tobacco-control policies and activities from all commercial and other vested interests related to novel and emerging tobacco products, including interests of the tobacco industry, in accordance with Article 5.3 of the WHO FCTC.'*[30]

The protection of tobacco control settings from all commercial and other vested interests also accords with Australia's obligations under Article 14 of the WHO FCTC (demand reduction measures concerning tobacco dependence and cessation).[31]

In 2019, the Australian Government published *Guidance for Public Officials on Interacting with the Tobacco Industry* (the Guide). The Guide was informed by the Article 5.3 Guidelines and outlines the legal obligations placed on Australian Government agencies and officials by the WHO FCTC. The Guide extends to the e-cigarette industry and e-cigarettes.[32]

4.2 Protecting tobacco control research from commercial and other vested interests

To date, the Chief Executive Officer (CEO) of the National Health and Medical Research Council (NHMRC) has published two statements on e-cigarettes to assist consumers and policy makers to understand the evidence base in relation to these products. The first statement was published in March 2015 and an updated statement was published in April 2017. A further revised statement is currently being prepared by the NHMRC and is due for publication in 2021.

The NHMRC's 2017 CEO statement on e-cigarettes encourages consumers and policy-makers to consider the extent to which authors of e-cigarette related research hold any conflicts of interest that could potentially bias their findings, and whether the research is funded by an organisation with a financial interest in the outcomes, such as e-cigarette manufacturers.[33]

Following the publication of the NHMRC's 2017 CEO statement on e-cigarettes, a 2018 review of 414 papers related to e-cigarettes found that papers with findings that were favourable to e-cigarettes were more likely to have a conflict of interest.[34]

Similar conclusions were also reached in a 2017 Cochrane Review, which highlighted that sponsorship of studies related to drugs and devices by the manufacturing company leads to more favourable conclusions than sponsorship by other sources.[35] More recently, a systematic review published in 2019 analysed 826 articles relevant to products promoted as

a tobacco harm reduction tool, including e-cigarettes and smokeless tobacco products, to assess funding sources and the articles' position on these products. The review found that e-cigarette, tobacco and pharmaceutical industry funded papers were more likely to be in favour of tobacco harm reduction products, compared to non-industry funded literature which were more evenly divided in stance.[36]

The Department acknowledges that industry sponsorship is not the only source of a conflict of interest, and that a conflict of interest does not necessarily lead to bias.[37] However, in the context of evidence creation and dissemination relevant to tobacco control and e-cigarettes, these findings highlight a strong association between industry sponsorship and bias. These findings also reinforce the importance of carefully assessing all available evidence, including the validity, quality, credibility and independence of each study.

Part five: Industry marketing activities

5.1 Tobacco industry marketing strategies and approaches

Evidence shows that the tobacco industry has a long history of marketing a diverse range of products to: support its commercial interests; ensure its future viability by recruiting new users; and divert public resources away from evidence-based approaches to reduce tobacco use.

Based on a comprehensive review of scientific evidence, the 2012 US Surgeon General's report concluded that advertising and promotional activities undertaken by tobacco companies have been shown to cause the onset and continuation of smoking among youth. The report also refers to evidence which '*consistently and coherently points to the intentional marketing of tobacco products to youth as being a cause of young people's tobacco use.*'[38]

In addition to the marketing of conventional tobacco products, the tobacco industry continues to invest in a range of novel and emerging products, including e-cigarettes, heated tobacco products, and other tobacco and nicotine products that do not involve heating. All major tobacco companies have invested in the global e-cigarette market.[39] For example, in December 2018, Altria, the makers of Marlboro cigarettes, announced its purchase of a 35% share in JUUL Labs, a leading e-cigarette company marketed globally.[40]

Tobacco companies have a long history of using reduced exposure claims to mislead consumers into believing that particular products have reduced risk, most notably in Australia through the use of 'light' and 'mild' cigarette claims.[41] In 2015, following a lengthy investigation, the Australian Competition and Consumer Commission obtained court enforceable undertakings from British American Tobacco Australia Limited,[42] Philip Morris Limited[43] and Imperial Tobacco Australia Limited[44] to remove these descriptors from their products and contribute $9 million towards an awareness campaign to inform consumers that low-yield tobacco products are not safer or healthier than those of regular or higher-yield.

In recent years, transnational tobacco companies have increasingly adopted 'harm reduction' in their corporate messaging to showcase their investments in new and novel products such as e-cigarettes, to gain access to policy makers, and to improve their corporate image.[45, 46] However, the tobacco industry has continued ongoing and widespread marketing of tobacco and other novel products to non-smokers, contrary to this 'harm reduction' approach.

5.2 Industry marketing strategies to advertise and promote e-cigarettes

To date, the tobacco and e-cigarette industries have employed a wide range of strategies and channels to advertise and promote e-cigarettes, often using the same strategies and tactics that have been shown to increase youth initiation of tobacco products. For example, common marketing messages have drawn on themes such as freedom, good taste, romance, sexuality, and sociability. Other common marketing messages relate to themes that: e-cigarettes are safer alternatives to cigarettes; helpful in smoking cessation; and can be used in smoke free areas.[47]

Industry strategies that may be used to appeal to youth include but are not limited to, introducing a wide range of e-cigarette flavours that taste like fruit, mint and candy, as well as colourful packaging. Notably, evidence from the 2016-17 wave of the US Population

Assessment of Tobacco and Health study found that 96% of 12-17 year olds who had initiated e-cigarette use since the previous survey wave started with a flavoured product.[48]

The widespread advertising and promotion of products via digital media and other communication platforms is also being used to increase the appeal of e-cigarettes to youth. For example, one study found that 8 out of 10 of JUUL's Twitter followers in April 2018 were between the ages of 13 -20, and about 4 in 10 were aged between 13-17 years old.[49]

Part six: Public health impacts of e-cigarettes

6.1 Direct health harms associated with e-cigarette products

Harms from direct e-cigarette use

There is a body of evidence that e-cigarette products with and without nicotine pose a range of harms to human health. Evidence from observational and experimental studies have implicated the use of e-cigarettes to various harms to the heart and lungs.[8,10,50] Known carcinogens have also been found in e-cigarette aerosols, although the extent to which e-cigarette use increases the risk of cancer remains to be determined.[51]

The wide variation in e-cigarette products and the ability of users to customise their experience, makes it difficult to assess the direct health harms of individual products because the results from research involving one particular product may not be applicable to all e-cigarettes or all users.[52] For example, thousands of different flavouring compounds are marketed and used with e-cigarettes. While many flavouring compounds may be recognised as safe for use in food products, no flavouring product have been assessed as safe for inhalation via an e-cigarette.

