The Senate

Select Committee on Tobacco Harm Reduction

Report

December 2020

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Contents

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Committee Report by the Majority

Chapter 1
Introduction

1.1 On 6 October 2020, the Senate established the Select Committee on Tobacco Harm Reduction (the committee) to inquire into and report on tobacco reduction strategies, with particular reference to:

(a) the treatment of nicotine vaping products (electronic cigarettes and smokeless tobacco) in developed countries similar to Australia (such as the United Kingdom, New Zealand, the European Union and United States), including but not limited to legislative and regulatory frameworks;
(b) the impact nicotine vaping products have had on smoking rates in these countries, and the aggregate population health impacts of these changes in nicotine consumption;
(c) the established evidence on the effectiveness of e-cigarettes as a smoking cessation treatment;
(d) the established evidence on the uptake of e-cigarettes amongst non-smokers and the potential gateway effect onto traditional tobacco products;
(e) evidence of the impact of legalising nicotine vaping products on youth smoking and vaping rates and measures that Australia could adopt to minimise youth smoking and vaping;
(f) access to e-cigarette products under Australia's current regulatory frameworks;
(g) tobacco industry involvement in the selling and marketing of e-cigarettes; and
(h) any other related matter.[1]

1.2 The committee was required to present its final report on or before 1 December 2020. Following a resolution of the committee on 2 November 2020, and in accordance with the motion agreed by the Senate on 23 March 2020,[2] the reporting date for the inquiry was extended to 18 December 2020.

Conduct of the inquiry

1.3 The committee advertised the inquiry on its webpage and invited submissions from a range of relevant stakeholders, including interest groups, government agencies, public health organisations, industry, universities and research bodies.

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1 *Journals of the Senate*, No. 67, 6 October 2020, pp. 2341–2342.

2 *Journals of the Senate*, No. 47, 23 March 2020, p. 1545.

1.4 The committee received over 13 000 documents, comprised of submissions, form letters and correspondence. This included 900 public and name withheld submissions, which are detailed in Appendix 1. Further to this, the inquiry received over 30 confidential submissions.

1.5 The committee also received 8 324 form letters, with substantially similar content, from ex, current and non-smokers across three email campaigns.[3] A summary of the main points made by individuals is available on the committee's website.

1.6 In addition, the committee received approximately 362 pieces of correspondence.

1.7 The committee held public hearings in Canberra on 13 November 2020 and in Sydney on 19 November 2020. A list of witnesses who participated in the public hearings is at Appendix 2.

1.8 The committee undertook the inquiry following established parliamentary practices and procedures, and sought the views of a wide range of organisations and individuals. Public hearings were accessible to members of the public: proceedings were broadcast online and transcripts of the hearings are available on the inquiry webpage.

World Health Organization Guidelines

1.9 Several committee members and inquiry participants raised the importance of ensuring that the inquiry was cognisant of Australia's obligations under Article 5.3 of the *World Health Organization's Framework Convention on Tobacco Control* (WHO FCTC).[4] The guidelines for implementing Article 5.3 (the Guidelines) state that Parties to the WHO FCTC 'need to be alert to any efforts by the tobacco industry to undermine or subvert tobacco control efforts'.[5]

1.10 The Guidelines also state that Parties should 'establish measures to limit interactions with the tobacco industry and ensure the transparency of those interactions that occur'. Where interactions with the Tobacco Industry are necessary, Parties should ensure they are conducted transparently and that 'whenever possible, interactions should be conducted in public, for example through public hearings, public notice of interactions [and] disclosure of records of such interactions to the public'.[6]

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3 An additional 3,597 duplicates have not been included in this figure.

4 WHO FCTC, Geneva, 21 May 2003, entry into force on 27 February 2005, [2005] ATS 7.

5 World Health Organization, *Guidelines for Implementation of Article 5.3*, November 2008, p. 1.

6 World Health Organization, *Guidelines for Implementation of Article 5.3*, November 2008, p. 4.

1.11 The Tobacco Industry and its representatives lodged submissions to the inquiry which are published on the inquiry website. All hearings were accessible to members of the public, an audio stream of the hearings was available on the internet, and the transcripts of the hearings are available on the inquiry webpage.

1.12 Accordingly, and given the vital importance of transparency in this respect, some inquiry participants who either appeared at hearings or made submissions were asked to make declarations as to whether they have been or are in receipt of assistance from the Tobacco Industry. Their responses are available on the inquiry website.

What are electronic cigarettes?

1.13 Smoke-free products deliver nicotine in the absence of both combustion and smoke. The term covers a broad range of products including electronic cigarettes, heat-not-burn tobacco products, chewing tobacco, snuff and other novel nicotine products.

1.14 Electronic cigarettes (also known as e-cigarettes, e-cigs, electronic nicotine delivery systems, electronic non-nicotine delivery systems, alternative nicotine delivery systems, personal vaporisers, e-hookahs, vape pens or vapes) are battery powered devices that deliver an aerosol by heating a solution that users breathe in.[7] For the purpose of this report, electronic cigarettes are referred to as e-cigarettes. Heat-not-burn tobacco products are also battery-powered electronic devices, however, they differ from e-cigarettes in that they heat tobacco up to 350 degrees celsius to produce aerosols containing nicotine and other chemicals, which are inhaled by users.[8] Other smokeless tobacco products, including chewing tobacco and snuff, involve oromucosal nicotine delivery.

1.15 E-cigarette devices consist of three parts: a battery (usually rechargeable); a tank or 'pod' for the e-liquid; and a 'coil' or heating element.[9] E-cigarettes have evolved as a product since first entering the market, with products now ranging from early 'first generation' devices that resemble cigarettes, to second

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[7] Department of Health, *About e-cigarettes*, 17 March 2020, www.health.gov.au/health-topics/smoking-and-tobacco/about-smoking-and-tobacco/about-e-cigarettes (accessed 30 November 2020).

[8] World Health Organisation, *Heat-Not-Burn tobacco products information sheet*, apps.who.int/tobacco/publications/prod_regulation/heat-not-burn-products-information-sheet/en/index.html (accessed 7 December 2020).

[9] Australian Tobacco Harm Reduction Association, *Switching to vaping in 5 easy steps*, 27 December 2019, athra.org.au/wp-content/uploads/2019/12/Switch-to-Vaping-in-5-easy-steps-flyer26Dec2019.pdf (accessed 30 November 2020).

and third generation devices that enable users to modify characteristics of the device, such as adjusting the voltage.[10]

1.16 E-cigarettes and combustible cigarettes are substantially different products. A combustible cigarette burns tobacco at around 600 degrees celsius and produces smoke which contains high levels of harmful and potentially harmful constituents, including carbon monoxide and tar, whereas e-cigarettes deliver nicotine without smoke.[11] E-cigarettes do not contain tobacco and heat nicotine liquid, rather than burning it.[12] The absence of burning and its by-product, smoke, is significant because '[b]urning tobacco causes almost all the harm from smoking. It releases over 7,000 chemicals, tars, carbon monoxide, other toxic gases and solid particles'.[13]

1.17 The solution used in e-cigarettes is e-liquid (also known as 'e-juice' or 'vape juice'). E-liquids may contain propylene glycol, vegetable glycerine or glycerol, flavouring, colour additives and, in some cases, water. E-liquids may or may not contain nicotine.[14] Vapourised e-liquid is often referred to as 'vapour', while the action of inhaling this aerosol is referred to as 'vaping'.[15]

1.18 E-liquids can be purchased pre-mixed or made by mixing together separate ingredients. Commercial e-liquids often come in nicotine concentrations of 0mg/mL (no nicotine), 3mg/mL, 6mg/mL and 12mg/mL, although higher concentrations may reach up to 50mg/mL.[16] These values represent the amount

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[10] National Health and Medical Research Council, *CEO Statement: Electronic cigarettes*, 3 April 2017, www.nhmrc.gov.au/about-us/resources/ceo-statement-electronic-cigarettes (accessed 1 December 2020).