Exposure to nicotine via e-cigarette use may pose adverse cardiovascular, respiratory and reproductive effects and negative effects on foetal and adolescent development.[53] A 2016 report of the US Surgeon General concluded that exposure to nicotine in adolescents may have long-term and damaging consequences for brain development, potentially leading to learning and mood disorders.[54] Evidence from the International Agency for Research on Cancer also suggests that nicotine is associated with DNA damage and other pathways of carcinogenesis.[55]

Aside from nicotine, the e-cigarette aerosol that users inhale from the device and exhale can contain a range of harmful and potentially harmful substances. These include but may not be limited to: ultrafine particles, flavourings, volatile organic compounds, cancer-causing chemicals, heavy metals, propylene glycol, vegetable glycerine, cannabinoids and vitamin E acetate.[7]

The types of materials used to manufacture e-cigarettes may also pose health risks. For example, a recent study conducted in an animal model found that lung injury could occur with e-cigarette devices operated at a high power setting and a nichrome heating coil, without the use of substances that have been more generally associated with lung injury including tetrahydrocannabinol, vitamin E acetate and nicotine.[56]

There have also been reports of e-cigarettes overheating, catching fire or exploding, some of which have resulted in life-threatening injury, permanent disfigurement or disability, and major property damage.[33] There is conclusive evidence that e-cigarette devices can explode and cause burns and other injuries.[11]

Harms of e-cigarette use to others

There is a range of risks specific to nicotine exposure via e-cigarettes. Nicotine is highly toxic and ingestion of just 1-2 mL in e-cigarette fluid refills, many of which have fruit or candy flavours and thus are attractive to children, can kill a toddler. [57] Since 2013, there has been a significant increase in the number of calls to Australian Poisons Centres involving cases related to e-cigarette exposures (191 between 2013 and 2016),[57] and in 2018, a young child in Victoria died from poisoning after consuming an e-liquid containing nicotine.[58] The number of related cases reported to Poisons Centres in overseas jurisdictions has also

increased substantially since 2010, and at least two fatalities have been recorded in the US alone during this period.[59]

Nicotine is highly addictive and exposure via e-cigarettes can also lead to 'Nic-sick', a condition associated with a range of non-specific symptoms such as nausea, vomiting, headaches, fatigue, and seizures.[60, 61]

E-cigarettes also provide health risks to bystanders from exposure to exhaled aerosol from e-cigarette users. A recent systematic review of the health risks from second-hand e-cigarette aerosol concluded that *'the absolute impact from passive exposure to electronic cigarette vapour has the potential to lead to adverse health effects'*.[62]

6.2 Overall impacts of e-cigarettes on nicotine consumption

Net nicotine consumption comes from various sources, including tobacco products, e-cigarettes, and pharmacotherapies used for smoking cessation. Currently, available data does not allow firm conclusions to be drawn regarding the net impact e-cigarette use has on total nicotine consumption in Australia. However, there is evidence that e-cigarettes might have the potential to contribute to net increases in nicotine consumption.

Many e-cigarettes contain nicotine at higher concentrations than in cigarettes, which may contribute to increasing rather than decreasing nicotine dependence. Further, compared to all TGA approved nicotine pharmacotherapies, there is a higher risk of longer term nicotine dependence with e-cigarette use due to the type and concentration of nicotine in specific products, and the efficient manner in which it is delivered to the brain in many devices.[11]

There is strong evidence that the use of e-cigarettes by non-smokers predicts future smoking.[12] There is also strong evidence that dual use of e-cigarettes and conventional tobacco products is common and some evidence that e-cigarette use may lead former smokers to take up smoking again.[12] There is also inadequate evidence to conclude that e-cigarettes increase smoking cessation at a population level.[63, 64, 65, 66]

6.3 E-cigarettes and impact on smoking prevalence

General considerations

The Department monitors smoking rates in a range of countries, including those with established markets for e-cigarettes. Many regions have made substantial progress in reducing smoking rates in recent years, including the US and many countries across Europe and the UK. However, the rate of decline in smoking rates in these regions has varied and has occurred over a period of time which has also seen a diverse range of regulatory responses to e-cigarettes.

Current available evidence does not allow firm conclusions to be drawn about the relationship between the sale of e-cigarettes and overall smoking rates in a particular country or region.

E-cigarettes and the hardening hypothesis

The Department is aware of the 'hardening hypothesis' which proposes that tobacco control measures have more readily influenced smokers who found it relatively easy to quit, creating a 'hardening' effect with the remaining smokers being increasingly resistant to tobacco control measures. Indicators of hardening may be associated with motivation to quit, nicotine dependence, quit outcomes or a combination of these factors. However, a multifaceted approach to tobacco control has proven to positively impact hardening

indicators by increasing motivation to quit and reducing opportunities for tobacco use.[67] To date, the hardening hypothesis has been referred to by advocates of e-cigarettes and other novel tobacco products as a reason to justify increased marketing, access and availability of these products and promote them as a harm reduction tool for smokers who find it difficult to quit nicotine use.

A recent review conducted by the National Centre for Epidemiology and Population Health (NCEPH) at the Australian National University found that the weight of available evidence does not support the hardening hypothesis. The review found that on average, the Australian population of smokers has softened over time. The findings suggest that smokers have instead become more motivated to quit and less dependent on smoking.[67] Findings from the review were consistent with other studies which also did not find evidence of hardening.[68]

6.4 Uptake of e-cigarettes by non-smokers

There is evidence internationally of substantial increases in e-cigarette use among young people who have never smoked. For example, an analysis of changes in e-cigarette use among adolescents from the US, Canada, and England between 2017 and 2019 found substantial increases in e-cigarette use among those surveyed, particularly among US and Canadian adolescents. The analysis also found that among those who reported using an e-cigarette in the past 30 days of being surveyed, the proportion of never smokers increased in all three countries.[27] Similarly, a recent analysis of US adults found the largest absolute population increase in e-cigarette users between 2014 and 2018 was among younger-adult never smokers.[63]

While Australian data are more limited, findings from the National Drug Strategy Household Survey show that the proportion of people in their 20s reporting current use of e-cigarettes more than doubled between 2016 and 2019, for both smokers (from 4.5% to 16.5%) and non-smokers (from 1.4% to 3.0%).[69] Non-smokers include ex-smokers and never smokers.[iii]

6.5 E-cigarette use as a potential gateway onto traditional tobacco products

There is strong evidence that the use of e-cigarettes by non-smokers predicts future smoking. For instance, a preliminary review of evidence published by NCEPH in September 2020 found that never smokers who had used e-cigarettes were, on average, three times as likely as those who have not used e-cigarettes to try conventional cigarettes and transition to tobacco smoking.[12] This conclusion was based on observational evidence from three systematic reviews and 25 primary research studies from multiple countries. Notably, the authors of this review clarified that *'All studies found evidence of an increased risk...'*.[12]

Broadly similar findings have been reported in other comprehensive and credible evidence reviews conducted in Australia and overseas. For example, a May 2020 evidence review published by Ireland's Health Research Board found a four-fold positive association between ever using e-cigarettes and initiating conventional cigarette smoking in adolescents.[70] Prior to this, a 2018 review published by the National Academies of Science, Engineering and Medicine found that young people who use e-cigarettes are more likely to try conventional cigarettes, and their e-cigarette use may be associated with increased frequency and intensity of subsequent cigarette smoking.[11] Further, a 2018 review published by the Commonwealth, Scientific and Industrial Research Organisation concluded that: *'The*

[iii] The 2016 non-smokers estimate has a relative standard error between 25% and 50% and should be used with caution.

evidence for a strong positive relationship between use of e-cigarettes and later cigarette smoking amongst youth continues to accumulate. The evidence is consistent in observational studies and across different countries.[9]

6.6 Effectiveness of e-cigarettes as a smoking cessation aid

General considerations

Smoking cessation is a common reason for the reported use of e-cigarettes, particularly among adults.