[11] United States Food & Drug Administration, *Harmful and Potentially Harmful Constituents (HPHCs)*, content current as of 10 July 2019, www.fda.gov/tobacco-products/products-ingredients-components/harmful-and-potentially-harmful-constituents-hphcs (accessed 7 December 2020).

[12] Department of Health, *About e-cigarettes*, www.health.gov.au/health-topics/smoking-and-tobacco/about-smoking-and-tobacco/about-e-cigarettes (accessed 3 December 2020).

[13] Australian Tobacco Harm Reduction Association, *Submission 166*, p. 23.

[14] Victorian Government, Better Health Channel, *E-liquids for use in e-cigarettes*, July 2019, www.betterhealth.vic.gov.au/health/healthyliving/e-liquids-for-use-in-e-cigarettes (accessed 30 November 2020).

[15] Department of Health, *About e-cigarettes*, 17 March 2020, www.health.gov.au/health-topics/smoking-and-tobacco/about-smoking-and-tobacco/about-e-cigarettes (accessed 30 November 2020).

[16] E-liquids ranging in nicotine concentration from 0mg/mL to 50mg/mL are advertised for commercial sale through a number of websites.

of nicotine in each 1mL of e-liquid. For contrast, the nicotine content in a cigarette is generally between 13mg and 30mg.[17]

Previous inquiries

1.19 In recent years, there have been a number of parliamentary committees which have inquired into various aspects of e-cigarettes, including a House of Representatives standing committee in the 45th Parliament and Senate committees in the 44th and 45th Parliaments.[18]

Acknowledgements

1.20 The committee thanks the individuals and organisations who contributed to this inquiry. While the committee does not have the power to intervene in, or investigate, personal circumstances, members of the committee sincerely appreciate the time and effort taken by individuals, as well as their friends and family, to participate in the inquiry. The committee thanks everyone who took the time to contact the committee and recount their personal experiences with e-cigarette use and also thanks all those who provided their expertise to the committee's deliberations. Their contributions have been an invaluable resource to the inquiry.

References to Hansard

1.21 In this report, references to *Committee Hansard* are to proof transcripts. Page numbers may vary between proof and official transcripts.

Structure of the report

1.22 This report is structured as follows:

- Chapter 1 provides information about the context and administrative details of the inquiry.
- Chapter 2 discusses Australia's regulatory approach to e-cigarettes, including the prevalence of tobacco smoking and e-cigarette use in Australia.
- Chapter 3 sets out international approaches to regulating e-cigarettes.
- Chapter 4 considers the health impacts of e-cigarettes.

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[17] Therapeutic Goods Administration, *Scheduling delegate's interim decisions and invitation for further comment: ACCS/ACMS, November 2016*, 2 February 2017, www.tga.gov.au/book-page/21-nicotine (accessed 4 December 2020).

[18] House of Representatives Standing Committee on Health, Aged Care and Sport, *Report on the inquiry into the use and marketing of electronic cigarettes and personal vaporisers in Australia*, March 2018; Senate Community Affairs Legislation Committee, *Vaporised Nicotine Products Bill 2017*, September 2017; Senate Select Committee on Red Tape, *Effect of red tape on tobacco retail: Interim report*, June 2017; and Senate Economics References Committee, *Personal choice and community impacts. Interim report: the sale and use of tobacco, tobacco products, nicotine products and e-cigarettes (term of reference a)*, May 2016.

- Chapter 5 examines the relative strengths and weaknesses of a prescription-based model in comparison to other regulatory approaches.
- Chapter 6 concludes with the committee view and recommendations.

Chapter 2
The Australian context

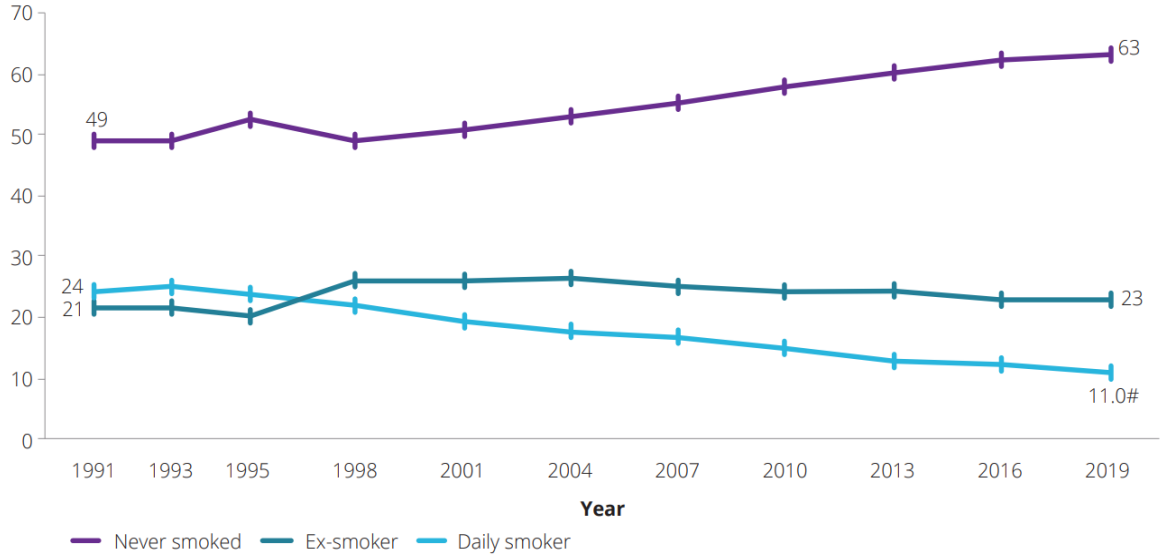
Introduction

2.1 This chapter discusses tobacco smoking and e-cigarette use in Australia, before going on to summarise the Australian Government's approach to e-cigarette products and their regulation as a therapeutic good.

Tobacco smoking in Australia

2.2 Smoking rates have dropped steadily in Australia since the early 1990s. The most recent data shows that, from 2016 to 2019, daily smoking prevalence decreased in Australia by 1.2 percentage points, to 11 per cent of Australians aged over 14 years.[1] The rates of daily smoking in Australia have reduced from 12.2 per cent (2.4 million people) in 2016 to 11.0 per cent (2.3 million) in 2019. This compares with 24 per cent of Australians smoking tobacco daily in 1991.[2]

Figure 2.1 Tobacco smoking status, people aged 14 and over, 1991–2019



Source: Australian Institute of Health and Welfare, National Drug Strategy Household Survey 2019, 16 July 2020, p. 6.

2.3 The number of Australians (aged 14 and older) who have never smoked has increased from 55.4 per cent in 2007 to 63.1 per cent in 2019.[3] In particular, the

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1 Australian Institute of Health and Welfare, *National Drug Strategy Household Survey 2019*, 16 July 2020, p. vii.

2 Australian Institute of Health and Welfare, *Submission 214*, p. 4.

3 Australian Institute of Health and Welfare, *Submission 214*, p. 8.

Australian Institute of Health and Welfare reported that the 14–17 year age group was the most likely of all age demographics to have never smoked.[4]

2.4 The *National Drug Strategy Household Survey 2019* estimated that tobacco smoking accounts for 22 per cent of the total cancer burden in Australia.[5] The committee also heard that tobacco smoking remains a leading cause of preventable death and disability in Australia, estimated to have killed almost 21 000 Australians in 2015.[6] It was also noted that tobacco smoking compounds health and social inequalities and is a major contributor to poorer health status in socioeconomically disadvantaged populations.[7]

2.5 The Department of Health estimated 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.[8]

2.6 The Australian Government has set a national target for the rate of daily smoking amongst adults of '10 per cent by 2025'.[9] This new target was announced after the previous target set under the National Healthcare Agreement of '10 per cent by 2018' was not met.[10] Other countries have set more ambitious targets, including New Zealand, which aims to be smoke-free (defined as achieving a smoking rate of less than 5 per cent) by 2025.[11]

Use of e-cigarettes

2.7 E-cigarette use has increased annually in Australia in recent years. In 2019, the *National Drug Strategy Household Survey* found that the proportion of people who have ever used e-cigarettes rose from 8.8 per cent (1.7 million people) to 11.3 per cent (2.4 million people) and the proportion of people who used

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4 In 2007, 93 per cent of those aged 14-17 years had never smoked, while in 2019 96.6 per cent had never smoked.

5 Australian Institute of Health and Welfare, *National Drug Strategy Household Survey 2019*, 16 July 2020, p. 1.

6 Department of Health, *Submission 167*, p. 10.

7 Department of Health, *Submission 167*, p. 10.

8 Department of Health, *Submission 167*, p. 10.

9 The Hon Greg Hunt MP, Minister for Health, 'National Press Club address—Long Term National Health Plan', *Media Release*, 15 August 2019.

10 Productivity Commission, *National Healthcare Agreement—Performance Reporting Dashboard*, https://performancedashboard.d61.io/healthcare (accessed 7 December 2020).

11 Health Promotion Agency, *Smokefree Aotearoa 2025*, content current as of 9 June 2019, https://www.smokefree.org.nz/smokefree-in-action/smokefree-aotearoa-2025 (accessed 7 December 2020).

e-cigarettes rose from 1.2 per cent (200 000 people) to 2.5 per cent (500 000 people).[12]

2.8 The committee notes that the *National Drug Strategy Household Survey 2019* does not distinguish between e-cigarette products containing nicotine and those without nicotine.[13]

2.9 The Department of Health commented that:

> 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 in 2020. 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.[14]

2.10 The Department of Health noted that the fall in cigarette use in Australia is not due to the relatively recent uptake in e-cigarettes, but due to the long-term tobacco control measures implemented since 1990, such as advertising bans, excise increases, package warnings and plain packaging.[15] It also noted that smoking prevalence has dropped in Australia without the high use of e-cigarettes seen in other countries:

> 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.[16]

The Australian Government's position on e-cigarettes

2.11 Australia has led the world in implementing tobacco control measures including:

- substantial increases in excise on tobacco products;
- education programmes and campaigns;
- bans on smoking in public places;
- plain packaging of tobacco products;
- bans on retail displays of tobacco products;
- labelling with updated and larger graphic health warnings;
- prohibiting tobacco advertising, promotion and sponsorship; and
- providing support for smokers to quit, including through nicotine replacement therapies on the Pharmaceutical Benefits Scheme.[17]

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[12] Australian Institute of Health and Welfare, *National Drug Strategy Household Survey 2019*, 16 July 2020, p. 9.

[13] Australian Institute of Health and Welfare, *Submission 214*, p. 2.

[14] Department of Health, *Submission 167*, p. 13.

[15] Department of Health, *Submission 167*, p. 11.

[16] Department of Health, *Submission 167*, p. 5.

2.12 In respect to e-cigarettes, the Australian Government has adopted a precautionary approach:

> The precautionary approach encourages action to prevent harm when there is scientific uncertainty and until a body of evidence establishes the requirement for alternative regulation. This includes the lack of conclusive evidence around the safety risks posed to users by the unknown inhalation toxicity of nicotine and other chemicals used with e-cigarettes, passive exposure to e-cigarette vapour, risks associated with child poisoning, and issues around quality control and efficacy. The precautionary approach also takes into account the broader risks that e-cigarettes may pose to population health, namely their potential to disrupt the decline in tobacco use in Australia.[18]

2.13 In June 2020, the Australian Government responded to a report by the House of Representatives Standing Committee on Health, Aged Care and Sport on the use and marketing of e-cigarettes and personal vaporisers in Australia. The response noted evidence linking e-cigarettes to tobacco use and nicotine addiction, and the risks of e-cigarette use leading to future smoking in the young adult population. The response concluded:

> The Government will continue to monitor the impact of e-cigarettes on smoking cessation. However, at a population level, there is currently insufficient evidence to promote the use of e-cigarettes for smoking cessation. The Government will also continue to monitor emerging evidence regarding the direct harms e-cigarettes pose to human health, their impacts on smoking initiation, uptake among youth and dual use with conventional tobacco products.[19]

2.14 In September 2019, Australia's Chief Medical Officer and the state and territory Chief Health Officers presented a joint statement about the emerging link between e-cigarette use and lung disease. The statement reported that:

> All Australian governments are united in maintaining a precautionary approach to the marketing and use of e-cigarettes. There is growing evidence implicating e-cigarettes in a range of harms to individual and population health. E-cigarettes are relatively new products and the long-term safety and health effects associated with their use and exposure to second-hand vapour are unknown.[20]

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17 Department of Health, *Submission 167*, p. 10.

18 Australian Government, Department of Health, *Policy and regulatory approach to electronic cigarettes (e-cigarettes) in Australia*, 28 November 2019.

19 Australian Government, *Australian Government response to the Standing Committee on Health, Aged Care and Sport Report on the Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia*, 17 June 2020, p. 9.

20 Chief Medical Officer and State and Territory Chief Health Officers, 'E-cigarettes linked to severe lung illness', *Media Release*, 13 September 2019.

2.15 Similarly, Commonwealth and state and territory ministers discussed the growing amount of evidence in relation to 'the direct harms e-cigarettes pose to human health, their impact on smoking initiation and cessation, uptake among youth and dual use with conventional tobacco products' at a meeting of the Ministerial Drug and Alcohol Forum.[21]

2.16 The Ministerial Drug and Alcohol Forum agreed to a set of updated national guiding principles for e-cigarettes. The principles, released by the Department of Health in November 2019, reaffirm the precautionary approach to e-cigarettes being taken by all Australian governments and note that any change to the regulation of e-cigarettes in Australia will have the protection of the health of children and young people as its primary focus and goal.[22]

2.17 In addition, the Department of Health noted 'the evidence is clear that e-cigarettes in Australia are increasingly marketed to appeal to children and young Australians' and stated that any change to the regulation of e-cigarettes should:

- make protecting children and young people as its primary focus and goal, and place protecting the health of existing adult cigarette smokers as its second key goal;
- take into account the conclusions reached by credible health and scientific agencies in relation to the interpretation and advice of evidence;
- be precautionary in nature;
- minimise the proliferation of e-cigarette marketing and use, particularly among young people while maximising the impact of effective tobacco control measures; and
- complement jurisdictional legislation and take into account the approaches taken by Australian and state and territory governments and other countries to e-cigarettes.[23]

Regulation as a therapeutic good

2.18 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 a prescription.[24] Australia's regulatory treatment of e-cigarettes containing nicotine is a shared

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[21] Ministerial Drug and Alcohol Forum, *Ministerial Drug and Alcohol Forum Communiqué*, 28 November 2019, p. 1.

[22] Australian Government, Department of Health, *Policy and regulatory approach to electronic cigarettes (e-cigarettes) in Australia*, 28 November 2019.

[23] Australian Government, Department of Health, *Policy and regulatory approach to electronic cigarettes (e-cigarettes) in Australia*, 28 November 2019, pp. 1-4.