Considerations given to e-cigarettes as a smoking cessation aid should also take into account emerging evidence regarding extent of future use of tobacco products in former smokers. For instance, there is some evidence to suggest that previous smokers who had used e-cigarettes to quit smoking were around twice as likely to take up smoking again in comparison to those who had not used e-cigarettes.[12]

E-cigarettes and smoking cessation – current state of evidence

The available evidence published to date does not support any firm conclusion regarding the effectiveness of e-cigarettes as a smoking cessation tool. Further independent evidence from high quality studies is needed to clarify whether e-cigarettes have the potential to increase or depress smoking cessation at a population level.

Epidemiological evidence from both well-designed randomised controlled trials (RCTs) and observational studies is relevant when attempting to determine whether or not e-cigarettes are an effective aid to smoking cessation. While both study designs have strengths and limitations, RCTs provide the strongest study design to protect against threats to internal validity.[iv] However, unlike well designed observational studies that are based on large nationally representative samples of individuals, RCTs do not reflect the 'real world' conditions of e-cigarette use that occurs outside of clinically ideal trial settings.[11, 71, 72]

Preliminary findings from a recent systematic review of RCTs published in September 2020 found no significant difference in quit rates between smokers randomised to nicotine-delivering e-cigarettes versus no intervention or non-nicotine e-cigarettes. The authors of these findings further noted that: '*The overall quality of the evidence was rated as low and uncertain: the few RCTs conducted were generally small, employed a wide range of study designs across diverse settings and the majority had methodological issues indicating a high risk of bias'.*[12]

An updated Cochrane Review published in October 2020 concluded that there is *'moderate-certainty evidence'* that e-cigarettes with nicotine increase quit rates compared to e-cigarettes without nicotine and compared to nicotine replacement therapy (NRT). The study's results indicate that for every 100 people using nicotine e-cigarettes to stop smoking, 10 might successfully stop, compared with only six of 100 people using NRT or nicotine-free e-cigarettes, or four of 100 people having no support or behavioural support only. However, the authors also noted their findings were based on a small number of studies, and in some, the measured data varied widely. Notably, only four studies were considered at low risk of bias in the review and these four studies formed the basis for the report's main comparisons.[13]

[iv] Internal validity is a measure of how likely the finding of an association or causal relationship is accurate, which is determined by the degree to which a study minimises systematic error (bias). External validity addresses the extent to which a finding can be generalised to another context or to the general population.

Findings from a number of recent prospective cohort studies also call into the question the overall effectiveness of e-cigarettes as a smoking cessation tool.[14, 65, 73, 74] An important limitation of observational studies is that they do not randomly assign individuals to an exposure, and characteristics associated with self-selection may confound analyses. Findings from these studies further contribute to the uncertainty about the effectiveness of e-cigarettes on smoking cessation at a population level.

E-cigarettes as a smoking cessation aid in Australia

In January 2020, the Royal Australian College of General Practitioners (RACGP) released *'Supporting smoking cessation: A guide for health professionals'* (the RACGP Guidelines). The RACGP Guidelines advise that nicotine containing e-cigarettes are not first-line treatments for smoking cessation and should be considered a last resort for people who have tried evidence-based smoking cessation methods and not succeeded in quitting. The RACGP Guidelines also advise that for smoking cessation, the strongest evidence base for efficacy and safety is for currently approved pharmacological therapies combined with behavioural support. [75]

In circumstances where individuals are unsuccessful in achieving smoking cessation with approved pharmacotherapies, but remain motivated to quit smoking and have raised e-cigarette use with their healthcare practitioner, the RACGP Guidelines provide that e-cigarettes may be a reasonable intervention.[75] Medical practitioners are well placed to support patients in smoking cessation and advise on how to reduce the risks associated with nicotine use. Access to these products through a prescription also provides an opportunity for medical practitioners to assess the patient's progress and whether e-cigarettes are a suitable tool to aid the patient in quitting smoking.[75]

A number of leading public health organisations have expressed their position on the effectiveness of e-cigarettes as smoking cessation aids which align with the Australian Government's precautionary approach. The Thoracic Society of Australia and New Zealand (TSANZ) released its position statement in July 2020 and stated that based on comprehensive reviews of e-cigarettes undertaken to date, there is currently *'limited evidence that e-cigarettes are effective in promoting smoking cessation and a lack of evidence as to whether e-cigarettes are more or less effective than existing approved cessation aids or no treatment'*.[76] Similar views have also been put forward by the Australian Medical Association (AMA)[77] and Royal Australasian College of Physicians[78] and in 2018, a joint statement was published by the AMA, Cancer Australia, Cancer Council Australia, National Heart Foundation of Australia and TSANZ.[79]

6.7 E-cigarettes as a harm reduction tool

The Department is aware of claims that e-cigarettes are around 95 per cent safer to users than smoking tobacco products. Under typical conditions of use, the number and concentrations of potentially toxic substances emitted from unadulterated e-cigarettes are generally lower than tobacco smoke.[80] However, insufficient research has been conducted to support a conclusion on any particular type of e-cigarette, or claims about the extent of harm that these products may pose compared to conventional tobacco products .[8]

The claim that e-cigarettes are around 95 per cent safer has also been disputed in several leading international medical journals, such as the Lancet[81] and British Medical Journal,[82] and by experts.[83] It is also inconsistent with the position of numerous public health bodies, such as the NHMRC and WHO, who have indicated that no specific figure about how much

'safer' the use of e-cigarettes is compared to tobacco smoking can be given any scientific credibility at present.[33, 71]

Evidence that e-cigarettes are commonly used concurrently with conventional tobacco products also calls into question whether these products will reduce harm among most smokers. As noted above, current evidence also suggests that nicotine containing e-cigarettes can result in prolonged exposure to nicotine through ongoing exclusive e-cigarette use or dual use with combustible cigarettes.[12]

E-cigarettes have also been reported as a mechanism to help cut down on tobacco smoking. However, evidence suggests that the health benefits of reduced tobacco consumption may be minimal. [84] For example, several large cohort studies have shown little evidence of reduced mortality in smokers that reduce cigarette consumption, and no association between smoking reduction and a decline in all-cancer risk.[85, 86, 87] In addition to any independent health risks introduced by e-cigarettes, even infrequent smoking poses serious health risks.[88] Tobacco smoking is still harmful regardless of the level in which it occurs and there is no safe level of tobacco consumption.[89]

Appendix A – Current policy and regulatory approach to e-cigarettes in other countries

The Department has compiled the following information on policy and regulatory approaches to e-cigarettes in other countries to assist the Committee. This information is not exhaustive and has been provided as a guide only.

Brazil

In Brazil, e-cigarettes are classified as tobacco-derived products, and in 2009, the country prohibited the marketing, sale, advertisement, distribution and importation of e-cigarettes, with or without nicotine.[90, 91] The ban remains in place until further scientific studies and evaluations have been undertaken to identify the risks and purported effectiveness of e-cigarettes as a smoking cessation tool.[92] The use of e-cigarettes is also banned in places where smoking is prohibited, including public places and transportation.[93]

Canada

Canada's approach to e-cigarettes allows adults to access vaping products as an alternative to smoking while attempting to reduce and prevent uptake by youth and adults who do not smoke tobacco products.[94, 95] Vaping products manufactured, advertised, imported or sold in Canada are subject to federal legislation. Provincial, territorial and municipal laws also regulate vaping products and their use.

At the federal level, the *Tobacco and Vaping Products Act* (TPVA) took effect in Canada from 23 May 2018 with the purpose of regulating the manufacture, sale, labelling and promotion of tobacco products and vaping products. In relation to vaping products, the TVPA aims to protect Canadians from nicotine addiction and from inducements to use tobacco and, in particular for youth, from vaping products use.[96] In December 2019, Canada Health introduced new *Vaping Products Promotion Regulations* under the TVPA to restrict the advertising and promotion of vaping products and make health warnings on vaping products mandatory. The new regulations took effect in August 2020.[97]

The manufacturing, importation, advertisement and sale of vaping products that do not make health claims are also subject to the *Canada Consumer Product Safety Act* (CCPSA). The CCPSA includes requirements for child-resistant containers, and other health or safety considerations, such as those to address certain electrical and mechanical hazards for vaping products that are manufactured, imported, advertised, or sold in Canada.[96]

Canada's *Food and Drug Act* also applies to vaping products that make a health claim, such as efficacy as a smoking cessation tool. These products must receive an authorisation from Health Canada before they can be advertised, sold and commercially imported.[96]

European Union (EU) and the United Kingdom (UK)

The EU has established the Tobacco Products Directive (TPD) to govern the manufacture, presentation and sale of tobacco and related products, including the use of e-cigarettes.[98] However, the regulatory arrangements applicable to e-cigarettes in Europe vary considerably, including among countries that are Members of the EU**.**

From May 2016, the TPD introduced new rules under Article 20 for nicotine containing e-cigarettes. Article 20 of the TPD includes regulations on safety and quality requirements, packaging and labelling requirements, and monitoring and reporting requirements for

e-cigarette manufacturers, importers, EU Member States and the European Commission. The TPD also sets a maximum nicotine concentration for nicotine liquid containers.[99]

In the UK, nicotine containing e-cigarettes are regulated through the TPD and translated into UK law through the Tobacco and Related Products Regulations 2016. Non-nicotine containing e-cigarettes in the UK are regulated through the General Product Safety Regulations 2005 and are enforced by local trading standards.[100]

New Zealand (NZ)

In 2011, the NZ Government announced a new goal to achieve a smokefree nation by 2025.[101] Following this announcement, the NZ Government has noted that *'vaping products have the potential to make a contribution to the Smokefree 2025 goal'*.[102] The importation and sale of nicotine for use in e-cigarettes is lawful in NZ, subject to certain provisions in NZ's *Smoke-free Environments Act 1990* (SE Act) and *Medicines Act 1981.*[103]

In August 2020, the *Smokefree Environments and Regulated Products (Vaping) Amendment Bill* (the Bill) was passed in Parliament. The Bill proposed amendments to the SE Act to bring e-cigarettes and smokeless tobacco products under the existing legislation. The *Smokefree Environments and Regulated Products (Vaping) Amendment Act 2020* comes into force from November 2020 and includes new laws for the manufacture, import, advertising, sale, supply of e-cigarettes and smokeless tobacco products.[103]

Under the Medicines Act, nicotine is classified under Part 1, Schedule 1, as a prescription medicine for therapeutic purposes when used in nasal spray as a smoking cessation product, or when used in medicines other than for smoking cessation.[104] Only products approved by NZ's medicines regulator[v] under this notice can use the health claims about assisting with smoking cessation.

United States (US)

E-cigarettes in the US are regulated at both a federal and state level, with approaches differing across jurisdictions. For instance, a Senate Bill proposing to prohibit the sale of flavoured tobacco products, including e cigarettes, was passed in the state of California in October 2020 and will take effect as of 1 January 2021.[105]

In 2016, the Food and Drug Administration (FDA) issued a deeming rule extending its authority to regulate all tobacco products at a federal level, including e-cigarettes and other products containing nicotine that are derived from tobacco.[106] The FDA's Tobacco Control Act includes provisions for prohibiting or restricting advertising and sale to youth, prohibiting sales of tobacco products to minors, vending machine sales (except in adult-only facilities), tobacco-brand sponsorship of sports and entertainment events or other social or cultural events and brand-name non-tobacco promotional items.[107]

The 2016 deeming rule by the FDA means that generally, e-cigarettes are regulated under federal law as tobacco products unless explicit therapeutic claims are made (e.g. smoking cessation claims).[108] The deeming rule also means that specific e-cigarette products that do not receive FDA marketing authorisation will no longer be lawfully available for sale in the US.[vi] The FDA's assessment to grant market authorisation to new tobacco products such as

[v] Medsafe (New Zealand Medicines and Medical Devices Safety Authority), is the medical regulatory body responsible for the regulation of therapeutic products in New Zealand.

[vi] The FDA have clarified that it may continue to defer enforcement of the premarket requirements for e-cigarette suppliers for up to one year through to 9 September 2021, unless a negative action is issued by the FDA on an application during that time.

e-cigarettes takes into account a range of factors including product ingredients, product features, health risks and attractiveness to youth and non-users.[108, 109]

In January 2020, the FDA issued a policy prioritising enforcement against certain unauthorised flavoured e-cigarettes, including flavours that appeal to children. Under this policy, companies that do not cease the marketing, manufacture, distribution and sale of unauthorised flavours, other than tobacco or menthol, risk FDA enforcement actions. The FDA also further clarified that e-liquids that do not contain nicotine or other material made or derived from tobacco, but that are intended or reasonably expected to be used with or for the human consumption of a tobacco product, may be components or parts and, therefore, subject to FDA's tobacco control authorities.[110]

Singapore

Since 1 February 2018, Singapore has banned the importation, sale, distribution, possession, use and purchase of emerging and imitation tobacco products, including e-cigarettes and other types of vaporisers, through amendments to Singapore's *Tobacco (Control of Advertisements and Sale)* Act.[111]

Other countries

A number of other countries, including Uruguay,[112] Jordan,[113] Oman,[114] Qatar[115] and India[116] have banned the sale of e-cigarettes (with or without nicotine).

References

1. Therapeutic Goods Administration. Interim decision of entry of nicotine in the Poisons Standard: Information for consumers. Canberra: TGA; 23 September 2020. Available from: https://www.tga.gov.au/interim-decision-entry-nicotine-poisons-standard-information-consumers.
2. Australian Institute of Health and Welfare. National Drug Strategy Household Survey 2019. Drug statistics series no. 32. Cat. no. PHE 214. Canberra: AIHW; 2020. Available from: https://www.aihw.gov.au/getmedia/3564474e-f7ad-461c-b918-7f8de03d1294/aihw-phe-270-NDSHS-2019.pdf.aspx?inline=true.
3. Guerin N and White V. Australian secondary students' use of tobacco, alcohol, over-the-counter drugs, and illicit substances. ASSAD 2017 Statistics & Trends. Melbourne: Cancer Council Victoria; 2018. Available from: https://www.health.gov.au/ resources/publications/secondary-school-students-use-of-tobacco-alcohol-and-other-drugs-in-2017.
4. Health Canada. Summary of results for the Canadian Student Tobacco, Alcohol and Drugs Survey 2018-19. Ontario: Health Canada; 2019. Available from: https://www.canada.ca/en/health-canada/services/canadian-student-tobacco-alcohol-drugs-survey/2018-2019-summary.html.
5. Australian Government Department of Health. Policy and regulatory approach to electronic cigarettes (e-cigarettes) in Australia. Canberra: Australian Government Department of Health; 2019. Available from: https://www.health.gov.au/ resources/publications/policy-and-regulatory-approach-to-electronic-cigarettes-e-cigarettes-in-australia.
6. New South Wales Department of Health. NSW Health Alert – Warning on e-liquids. Sydney: New South Wales Department of Health; 23 October 2013. Available from: https://www.health.nsw.gov.au/news/Pages/20131023_00.aspx.
7. Centers for Disease Control and Prevention. Quick Facts on the Risks of E-cigarettes for Kids, Teens and Young Adults. Atlanta: U.S. Department of Health & Human Services; 2020. Available from: https://www.cdc.gov/tobacco/basic_information/e-cigarettes/Quick-Facts-on-the-Risks-of-E-cigarettes-for-Kids-Teens-and-Young-Adults.html#flavors-marketing-appealing-to-youth.
8. Gotts JE, Jordt SE, McConnell R and Tarran R. What are the respiratory effects of e-cigarettes? BMJ 2019; 366: l5275. doi: 10.1136/bmj.l5275.
9. Byrne S, Brindal E, Williams G, Anastasiou KM, Tonkin A, Battams S, et al. E-cigarettes, smoking and health. A literature review update. Canberra: CSIRO; 2018. Available from: https://www.csiro.au/~/media/BF/Files/E-cigarettes/E-cigarettes-Consolidated-Final-Report240618-pdf.pdf?la=en&hash=F03466E531949D4A93E61B03FA730F45347A3919.
10. Kennedy CD, van Schalkwyk MCI, McKee M and Pisinger C. The cardiovascular effects of electronic cigarettes: a systematic review of experimental studies. Prev Med 2019; 127: 105770. doi: 10.1016/j.ypmed.2019.105770.