[24] The possession of nicotine for use in e-cigarettes without a prescription is illegal in all states and territories except South Australia. See Department of Health, *Submission 167*, p. 8.

responsibility between the Commonwealth and state and territory governments.[25] The current regulatory framework draws on existing legislation and regulations that apply to tobacco products, poisons, therapeutic goods and consumer goods. E-cigarettes containing nicotine are regulated differently from those that do not contain nicotine.[26]

2.19 In Australia, it is illegal to import or sell products that make therapeutic claims, unless they have received market authorisation by the Therapeutic Goods Administration (TGA) or they are otherwise exempt or subject to an approval or authority granted by the TGA.[27]

2.20 Nicotine is currently classified as a dangerous poison under Schedule 7 of the Standard for the Uniform Scheduling of Medicines and Poisons (the Poisons Standard) except in preparations for human therapeutic use, tobacco prepared and packed for smoking, and when labelled and packed for the treatment of animals.[28]

2.21 Part 4 of the Poisons Standard is a record of decisions regarding the classification of medicines and chemicals into schedules. Decisions regarding the scheduling of substances for inclusion in the Poisons Standard are made by the Secretary of the Department of Health. In practice, decisions for medicines scheduling are made by their delegate who is a senior medical officer in the Department of Health.[29]

2.22 The Poisons Standard is a legislative instrument under the *Therapeutic Goods Act 1989* (Cth) and is given legal effect through relevant state and territory drugs, poisons and controlled substances legislation.[30]

2.23 States and territories can adopt the current Poisons Standard as made, or adopt it subject to variations. In addition, each state and territory has its own laws that determine where consumers can buy a particular drug or poison, how it is to be packaged and labelled and penalties for possession, use and supply.[31]

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25 Department of Health, *Submission 167*, p. 6.

26 E-cigarette devices and e-liquid refills that do not contain nicotine are generally classified as legal consumer goods and can be sold legally in all Australian states and territories, except for Western Australia.

27 Department of Health, *Submission 167*, p. 6.

28 Poisons Standard October 2020 (Cth).

29 Department of Health, *Submission 167*, p. 7.

30 TGA, *Contacts for State/Territory medicines & poisons regulation units*, 18 February 2020, https://www.tga.gov.au/contacts-stateterritory-medicines-poisons-regulation-units (accessed 8 December 2020),

31 Department of Health, *Submission 167*, p. 7. For state and territory legislation regulating e-cigarettes, please see Heather Douglas, Wayne Hall and Coral Gartner, 'E-cigarettes and the law in Australia', *Australian Family Physician*, vol. 44, no. 6, 2015, Appendix 1.

2.24 Although each Australian jurisdiction may make its own laws to determine the availability of poisons and medicines, they have classified nicotine consistently with the Poisons Standard.[32]

2.25 There is a general prohibition on the commercial supply of nicotine e-cigarette products in every Australian jurisdiction. Other dealings with nicotine (such as possession, manufacturing and use) may also be prohibited and each state and territory has its own set of nicotine-related offences. States and territories have amended their tobacco control laws to treat the advertising, sale and use of e-cigarettes in a similar manner as tobacco products.[33]

Access to unapproved therapeutic goods

2.26 E-cigarettes containing nicotine can be legally imported by individuals through the Personal Importation Scheme under the *Therapeutic Goods Act 1989* (Cth), provided that appropriate rules are followed, including:

- the product is for personal use to quit smoking;[34]
- the importer must have a current valid prescription from an Australian-registered medical practitioner; and
- the importer cannot import more than 3 months' supply at one time under the Personal Importation Scheme, unless a doctor has applied to the TGA for approval for a longer duration of supply.[35]

2.27 In addition to the Personal Importation Scheme, two further pathways to access unapproved therapeutic goods exist: the Special Access Scheme and the Authorised Prescriber Scheme.

2.28 Under the Authorised Prescriber pathway, the TGA is able to grant a medical practitioner authority to prescribe a specified unapproved nicotine product to a class of patients in their immediate care. Whereas, the Special Access Scheme provides for the import and/or supply of an unapproved therapeutic good for a single patient, on a case by case basis.

2.29 In addition, the Department of Health submitted that:

> 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

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[32] As at 9 October 2018, only the Australian Capital Territory, Tasmania and Western Australia had adopted Part 4 of the Poisons Standard subject to variations. See TGA, *Australian State & Territory variations from Part 4 of the Poisons Standard*, 31 May 2019, https://www.tga.gov.au/australian-state-territory-variations-part-4-poisons-standard (accessed 3 November 2020).

[33] TGA, *Electronic cigarettes*, 25 October 2019, https://www.tga.gov.au/community-qa/electronic-cigarettes (accessed on 29 October 2020).

[34] An individual may also import these products for immediate family members, provided that family member holds a valid prescription.

[35] TGA, *Electronic cigarettes*, 25 October 2019, https://www.tga.gov.au/community-qa/electronic-cigarettes, (accessed on 29 October 2020).

> constitute therapeutic goods and therefore do not come within the TGA's regulatory remit, regardless of their nicotine content.[36]

Pathway for approval

2.30 Chemicals with a therapeutic use (such as a chemical that aids in the cessation of cigarette smoking by influencing, inhibiting or modifying a physiological process) must be authorised for use by the TGA. As indicated in Schedule 7 of the Poisons Standard, nicotine may legally be used for human use in tobacco prepared and packed for smoking and for therapeutic purposes where appropriate approvals and licences have been granted.[37]

2.31 Registered (TGA-approved) smoking cessation medicines in Australia include nicotine replacement therapies (such as sprays, patches, lozenges and chews) available without prescription either over-the-counter in pharmacies or, in some cases, from other retailers. The committee notes that a number of these products were initially available with a prescription only before being subsequently rescheduled by the TGA once sufficient evidence was provided that they had no or very low adverse health effects.[38]

2.32 There is no legal impediment to submitting e-cigarette products that contain nicotine for TGA approval. An application for registration on the Australian Register of Therapeutic Goods could be made, which would involve an assessment of safety, efficacy and quality by the TGA, consistent with the requirements for existing nicotine replacement products.

2.33 However, the committee heard that product registration is viewed by the Australian Tobacco Harm Reduction Association as 'enormously costly and onerous'.[39] The National Retail Association explained that 'there are many suppliers that would look to move their manufacturing on-shore should smoke-free nicotine products be made legal'.[40] In addition:

> What would make this untenable is for the product to be regulated by the TGA. Every product, including every flavour or composition, would have to be approved by the TGA which would incur huge costs to the supplier. This is why the regulation should be carried out by the ACCC who can ensure principles and standards of the product instead.[41]

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36 Department of Health, *Submission 167*, p. 7.

37 Department of Health, *Submission 167*, p. 6.

38 Emeritus Professor Simon Chapman, School of Health, University of Sydney, *Committee Hansard*, 19 November 2020, p. 10.