11. Stratton K, Kwan LY and Eaton DL. Public Health Consequences of E-Cigarettes. Washington DC: The National Academies of Sciences, Engineering and Medicine; 2018. Available from: https://www.nap.edu/resource/24952/012318ecigaretteConclusionsbyEvidence.pdf.
12. Banks E, Beckwith K and Joshy G. Summary report on use of e-cigarettes and relation to tobacco smoking uptake and cessation, relevant to the Australian context. Acton ACT: Australian National University, Research School of Population Health, National Centre for Epidemiology & Population Health; 2020. Available from: https://openresearch-repository.anu.edu.au/bitstream/1885/211618/3/E-cigarettes%20smoking%20behaviour%20summary%20report%20final%20200924.pdf.
13. Hartmann-Boyce J, McRobbie H, Lindson N, Bullen C, Begh R, Theodoulou A et al. Electronic cigarettes for smoking cessation. Cochrane Database of Systematic Reviews 2020; (10): CD010216. doi: 10.1002/14651858.CD010216.pub4.
14. Pierce JP, Benmarhnia T, Chen R, White M, Abrams DB, Amrose BK et al. Role of e-cigarettes and pharmacotherapy during attempts to quit cigarette smoking: The PATH Study 2013-16. PLoS ONE 2020; 15(9): e0237938. doi: 10.1371/journal.pone.0237938.
15. World Health Organization Framework Convention on Tobacco Control. Opened for Signature 16 June 2003, 2302 UNTS 166 (entered into force 27 February 2005).
16. World Health Organization Framework Convention on Tobacco Control. The Convention Secretariat calls Parties to remain vigilant towards novel and emerging nicotine and tobacco products. Geneva: WHO; 13 September 2019. Available from: https://www.who.int/fctc/mediacentre/news/2019/remain-vigilant-towards-novel-new-nicotine-tobacco-products/en/.
17. Therapeutic Goods Administration. What are 'therapeutic goods'? Canberra: TGA; 28 August 2020. Available from: https://www.tga.gov.au/what-are-therapeutic-goods.
18. Therapeutic Goods Administration. Accessing unapproved products. Canberra: TGA; 2020. Available from: https://www.tga.gov.au/accessing-unapproved-products.
19. Australian Industrial Chemicals Introduction Scheme. Categorisation of chemicals in e-cigarettes and personal vaporisers. Canberra: AICIS; 2020. Available from: https://www.industrialchemicals.gov.au/help-and-guides/extra-resources-help-you-categorise-your-introduction/categorisation-chemicals-e-cigarettes-and-personal-vaporisers.
20. Western Australia Department of Health. Electronic cigarettes in Western Australia. Tobacco Control Branch; 18 February 2020. Available from: https://ww2.health.wa.gov.au/Articles/A_E/Electronic-cigarettes-in-Western-Australia.
21. Supreme Court of Western Australia (Court of Appeal). Decision: Van Heerden v Hawkins 2016 WASCA 42.
22. Therapeutic Goods Administration. Prohibition on importing e-cigarettes containing vaporiser nicotine. Canberra: TGA; 29 June 2020. Available from: https://www.tga.gov.au/behind-news/prohibition-importing-e-cigarettes-containing-vaporiser-nicotine.

23. Australian Institute of Health and Welfare. Burden of tobacco use in Australia: Australian Burden of Disease Study 2015. Australian Burden of Disease series no. 21. Cat. no. BOD 20. Canberra: AIHW; 2019. Available from: https://www.aihw.gov.au/getmedia/953dcb20-b369-4c6b-b20f-526bdead14cb/aihw-bod-20.pdf.aspx?inline=true.
24. Tait R, Whetton S and Alsop S. Identifying the social costs of tobacco use in Australia in 2015/16. Perth: National Drug Research Institute, Curtin University; October 2019. Available from: https://ndri.curtin.edu.au/ndri/media/documents/publications/T273.pdf.
25. Australian Institute of Health and Welfare. Alcohol, tobacco & other drugs in Australia. Canberra: AIHW; 2020. Available from: https://www.aihw.gov.au/reports/alcohol/alcohol-tobacco-other-drugs-australia/contents/drug-types/tobacco.
26. Wang TW, Neff LJ, Park-Lee E, Ren C, Cullen KA and King BA. E-cigarette Use Among Middle and High School Students — United States, 2020. Morbidity and Mortality Weekly Report 2020; 69:1310-12. doi : 10.15585/mmwr.mm6937e1.
27. Hammond D, Rynard VL and Reid JL. Changes in Prevalence of Vaping Among Youths in the United States, Canada, and England from 2017 to 2019. JAMA Pediatrics 2020; 174(8): 797-800. doi: 10.1001/jamapediatrics.2020.0901.
28. World Health Organization Framework Convention on Tobacco Control. Guidelines for implementation of Article 5.3 of the WHO Framework Convention on Tobacco Control (Protection of public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry). FCTC/COP3(7). Geneva: WHO; November 2008. Available from: https://www.who.int/fctc/guidelines/article_5_3.pdf.
29. World Health Organization Framework Convention on Tobacco Control. Report of the sixth session of the Conference of the Parties to the WHO Framework Convention on Tobacco Control. Geneva: WHO; 13-18 October 2014. Available from: https://www.who.int/fctc/cop/sessions/COP6_report_FINAL_04122014.pdf.
30. World Health Organization Framework Convention on Tobacco Control. Novel and emerging tobacco products. FCTC/COP8(22). 6 October 2018. Available from: https://www.who.int/fctc/cop/sessions/cop8/FCTC_COP8(22).pdf.
31. World Health Organization Framework Convention on Tobacco Control. Guidelines for implementation of Article 14 of the WHO Framework Convention on Tobacco Control (Demand reduction measures concerning tobacco dependence and cessation). FCTC/COP4(8). Geneva: WHO; November 2010. Available from: https://www.who.int/fctc/Guidelines.pdf.
32. Australian Government Department of Health. Guidance for public officials on interacting with the tobacco industry. Canberra; 2019. Available from: https://www.health.gov.au/sites/default/files/documents/2019/11/guidance-for-public-officials-on-interacting-with-the-tobacco-industry_1.pdf.