39 Australian Tobacco Harm Reduction Association, *Submission 166*, p. 23.

40 National Retail Association, *Submission 156*, p. 6.

41 National Retail Association, *Submission 156*, p. 6.

2.34 Professor Simon Chapman suggested that e-cigarette products, including flavourings, have not been submitted to the TGA for regulatory approval because there isn't the safety data to support registration:

> I think the main reason is likely to be that they know that inhaling vaporised flavouring chemicals is going to have a snowball's chance in hell of getting through therapeutic regulation. That's why asthma drugs have been unable to [add flavourings]. The American manufacturing association for extracts and flavouring, FEMA, has said as recently as June or July this year that anyone claiming that the inhalation of these products has somehow been ticked off as safe is being false and misleading.[42]

2.35 At the time of reporting, no e-cigarette products have been approved by the TGA as a therapeutic good for smoking cessation.[43]

Relevant decisions of the Therapeutic Goods Administration

Proposal to exempt nicotine from Schedule 7 at 36mg/mL

2.36 On 23 March 2017, the TGA ruled against a proposal to exempt nicotine for use in e-cigarettes from Schedule 7 of the Poisons Standard. The proposed amendment would have allowed for a maximum nicotine concentration of 3.6 per cent in e-cigarettes, a maximum container size of 900 milligrams and required safety and labelling standards for packaging.[44]

2.37 The TGA ruled that the current scheduling of nicotine, which restricts access to the substance under the Poisons Standard, was appropriate. The TGA's reasons for choosing not to exempt nicotine from Schedule 7 of the Poisons Standard included that:

- the possibility of e-cigarettes leading to nicotine dependence and a greater uptake of smoking among young people;
- the lack of evidence regarding the safety of long term nicotine use;
- the risk of nicotine poisoning, especially for children, and the increased rate of nicotine poisoning seen overseas following the growth in usage of e-cigarettes;
- uncertainties around the effectiveness of e-cigarettes as an aid for quitting smoking;
- risks of inappropriate marketing of e-cigarettes and inadequate protections against the sale of e-cigarettes to people under 18 years of age; and

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42 Emeritus Professor Simon Chapman, School of Health, University of Sydney, *Committee Hansard*, 19 November 2020, p. 7.

43 Department of Health, *Submission 167*, p. 6.

44 TGA, *Scheduling delegate's final decisions, March 2017*, 23 March 2017, https://www.tga.gov.au/book-page/21-nicotine-0 (accessed 2 December 2020).

- under existing regulation it is already possible for an e-cigarette product to be approved by the TGA if it is proven to be effective as a smoking cessation aid.[45]

Interim decision for scheduling of nicotine

2.38 On 23 September 2020, the TGA announced an interim decision that, if finalised, would clarify the scheduling of nicotine in the Poisons Standard. The proposed changes would mean that certain nicotine-containing products for human use could only be supplied with a doctor's prescription.[46]

2.39 As noted above, decisions related to the classification of medicines and poisons under the Poisons Standard are made by a senior medical officer (the delegate) in the Department of Health.[47]

2.40 During the course of its review of the proposed scheduling amendment, the Advisory Committee on Medicines and Chemicals Scheduling stated that the proposed scheduling amendment:

> …would remove a perceived inconsistency between Commonwealth and State and Territory laws regulating nicotine-containing e-cigarettes and help clarify the circumstances under which Australian Border Force may seize e-cigarettes containing nicotine, which are imported into Australia. In effect, it will remove the present uncertainty for some stakeholders over the regulatory treatment of nicotine.[48]

2.41 The TGA clarified that the Personal Importation Scheme would remain available to individuals to order their e-cigarettes containing nicotine online with a prescription under the *Therapeutic Goods Act 1989* (Cth).[49]

2.42 A final decision is expected in mid-December 2020.[50] However, the committee notes that the Australian Government's proposal to prohibit the importation of e-cigarettes containing nicotine (discussed below) would further restrict access

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[45] TGA, *Scheduling delegate's final decisions, March 2017*, 23 March 2017, https://www.tga.gov.au/book-page/21-nicotine-0 (accessed 2 December 2020).

[46] TGA, *Interim decision of entry of nicotine in the Poisons Standard: Information for consumers*, 23 September 2020, https://www.tga.gov.au/interim-decision-entry-nicotine-poisons-standard-information-consumers (accessed 30 November 2020).

[47] Department of Health, *Submission 167*, p. 9.

[48] TGA, *Interim decision of entry of nicotine in the Poisons Standard: Information for consumers*, 23 September 2020, https://www.tga.gov.au/interim-decision-entry-nicotine-poisons-standard-information-consumers (accessed 29 September 2020).

[49] TGA, *Interim decision of entry of nicotine in the Poisons Standard: Information for consumers*, 23 September 2020, https://www.tga.gov.au/interim-decision-entry-nicotine-poisons-standard-information-consumers (accessed 30 November 2020).

[50] TGA, *Notice and invitation to comment on an interim decision to amend the current Poisons Standard in relation to nicotine*, 30 October 2020, https://www.tga.gov.au/scheduling-decision-interim/notice-interim-decision-amend-current-poisons-standard-relation-nicotine (accessed 15 December 2020).

to e-cigarette products. The interim decision on nicotine scheduling is a separate process from the Australian Government's proposed prohibition on the importation of e-cigarettes containing vaporiser nicotine.[51]

Proposal to prohibit the importation of e-cigarettes containing nicotine

2.43 In June 2020, the Australian Government announced its intention to amend the Customs (Prohibited Import) Regulations 1956 (Cth) to prohibit the importation of e-cigarettes containing vaporiser nicotine (nicotine in solution or in salt or base form) and nicotine-containing refills unless on prescription from a doctor.[52]

2.44 In an announcement on 26 June 2020, the Minister for Health, the Hon Greg Hunt MP, stated:

> In particular, around the world we have seen strong evidence of non-smokers being introduced to nicotine through vaping for the first time.
>
> Therefore the Government is responding to the advice by ensuring that nicotine based e-cigarettes can only be imported on the basis of a prescription from a doctor.
>
> This will help prevent the introduction of non-smokers to nicotine via vaping.
>
> However there is a second group of people who have been using these e-cigarettes with nicotine as a means to ending their cigarette smoking.
>
> In order to assist this group in continuing to end that addiction we will therefore provide further time for implementation of the change by establishing a streamlined process for patients obtaining prescriptions through their GP.
>
> For this reason, the implementation timeframe will be extended by six months to 1 January 2021.[53]

2.45 The TGA advised that the effect of the importation ban would be that individuals would no longer be permitted to import nicotine for use in

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[51] TGA, *Interim decision of entry of nicotine in the Poisons Standard: Information for consumers*, 23 September 2020, https://www.tga.gov.au/interim-decision-entry-nicotine-poisons-standard-information-consumers (accessed 30 November 2020).

[52] The Customs (Prohibited Imports) Amendment (Vaporiser Nicotine) Regulations 2020 (Cth) came into force on 25 June 2020. Prior to commencement, the amendment was repealed to allow time for the scheduling delegate to reach a final decision for the scheduling of nicotine in the Poisons Standard.

[53] The Hon Greg Hunt MP, Minister for Health, 'Prescription Nicotine Based Vaping', *Media Release*, 26 June 2020.

e-cigarettes directly from an overseas supplier without a valid import permit.[54] The TGA clarified that:

> You will need a prescription from your doctor for an e-cigarette containing vaporiser nicotine, and it will need to be obtained on your behalf by a medical supplier or from a pharmacist who dispenses it for your use as the named patient. The company or the pharmacist will need to be given a copy of your prescription.[55]

2.46 In its submission, the Department of Health advised that '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'.[56]

2.47 The committee received evidence about the possible options for the regulation of nicotine e-cigarette products in Australia and the outcomes of consumer goods regulation as well as a prescription-based model. This is discussed further in Chapter 5.

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[54] TGA, *Prohibition in importing e-cigarettes containing vaporiser nicotine*, 29 June 2020, https://www.tga.gov.au/behind-news/prohibition-importing-e-cigarettes-containing-vaporiser-nicotine (3 November 2020).

[55] TGA, *Prohibition in importing e-cigarettes containing vaporiser nicotine*, 29 June 2020, https://www.tga.gov.au/behind-news/prohibition-importing-e-cigarettes-containing-vaporiser-nicotine (3 November 2020).

[56] Department of Health, *Submission 167*, p. 9.

Chapter 3
Jurisdictional comparison

Overview

3.1 Globally, there are significant differences in how countries regulate e-cigarettes and related products. Common approaches include regulating e-cigarettes as tobacco products, a unique product type, a consumer good, a therapeutic product or a combination of these approaches.