33. National Health and Medical Research Council. CEO Statement: Electronic cigarettes. Canberra: NHMRC; 3 April 2017. Available from https://www.nhmrc.gov.au/about-us/resources/ceo-statement-electronic-cigarettes#block-views-block-file-attachments-content-block-1.
34. Martinez C, Fu M, Galan I, Perez-Rios M, Martinez-Sanchez JM, Lopez MJ et al. Conflicts of interest in research on electronic cigarettes. Tobacco Induced Diseases 2018; 16: 28. doi: 10.18332/tid/90668.
35. Lundh A, Lexchin J, Mintzes B, Schroll JB and Bero L. Industry sponsorship and research outcome. Cochrane Database of Systematic Reviews 2017; (2): MR000033. doi: 10.1002/14651858.MR000033.pub3.
36. Hendlin YH, Vora M, Elias J and Ling PM. Financial Conflicts of Interest and Stance on Tobacco Harm Reduction: A Systematic Review. American Journal of Public Health 2019; 109(7): e1-8. doi: 10.2105/AJPH.2019.305106.
37. Parker L, Grundy Q and Bero L. Interpreting evidence in general practice: Bias and conflicts of interest. Australian Journal of General Practice 2018; 47(6): 337-40. doi: 10.31128/AJGP-12-17-4432.
38. US Department of Health and Human Services. Preventing tobacco use among youth and young adults: a report of the Surgeon General. Atlanta: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2012. Available from: https://www.ncbi.nlm.nih.gov/books/NBK99237/pdf/Bookshelf_NBK99237.pdf.
39. Bauld L, Angus K, de Andrade M and Ford A. Electronic Cigarette Marketing: Current Research and Policy. London: Cancer Research UK; October 2016. Available from: https://www.cancerresearchuk.org/sites/default/files/electronic_cigarette_marketing_report_final.pdf.
40. Warner J. Vaping or cannabis: where's the growth for Big Tobacco? London: IG; 18 February 2020. Available from: https://www.ig.com/au/news-and-trade-ideas/vaping-or-cannabis--wheres-the-growth-for-big-tobacco--200217.
41. Popova L, Lempert LK and Glantz SA. Light and mild redux: heated tobacco products' reduced exposure claims are likely to be misunderstood as reduced risk claims. Tobacco Control 2018; 27: s87-95. doi: 10.1136/tobaccocontrol-2018-054324.
42. Australian Competition & Consumer Commission. British American Tobacco Australia Limited – s.87B undertaking. Canberra: ACCC; 10 May 2005. Available from: https://www.accc.gov.au/public-registers/undertakings-registers/s87b-undertakings-register/british-american-tobacco-australia-limited-s87b-undertaking.
43. Australian Competition & Consumer Commission. Philip Morris (Australia) Limited – s.87B undertaking. Canberra: ACCC; 10 May 2005. Available from: https://www.accc.gov.au/public-registers/undertakings-registers/s87b-undertakings-register/philip-morris-australia-limited-s87b-undertaking.

44. Australian Competition & Consumer Commission. Imperial Tobacco Australia Limited – s.87B undertaking. Canberra: ACCC; 10 May 2005. Available from: https://www.accc.gov.au/public-registers/undertakings-registers/s87b-undertakings-register/imperial-tobacco-australia-limited-s87b-undertaking.
45. Dewhirst T. Co-optation of harm reduction by Big Tobacco. Tobacco Control 2020: 0; 1-3. doi: 10.1136/tobaccocontrol-2020-056059.
46. Peeters S and Gilmore AB. Understanding the emergence of the tobacco industry's use of the term tobacco harm reduction in order to inform public health policy. Tobacco Control 2015; 24: 182-89. doi: 10.1136/tobaccocontrol-2013-051502.
47. Glantz SA and Bareham DW. E-Cigarettes: Use, Effects on Smoking, Risks, and Policy Implications. Annual Review of Public Health 2018; 29: 215-35. doi: 10.1146/annurev-publhealth-040617-013757.
48. Campaign for Tobacco-Free Kids. Electronic Cigarettes and Youth. Campaign for Tobacco-Free Kids; 2020. Available from: https://www.tobaccofreekids.org/assets/factsheets/0382.pdf.
49. Kim AE, Chew R, Wenger M, Cress M, Bukowski T, Farrelly M et al. Estimated Ages of JUUL Twitter Followers. JAMA Pediatrics 2019; 173(7): 690-92. doi: 10.1001/jamapediatrics.2019.0922.
50. Fetterman JL, Keith RJ, Palmisano JN, McGlasson KL, Weisbrod RM, Majid S et al. Alterations in Vascular Function Associated With the Use of Combustible and Electronic Cigarettes. Journal of the American Heart Association 2020; 9(9): e014570. doi: 10.1161/JAHA.119.014570.
51. Bozier J, Chivers EK, Chapman DG, Larcombe AN, Bastian NA, Masso-Silva JA et al. The Evolving Landscape of e-Cigarettes: A Systematic Review of Recent Evidence. Chest 2020; 157(5): 1362-90. doi: 10.1016/j.chest.2019.12.042.
52. World Health Organization. E-cigarettes. Geneva: WHO; 29 January 2020. Available from: https://www.who.int/news-room/q-a-detail/tobacco-e-cigarettes.
53. US Department of Health and Human Services. The health consequences of smoking — 50 years of progress. A report of the Surgeon General. Atlanta: Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2014. Available from: https://www.ncbi.nlm.nih.gov/books/NBK179276/pdf/Bookshelf_NBK179276.pdf.
54. US Department of Health and Human Services. E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General. Atlanta: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2016. Available from: https://www.cdc.gov/tobacco/data_statistics/sgr/e-cigarettes/pdfs/2016_sgr_entire_report_508.pdf.
55. World Health Organization International Agency for Research on Cancer. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Report to the Advisory Group to Recommend Priorities for IARC Monographs during 2015-2019. Lyon: IARC; 2014. Available from: https://monographs.iarc.fr/wp-content/uploads/2018/08/14-002.pdf.