3.2 This chapter explores the approaches other jurisdictions have taken towards e-cigarette regulation. In particular, it sets out guidance provided by the World Health Organisation (WHO) and examines regulatory frameworks in New Zealand, the United States, the European Union (EU) and the United Kingdom (UK).

World Health Organization

3.3 The *World Health Organisation Framework Convention on Tobacco Control* (WHO FCTC), to which Australia is a party, has as its objective to:

> Protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke by providing a framework for tobacco control measures to be implemented by the Parties at the national, regional and international levels in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke.[1]

3.4 In 2014, the WHO reported that in countries with very low rates of tobacco smoking, the use of e-cigarettes did not result in reductions in the rates of disease and mortality caused by smoking.[2]

3.5 In 2016, the WHO reported on *Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS)*.[3] This report emphasised that the potential role for e-cigarettes in tobacco control was still subject to debate. The magnitude of health risks associated with e-cigarettes was assessed as likely to be lower than combustible cigarettes, but there was a dearth of evidence to quantify the relative risk between e-cigarettes and combustible cigarettes. In this report, the WHO advocated for measures to safeguard public

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1 WHO FCTC, Geneva, 21 May 2003, entry into force on 27 February 2005, [2005] ATS 7, Article 3.

2 WHO, *Electronic Nicotine Delivery Systems*, July 2014, p. 11.

3 WHO, *Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS)*, August 2016.

health, prevent the proliferation of tobacco addiction problems and protect tobacco control efforts.[4]

3.6 In 2019, the *WHO Report on the Global Tobacco Epidemic* observed that:

> The scientific evidence on e-cigarettes as cessation aids is inconclusive and there is a lack of clarity as to whether these products have any role to play in smoking cessation. There are also real concerns about the risk they pose to non-smokers who start to use them, especially young people. Unlike the tried and tested nicotine and non-nicotine pharmacotherapies that are known to help people quit tobacco use, WHO does not endorse e-cigarettes as cessation aids.[5]

Regulatory responses to e-cigarettes in other jurisdictions

3.7 Currently, there is no international consensus on the most appropriate regulatory framework for e-cigarettes. The regulatory arrangements applicable to e-cigarettes vary considerably within and across countries, ranging from prohibition to minimal or no regulation.

3.8 Broadly, e-cigarettes may be regulated under regulatory frameworks that apply to tobacco products, poisons, medicines (including medical devices) and consumer products.[6] In some countries, such as the UK, e-cigarettes containing nicotine are regulated either as consumer products or as medicines depending whether smoking cessation claims are made for the particular product.[7]

3.9 Professor Wayne Hall and Associate Professor Carol Gartner advised the committee that e-cigarettes may be regulated in a number of ways, including as:

- consumer goods to ensure consumer safety and minimise misleading advertising;
- tobacco products in much the same ways as combustible cigarettes (for example with age restrictions on sales, bans on advertising and no use permitted in enclosed public areas);
- therapeutic aids for smoking cessation; or
- dangerous poisons or drugs prohibited for use by adults.[8]

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4 WHO, *Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS)*, August 2016.

5 WHO, *WHO Report on the Global Tobacco Epidemic, 2019: Offer to help quit tobacco use*, July 2019, p. 47.

6 Department of Health, *Submission 167*, p. 14.

7 Department of Health, *Submission 297*, Standing Committee on Health, Aged Care and Sport, *Inquiry into the use and marketing of electronic cigarettes and personal vaporisers in Australia*, p. 6.

8 Professor Wayne Hall and Associate Professor Coral Gartner, *Submission 159*, p. 5.

3.10 While most countries do not have laws that specifically relate to e-cigarettes, a number of countries have introduced restrictions or bans, including:

- bans on commercial sale;
- bans on sale to minors;
- bans on use in public places;
- product safety;
- taxation; and
- advertising and promotion.[9]

3.11 The following section examines the regulatory frameworks of New Zealand, the United States, the EU and the UK.

[9] Elizabeth Greenhalgh, Randolph Grace and Michelle Scollo, 'Section 18B.9 International regulatory overview' in Michelle Scollo and Margaret Winstanley (eds), *Tobacco in Australia: Facts and issues*, Cancer Council Victoria, 2019.

Figure 3.1 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.					

Source: Department of Health, Submission 167, *p. 14.*

New Zealand

3.12 In New Zealand, e-cigarettes are regulated under the *Smokefree Environments and Regulated Products Act 1990* (NZ). The New Zealand Government recently passed the *Smokefree Environments and Regulated Products (Vaping) Amendment Act 2020* (the Amendment Act) which extended the existing restrictions on the advertising, promotion, sale, and distribution of tobacco products to all regulated products (including e-cigarettes).

3.13 According to the Ministry of Health, the Amendment Act 'strikes a balance between ensuring vaping products are available for smokers who want to

switch to a less harmful alternative and ensuring these products are not marketed or sold to young people'.[10] E-cigarette products that make therapeutic claims must be approved by Medsafe.

3.14 Under the Amendment Act a range of restrictions apply to e-cigarettes including:

- prohibition of vaping inside workplaces, schools, early childhood education and care centres, and legislated smokefree areas;
- prohibition of advertising and sponsorship relating to vaping products;
- prohibition on the sale of vaping products and toy vaping products to persons under 18 years of age;
- prohibition on the importation and sale of nicotine products for chewing or similar oral use;
- a requirement for manufacturers and importers to report any adverse reactions to vaping products;
- prohibition of vaping and smokeless tobacco products to contain colouring substances;
- prohibition of vaping in motor vehicles carrying children; and
- a requirement for regulated products (including e-cigarettes) to be notified to ensure product safety requirements are met.[11]

3.15 Regulations setting out requirements in relation to packaging and labelling are expected in 2021.

3.16 The Vaping Regulatory Authority is responsible for the regulation of e-cigarettes. As such, it manages applications from retailers to become specialist vape retailers (and to apply for approved vaping premises and approved internet sites) and receives annual reporting information from manufacturers, importers and specialist vape retailers.[12]

3.17 Local councils and individual businesses can make their own policies around vaping as long as they meet the minimum requirements of the law. For example, an employer may decide that a specific outdoor space can be used for

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[10] New Zealand Ministry of Health, *Regulation of vaping and smokeless tobacco products*, 11 November 2020, www.health.govt.nz/our-work/regulation-health-and-disability-system/regulation-vaping-and-smokeless-tobacco-products (accessed 2 December 2020).

[11] New Zealand Ministry of Health, *About the Smokefree Environments and Regulated Products (Vaping) Amendment Act*, 20 October 2020, www.health.govt.nz/our-work/regulation-health-and-disability-system/regulation-vaping-and-smokeless-tobacco-products/about-smokefree-environments-and-regulated-products-vaping-amendment-act (accessed 9 November 2020).

[12] New Zealand Ministry of Health, *About the Vaping Regulatory Authority*, 9 October 2020, www.health.govt.nz/our-work/regulation-health-and-disability-system/regulation-vaping-and-smokeless-tobacco-products/about-vaping-regulatory-authority (accessed 30 November 2020).

vaping, or alternatively no vaping should be allowed in any outdoor areas controlled by the employer.[13]

The United States

3.18 In the United States, the Food and Drug Administration (FDA) classifies e-cigarettes as tobacco products. The FDA regulates the manufacturing, distribution, retail sale and marketing of tobacco products under the *Family Smoking Prevention and Tobacco Control Act 2009* (US) (Tobacco Control Act). Products marketed for therapeutic purposes are regulated by the FDA Center for Drug Evaluation and Research.[14]

3.19 In the United States, a number of restrictions apply in relation to e-cigarettes. These include:

- a minimum age for purchase of tobacco products (including e-cigarettes);[15]
- restrictions on promotion and advertising;[16]
- requirements for packaging and product information (including child-resistant packaging for nicotine-containing e-liquid containers);[17]
- product quality and safety;[18]

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[13] New Zealand Ministry of Health and the Health Promotion Agency, *Vaping Law and Policy*, vapingfacts.health.nz/the-facts-of-vaping/vaping-law-and-policy/ (accessed 9 November 2020).

[14] FDA, *Development & Approval Process | Drugs*, content current as at 28 October 2019, www.fda.gov/drugs/development-approval-process-drugs (accessed 2 December 2020).

[15] On 20 December 2019, legislation that increased the federal minimum age for sale of tobacco products from 18 years to 21 years came into force. The new federal minimum age of sale applies to all retail establishments and persons with no exceptions. See FDA, *Tobacco 21*, content current as of 12 February 2020, www.fda.gov/tobacco-products/retail-sales-tobacco-products/tobacco-21 (accessed 9 November 2020).

[16] The Tobacco Control Act requires that smokeless tobacco packages and advertisements have larger and more visible warnings. For further information see FDA, *"Covered" Tobacco Products and Roll-Your-Own/ Cigarette Tobacco Labeling and Warning Statement Requirements*, 6 October 2020, www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/covered-tobacco-products-and-roll-your-own-cigarette-tobacco-labeling-and-warning-statement (accessed 30 November 2020).

[17] Any person involved in making, modifying, mixing, manufacturing, fabricating, assembling, processing, labelling, repacking, relabelling or importing any tobacco product including e-cigarettes for sale or distribution in the US is considered a tobacco product manufacturer and must comply with a range of FDA tobacco regulations including submitting tobacco product marketing applications, reporting, registration, ingredient listing, and including required warnings on packaging and advertisements. Packaging and advertisements of e-cigarettes must bear the following warning statement: 'WARNING: This product contains nicotine. Nicotine is an addictive chemical.' For e-cigarettes that are made or derived from tobacco but do not contain nicotine, the alternative statement, 'This product is made from tobacco' should be placed on packaging and advertisements. For further information see FDA, *Vaporizers, E-Cigarettes, and other Electronic Nicotine Delivery Systems (ENDS)*, content current as of 17 September 2020, www.fda.gov/tobacco-products/products-ingredients-components/vaporizers-e-cigarettes-and-other-electronic-nicotine-delivery-systems-ends (accessed 9 November 2020).

- restrictions on the use of flavours and ingredients;[19] and
- restrictions on where e-cigarettes are used.[20]

3.20 The United States also regulates novel tobacco products using a system of marketing and modified risk orders for novel tobacco products. A Premarket Tobacco Product Application must:

> …provide scientific data that demonstrates a product is appropriate for the protection of public health. In order to reach such a decision and to authorize marketing, FDA considers, among other things:
>
> - Risks and benefits to the population as a whole, including people who would use the proposed new tobacco product as well as nonusers;
> - Whether people who currently use any tobacco product would be more or less likely to stop using such products if the proposed new tobacco product were available;
> - Whether people who currently do not use any tobacco products would be more or less likely to begin using tobacco products if the new product were available; and
> - The methods, facilities, and controls used to manufacture, process, and pack the new tobacco product.[21]

3.21 A further regulatory pathway is available for modified risk tobacco products which 'demonstrate that the product will or is expected to benefit the health of the population as a whole.'[22]

3.22 The committee notes the recent comments of the Surgeon General of the United States Public Health Service 'that e-cigarette use has become an epidemic among our nation's young people'.[23] The committee also notes that the state of California has recently banned the retail sale of flavoured tobacco products, including e-cigarettes.[24]

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[18] See 15 USC § 1472a.

[19] In January 2020, the FDA released a policy prioritising enforcement against certain unauthorised flavoured e-cigarette products that appeal to youth, including fruit and mint flavours. For further information see FDA, *Enforcement Priorities for Electronic Nicotine Delivery System (ENDS) and Other Deemed Products on the Market Without Premarket Authorization: Guidance for Industry*, April 2020.

[20] Smoke-free laws are the responsibility of individual states.

[21] FDA, *Premarket Tobacco Product Applications*, content current as of 11 September 2020, www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications (accessed 7 December 2020).

[22] FDA, *Modified Risk Tobacco Products*, content current as of 1 December 2020, www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-tobacco-products (accessed 7 December 2020).

[23] Centers for Disease Control and Prevention, *Surgeon General's Advisory on E-cigarette Use Among Youth*, 9 April 2019, *www.cdc.gov/tobacco/basic_information/e-cigarettes/surgeon-general-advisory/index.html* (accessed 8 December 2020).

[24] Hilary Hanson, 'California Bans Sale of Flavoured Tobacco Products, Including E-Cigarettes', *Huffington Post*, 30 August 2020, available at: https://www.huffingtonpost.com.au/entry/california-

The European Union

3.23 In the EU, e-cigarettes are regulated as consumer products under the Tobacco Products Directive (TPD).[25] The TPD does not cover nicotine-containing products that are authorised as medicines.

3.24 The TPD sets out requirements for maximum nicotine concentration, packaging and labelling. The TPD requires EU Member States to:

- meet minimum product standards for the safety and quality of all e-cigarettes refill containers (otherwise known as e-liquids);[26]
- provide information to consumers so that they can make informed choices;
- restrict e-cigarette tanks to a capacity of no more than 2ml;
- restrict the maximum volume of nicotine-containing e-liquid for sale in one refill container to 10ml;
- restrict e-liquids to a nicotine strength of no more than 20mg/ml;
- require nicotine-containing products or their packaging to be child-resistant and tamper evident;
- ban certain ingredients including colourings, caffeine and taurine;
- include new labelling requirements and warnings;
- provide notification requirements prior to the placement of products on the market; and
- ban advertising of e-cigarettes.[27]

3.25 EU Member States implement domestic legislation to give effect to these requirements (as discussed below in relation to the UK).

The United Kingdom

3.26 In the UK, e-cigarettes containing nicotine are regulated as consumer goods under the TPD. The TPD is given legal effect through domestic legislation,[28] specifically in relation to safety,[29] sales to minors,[30] advertising,[31] and use of

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ban-flavored-tobacco-e-cigarettes_n_5f495ae6c5b64f17e13d7f1f?ri18n=true (accessed 17 December 2020).

[25] *Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC, [1994] OJ C 29 April 2014* [2014] OJ L 127/1, article 32.

[26] These include standards for ingredients and emissions.

[27] Medicines and Healthcare products Regulatory Agency, *E-cigarettes: regulation for consumer products*, 25 November 2020, www.gov.uk/guidance/e-cigarettes-regulations-for-consumer-products (accessed 30 November 2020).

[28] The Tobacco and Related Products Regulations 2016 (UK) implements the TPD in the UK and came fully into force on 20 May 2017.

[29] Manufacturers, importers and distributors of e-cigarettes also need to comply with the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 (UK). These regulations limit the amount of certain hazardous substances in specific electrical

e-cigarettes in public places and workplaces.[32] Non-nicotine containing e-cigarettes in the UK are regulated through the General Product Safety Regulations 2005 (UK) and are enforced by local trading standards.[33]

3.27 The Medicines and Healthcare products Regulatory Agency is the authority responsible for implementing the majority of provisions under Article 20 of the TPD.[34]

3.28 There are separate requirements to license e-cigarettes as medicines or medical devices in the UK.[35] The Medicines and Healthcare products Regulatory Agency is also responsible for regulating nicotine-containing products that are medicinal products, including e-cigarettes which make therapeutic claims.