56. Kleinman MT, Arechavala RJ, Herman D, Shi J, Hasen I, Ting A et al. E-cigarette or Vaping Product Use-Associated Lung Injury Produced in an Animal Model From Electronic Cigarette Vapor Exposure Without Tetrahydrocannabinol or Vitamin E Oil. Journal of the American Heart Association 2020; 9 (18): e017368. doi: 10.1161/JAHA.120.017368.
57. Wylie C, Heffernan A, Brown JA, Cairns R, Lynch A and Robinson J. Exposures to e-cigarettes and their refills: calls to Australian Poisons Information Centres, 2009-2016. MJA; 210(3): 126. doi: 10.5694/mja2.12032.
58. Coroners Court of Victoria. Finding into Death with Inquest: Inquest into the Death of Baby J. Victoria: Coroners Court of Victoria; 16 July 2019. Available from: https://www.coronerscourt.vic.gov.au/sites/default/files/2019-07/Baby%20J_277318.pdf.
59. Wang B, Liu S and Persoskie A. Poisoning exposure cases involving e-cigarettes and e-liquid in the United States, 2010-2018. Clinical Toxicology 2020; 58(6): 488-94. doi: 10.1080/15563650.2019.1661426.
60. American Lung Association. What it Means to be “Nic-Sick”. Chicago: American Lung Association; 2 October 2019. Available from: https://www.lung.org/blog/nic-sick.
61. United States Food and Drug Administration. Some E-cigarette Users Are Having Seizures, Most Reports Involving Youth and Young Adults. Maryland: FDA; 2019. Available from: https://www.fda.gov/tobacco-products/ctp-newsroom/some-e-cigarette-users-are-having-seizures-most-reports-involving-youth-and-young-adults.
62. Hess IM, Lachireddy K and Capon A. A systematic review of the health risks from passive exposure to electronic cigarette vapour. Public Health Research and Practice 2016; 26(2): 2621617. doi: 10.17061/phrp2621617.
63. Bandi P, Cahn Z, Sauer AG, Douglas CE, Drope J, Jemal A et al. Trends in E-Cigarette Use by Age Group and Combustible Cigarette Smoking Histories, U.S. Adults, 2014-2018. American Journal of Preventive Medicine 2020. doi: 10.1016/j.amepre.2020.07.026.
64. Hajek P, Phillips-Waller A, Przulj D, Pesola F, Myers Smith K, Bisal N et al. A Randomized Trial of E-cigarettes versus Nicotine-Replacement Therapy. N Engl J Med 2019; 380(7): 629-37. doi: 10.1056/NEJMoa1808779.
65. Coleman B, Rostron B, Johnson SE, Persoskie A, Pearson J, Stanton C et al. Transitions in electronic cigarette use among adults in the Population Assessment of Tobacco and Health (PATH) Study, Waves 1 and 2 (2013-2015). Tob Control 2019; 28(1): 50-59. doi: 10.1136/tobaccocontrol-2017-054174.
66. US Department of Health and Human Services. Smoking cessation. A report of the Surgeon General. Rockville: Public Health Service, Office of the Surgeon General; Atlanta: Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2020. Available from: https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf.

67. Harris M, Martin M, Yazidjoglou A, Ford L, Lucas RM and Banks E. Review of evidence regarding attributes and behaviours of smokers as smoking prevalence falls, including evidence statement to the 'hardening hypothesis'. Acton ACT: Australian National University, Research School of Population Health, National Centre for Epidemiology & Population Health; 2020. Available from: https://www.medrxiv.org/content/10.1101/2020.09.16.20195560v1.full.pdf.
68. Buchanan T, Magee CA, Igwe EO and Kelly PJ. Is the Australian smoking population hardening? Addictive Behaviours 2021; 112: 106575. doi: 10.1016/j.addbeh.2020.106575.
69. Australian Institute of Health and Welfare. Data tables: National Drug Strategy Household Survey 2019 - 2. Tobacco smoking chapter, Supplementary data tables. Canberra: AIHW, 2020. Available from: https://www.aihw.gov.au/reports/illicit-use-of-drugs/national-drug-strategy-household-survey-2019/data.
70. O'Brien D, Long J, Lee C, McCarthy A and Quigley J. Electronic cigarette use and tobacco cigarette smoking initiation in adolescents: An evidence review. Dublin: Health Research Board May 2020. Available from: https://www.drugsandalcohol.ie/33170/1/Electronic_cigarette_use_and_smoking_initiation_in_adolescents.pdf.
71. World Health Organization Framework Convention on Tobacco Control. Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS). FCTC/COP/7(11). Geneva: WHO; November 2016. Available from: https://www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf.
72. Chapman S. Would you take a drug that failed with 90% of users? New Cochrane data on "success". Simon Chapman; 15 October 2020. Available from: https://simonchapman6.com/2020/10/15/would-you-take-a-drug-that-failed-with-90-of-users-new-cochrane-data-on-vaping-success/.
73. Chen R, Pierce JP, Leas EC, White MM, Kealey S, Strong DR et al. Use of Electronic Cigarettes to Aid Long-Term Smoking Cessation in the United States: Prospective Evidence From the PATH Cohort Study. American Journal of Epidemiology 2020; kwaa161. doi: 10.1093/aje/kwaa161.
74. Osibogun O, Bursac Z, Mckee M and Li T. Cessation outcomes in adult dual users of e-cigarettes and cigarettes: the Population Assessment of Tobacco and Health cohort study, USA, 2013–2016. International Journal of Public Health 2020; 65(6): 923-36. doi: 10.1007/s00038-020-01436-w.
75. Royal Australian College of General Practitioners. Supporting smoking cessation: a guide for health professionals. 2nd ed. East Melbourne: RACGP; 2019. Available from: https://www.racgp.org.au/ clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/ supporting-smoking-cessation.
76. McDonald CF, Jones S, Beckert L, Bonevski B, Buchanan T, Bozier J et al. Electronic cigarettes: A position statement from the Thoracic Society of Australia and New Zealand. Respirology 2020; 25(10): 1082-1089. doi: 10.1111/resp.13904.

77. Australian Medical Association. Tobacco Smoking and E-cigarettes – 2015. AMA; 16 December 2015. Available from: https://ama.com.au/position-statement/tobacco-smoking-and-e-cigarettes-2015.
78. Royal Australasian College of Physicians. RACP clarifies position on vaping. RACP; 24 April 2020. Available from: https://www.racp.edu.au/news-and-events/media-releases/racp-clarifies-position-on-vaping.
79. Australian Medical Association, Cancer Australia, Cancer Council Australia, National Heart Foundation of Australia and Thoracic Society of Australia and New Zealand. Statement on e-cigarettes in Australia. Canberra: Cancer Australia; February 2018. Available from: https://www.canceraustralia.gov.au/sites/default/files/statement_on_e-cigarettes_february_2018_0.pdf.
80. World Health Organization. Electronic Nicotine and Non-nicotine Delivery Systems: A Brief. Copenhagen: WHO Regional Office for Europe; 2020. Available from: https://www.euro.who.int/__data/assets/pdf_file/0009/443673/Electronic-nicotine-and-non-nicotine-delivery-systems-brief-eng.pdf.
81. The Lancet. E-cigarettes: Public Health England's evidence-based confusion. The Lancet 2015; 386(9996): 829. doi: 10.1016/S0140-6736(15)00042-2.
82. McKee M and Capewell S. Evidence about electronic cigarettes: a foundation built on rock or sand? BMJ 2015; 351: H4863. doi: 10.1136/bmj.h4863.
83. Chapman S. Keep TGA control of e-cigarettes or risk repeating the smoking health disaster. Sydney Morning Herald; 19 June 2017. Available from: https://www.smh.com.au/opinion/keep-tga-control-of-ecigarettes-or-risk-repeating-the-smoking-health-disaster-20170619-gwtyux.html.
84. Pisinger C and Godtfredsen NS. Is there a health benefit of reduced tobacco consumption? A systematic review. Nicotine & Tobacco Research 2007; 9(6): 631-46. doi: 10.1080/14622200701365327.
85. Tverdal A and Bjartveit K. Health consequences of reduced daily cigarette consumption. Tobacco Control 2006; 15(6): 472-80. doi: 10.1136/tc.2006.016246.
86. Hart C, Gruer L and Bauld L. Does smoking reduction in midlife reduce mortality risk? Results of 2 long-term prospective cohort studies of men and women in Scotland. American Journal of Epidemiology 2013; 178(5): 770-9. doi: 10.1093/aje/kwt038.
87. Song Y, Sung J and Cho H. Reduction and Cessation of Cigarette Smoking and Risk of Cancer: A Cohort Study of Korean Men. Journal of Clinical Oncology 2008; 26(31): 5101-6. doi: 10.1200/JCO.2008.17.0498.
88. Hackshaw A, Morris JK, Boniface S, Tang J and Milenkovic D. Low cigarette consumption and risk of coronary heart disease and stroke: meta-analysis of 141 cohort studies in 55 study reports. BMJ 2018; 360: j5855. doi: 10.1136/bmj.j5855.
89. US Department of Health and Human Services. How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease. A Report of the Surgeon General. Atlanta, GA: Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2010. Available from: https://www.ncbi.nlm.nih.gov/books/NBK53017/pdf/Bookshelf_NBK53017.pdf.

90. Brazilian National Health Surveillance Agency. Legislation – Resolution of the Collegiate Board - RDC nº 46 of 08/28/2009. Sao Paulo: ANVISA; 2009. Available from: http://antigo.anvisa.gov.br/legislacao/?inheritRedirect=true#/visualizar/28428.
91. Brazilian Medical Association Tobacco Control Commission. AMB warns against the use of electronic nicotine delivery devices: Electronic and heated cigarettes. Brazilian Medical Association 2017; 63(10): 825-26. doi: 10.1590/1806-9282.63.10.825.
92. Oliveira da Silva AL and Moreira JC. The ban of electronic cigarettes in Brazil: success or failure? Public health science 2019; 24(8): 3013-23. doi: 10.1590/1413-81232018248.24282017.
93. Brazilian Presidency of the Republic Office of Civil Affairs. Decree No. 2.018, of October 1, 1996. San Paulo: Brazilian Presidency of the Republic; 1996. Available from: http://www.planalto.gov.br/ccivil_03/decreto/D2018.htm.
94. Health Canada. Notice of Intent – Potential Measures to Reduce the Impact of Vaping Products Advertising on Youth and Non-users of Tobacco Product. Ontario: Health Canada; 2019. Available from: https://www.canada.ca/en/health-canada/programs/consultation-measures-reduce-impact-vaping-products-advertising-youth-non-users-tobacco-products/notice-document.html.
95. Health Canada. Vaping and quitting smoking. Ontario: Health Canada; 2020. Available from: https://www.canada.ca/en/health-canada/services/smoking-tobacco/vaping/smokers.html.
96. Health Canada. Vaping product regulations. Ontario: Health Canada; 2020. Available from: https://www.canada.ca/en/health-canada/services/smoking-tobacco/vaping/product-safety-regulation.html.
97. Canada Gazette. Vaping Products Promotion Regulations: SOR/2020-143. Ontario: Government of Canada; 2020. Available from: http://gazette.gc.ca/rp-pr/p2/2020/2020-07-08/html/sor-dors143-eng.html.
98. European Commission. European Union Tobacco Products Directive 2014/40/EU of the European Parliament and of the Council. Brussels: European Commission; 2014. Available from: https://ec.europa.eu/health/sites/health/files/tobacco/docs/dir_201440_en.pdf.
99. European Commission. Electronic cigarettes. Brussels: European Commission; 2020. Available from: https://ec.europa.eu/health/tobacco/ecigarettes_en.
100. Public Health England. Vaping in England: 2020 evidence update summary. London: Public Health England; 2020. Available from: https://www.gov.uk/government/publications/vaping-in-england-evidence-update-march-2020/vaping-in-england-2020-evidence-update-summary.
101. New Zealand Ministry of Health. Smokefree Aotearoa 2025. Wellington: New Zealand Ministry of Health; 2020. Available from: https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/smokefree-aotearoa-2025.
102. New Zealand Ministry of Health. Position statement on vaping. Wellington: New Zealand Ministry of Health; 2020. Available from: https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/vaping-smokefree-environments-and-regulated-products/position-statement-vaping.

103. New Zealand Ministry of Health. Vaping – smokefree environments and regulated products. Wellington: New Zealand Ministry of Health; 2020. Available from: https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/vaping-smokefree-environments-and-regulated-products.
104. New Zealand Medicines and Medical Devices Safety Authority. Classification Database. Wellington: New Zealand Medicines and Medical Devices Safety Authority; 2019. Available from: https://www.medsafe.govt.nz/profs/class/classintro.asp.
105. Tobacco Free California. Governor Newsom Signs Landmark Bill, SB 793, to End the Retail Sale of Flavored Tobacco. California Department of Public Health; 21 October 2020. Available from: https://tobaccofreeca.com/health-equity/sb-793-saving-lives/.
106. United States Food and Drug Administration. FDA's Deeming Regulations for E-Cigarettes, Cigars, and All Other Tobacco Products. Maryland: FDA; 2020. Available from: https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/fdas-deeming-regulations-e-cigarettes-cigars-and-all-other-tobacco-products.
107. United States Food and Drug Administration. Family Smoking Prevention and Tobacco Control Act – An Overview. Maryland: FDA; 2020. Available from: https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/family-smoking-prevention-and-tobacco-control-act-overview.
108. United States Food and Drug Administration. FDA finalizes enforcement policy on unauthorized flavored cartridge-based e-cigarettes that appeal to children, including fruit and mint. Maryland: FDA; 2020. Available from: https://www.fda.gov/news-events/press-announcements/fda-finalizes-enforcement-policy-unauthorized-flavored-cartridge-based-e-cigarettes-appeal-children.
109. United States Food and Drug Administration. Effective and Compliance Dates Applicable to Retailers, Manufacturers, Importers, and Distributors of Deemed Tobacco Products. Maryland: FDA; 2020. Available from: https://www.fda.gov/tobacco-products/compliance-enforcement-training/effective-and-compliance-dates-applicable-retailers-manufacturers-importers-and-distributors-deemed.
110. United States Food and Drug Administration. Enforcement Priorities for Electronic Nicotine Delivery System (ENDS) and Other Deemed Products on the Market Without Premarket Authorization. Maryland: FDA; 2020. Available from: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-priorities-electronic-nicotine-delivery-system-ends-and-other-deemed-products-market.
111. Singaporean Ministry of Health. Commencement of the Tobacco (Control of Advertisements and Sale) Amendment Act 2017. Singapore: Singaporean Ministry of Health; 2018. Available from: https://www.moh.gov.sg/news-highlights/details/commencement-of-the-tobacco-(control-of-advertisements-and-sale)-amendment-act-2017.
112. World Health Organization. WHO report on the global tobacco epidemic, 2019 – Country profile: Uruguay. Geneva: WHO; 2019. Available from: https://www.who.int/tobacco/surveillance/policy/country_profile/ury.pdf?ua=1.

113. World Health Organization. WHO report on the global tobacco epidemic, 2019 – Country profile: Jordan. Geneva: WHO; 2019. Available from: https://www.who.int/tobacco/surveillance/policy/country_profile/jor.pdf?ua=1.
114. World Health Organization. WHO report on the global tobacco epidemic, 2019 – Country profile: Oman. Geneva: WHO; 2019. Available from: https://www.who.int/tobacco/surveillance/policy/country_profile/omn.pdf?ua=1.
115. World Health Organization. WHO report on the global tobacco epidemic, 2019 – Country profile: Qatar. Geneva: WHO; 2019. Available from: https://www.who.int/tobacco/surveillance/policy/country_profile/qat.pdf?ua=1.
116. World Health Organization. WHO statement on ban of e-cigarettes by Government of India. Geneva: WHO; 2019. Available from: https://www.who.int/india/news/detail/19-09-2019-who-statement-on-ban-of-e-cigarettes-by-government-of-india.