3.29 With the UK departure from the EU and the transition period ending on 31 December 2020, the UK made the Tobacco Products and Nicotine Inhaling Products (Amendment etc.) (EU Exit) Regulations 2019 (UK) which will 'ensure that, in the unlikely scenario that the UK leaves the EU with no deal,

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equipment, of which e-cigarettes are included. They place obligations onto manufacturers, importers and distributors of e-cigarette models. E-cigarette producers must inform Medicines and Healthcare products Regulatory Agency if they have reason to believe that a notifiable product is unsafe, not of good quality or not compliant with the TPD and provide details of the risk to human health and safety and any corrective action taken.

30 The Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015 (UK) prohibits the sale of nicotine inhaling products, also known as e-cigarettes and certain related parts of such devices to people under the age of 18 years and extends the offence of proxy purchasing of tobacco products to nicotine inhaling products.

31 Article 20(5) of the TPD requires EU Member States to introduce restrictions on the advertising of electronic cigarettes. In the UK, these rules have been implemented in the *Communications Act 2003* (UK), changes by Ofcom (the communications regulator in the UK) to the UK Code of Broadcast Advertising and in the Tobacco and Related Products Regulations 2016 (UK).

32 The *Health Act 2006* (UK) prohibits smoking in enclosed public places and workplaces, on public transport and in vehicles used for work. However, e-cigarette use is not covered by this smoke-free legislation as e-cigarettes do not burn tobacco and do not create smoke. Public Health England has issued guidance on the use of e-cigarettes in public places and workplaces which allows businesses and employers to create their own policies on the use of e-cigarettes. For further information see Public Health England, *Guidance: E-cigarettes in public places and workplaces: a 5-point guide to policy making*, 6 July 2016, www.gov.uk/government/publications/use-of-e-cigarettes-in-public-places-and-workplaces/e-cigarettes-in-public-places-and-workplaces-a-5-point-guide-to-policy-making (accessed 9 November 2020).

33 Department of Health, *Submission 167*, p. 27.

34 Medicines and Healthcare products Regulatory Agency, *E-cigarettes: regulations for consumer products*, 29 February 2016, www.gov.uk/guidance/e-cigarettes-regulations-for-consumer-products (accessed 9 November 2020).

35 Medicines and Healthcare products Regulatory Agency, *Guidance: Licensing procedure for electronic cigarettes as medicines*, 14 December 2017, www.gov.uk/guidance/licensing-procedure-for-electronic-cigarettes-as-medicines (accessed 2 December 2020).

there will continue to be a functioning statute book on exit day which maintains continuity in relation to tobacco control policy and legislation'.[36]

[36] Explanatory Memorandum, Tobacco Products and Nicotine Inhaling Products (Amendment etc.) (EU Exit) Regulations 2019 (UK), p. 1.

Chapter 4
Issues

4.1 In Australia, the sale of nicotine e-cigarette products is prohibited unless approved as an aid to quit smoking combustible cigarettes. At the time of writing, no e-cigarette products have been approved for this purpose.

4.2 Most medical colleges and public health researchers in Australia support Australia's precautionary approach and cite concern over the lack of evidence regarding the efficacy of e-cigarettes as a cessation aid and the long-term safety of e-cigarettes.[1]

4.3 Proponents of e-cigarettes argued that they are less harmful than combustible cigarettes and sought their promotion to adult smokers as a less harmful alternative.[2] However, the view that e-cigarettes are effective cessation devices, with considerable health benefits, is contested.

4.4 A number of submitters argued that e-cigarettes have the potential to be harmful and undermine tobacco control, with potentially damaging effects at the population level.[3]

4.5 This chapter examines the evidence presented in relation to:

- whether e-cigarettes are less harmful than smoking combustible cigarettes;
- whether e-cigarettes are effective in helping people to quit smoking combustible cigarettes;
- whether the greater availability of e-cigarettes is likely to result in the 'gateway effect' through which young people and non-smokers are more likely to take up smoking combustible cigarettes as a result of e-cigarette use; and
- the public health impacts of e-cigarettes.

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1 See, for example, The Royal Australasian College of Physicians, *Submission 170*, p. 3; Australian Medical Association, *Submission 183*, p. 2; Professor Nick Zwar, Royal Australian College of General Practitioners, *Committee Hansard*, 19 November 2020, p. 44.

2 See, for example, factasia, *Submission 45*, pp. 1-3; National Retail Association, *Submission 156*, p. 2; Ampol, *Submission 165*, pp. 1-2; Legalise Vaping Australia, *Submission 173*, pp. 4-5; Tasmanian Small Business Council, *Submission 208*, p. 1; TSG Franchise Management, *Submission 215*, pp. 1-2; UK Vaping Industry Association, *Submission 236*, p. 1 and p. 3; and Juul Labs, *Submission 242*, pp. 1-4.

3 See, for example, Dr Michelle Jongenelis, *Submission 66*, p. 4; Thoracic Society of Australia and New Zealand, *Submission 162*, pp. 304; Department of Health, *Submission 167*, pp. 10-18; RACP, *Submission 170*, pp. 2-3 and pp. 14-15; New South Wales Health, *Submission 171*, pp. 3-4; Cancer Council, *Submission 194*, p. 4 and pp. 7-9; European Tobacco Harm Reduction Advocates, *Submission 202*, pp. 7-8; Cancer Australia, *Submission 251*, pp. 2-3 and pp. 6-7; Asthma Australia, *Submission 273*, p. 4; and Australian Health Promotion Association, *Submission 274*, p. 1 and p. 4.

Harm reduction

4.6 Professor Emily Banks submitted that Australia is a world leader in reducing smoking prevalence.[4] The committee heard compelling evidence from a wide range of Australia's leading public health authorities that broad unregulated access to e-cigarettes poses a threat to decades of effective public health policy.[5]

4.7 The committee also heard compelling evidence that Australia's strong success in reducing smoking rates has been driven by innovations, such as plain packaging, and strategies such as tobacco excise and national anti-smoking campaigns.[6] However, a number of witnesses submitted that Australia cannot afford to 'rest on its laurels'[7] and must continue to implement proven measures, such as targeted education campaigns.[8]

4.8 Professors Mike Daube and Simon Chapman argued that 'the harm reduction measures proven to work against tobacco use as part of a comprehensive approach are as outlined in the *World Health Organisation Framework Convention on Tobacco* to which Australia is a Party'.[9] Key elements include: taxation, bans on tobacco advertising and promotion, eliminating exposure to second hand smoke, regulating manufacturing and packaging, evidence-based dependence treatment and sustained media campaigns.[10] Professors Daube, Chapman and Matthew Peters submitted:

> Australia has long been recognised as a global pioneer in tobacco control. It has among the world's highest priced cigarettes, and was the first nation to run well-funded national quit campaigns, to implement plain packaging, and to require tobacco products to be stored out-of-sight, and

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4 Professor Emily Banks, *Submission 157*, p. 4.

5 See, for example, Dr Michelle Jongenelis, University of Melbourne, *Committee Hansard*, 19 November 2020, p. 48; Dr Bernie Towler, Principal Medical Officer, Department of Health, *Committee Hansard*, 13 November 2020, p. 7; Professor Emily Banks, Professor of Epidemiology and Population Health, ANU, *Committee Hansard*, 13 November 2020, p. 27; Emeritus Professor Simon Chapman, School of Public Health, University of Sydney, *Committee Hansard*, 19 November 2020, p. 3.

6 See, for example, Emeritus Professor Simon Chapman, School of Public Health, University of Sydney, *Committee Hansard*, 19 November 2020, p. 9; Department of Health, *Submission 167*, p. 10; Professor Emily Banks, *Submission 195*, p. 1.

7 Dr Omar Khorshid, President, Australian Medical Association, *Committee Hansard*, 19 November 2020, p. 52.

8 Emeritus Professor Mike Daube, Private capacity, *Committee Hansard*, 19 November 2020, p. 2; and Dr Omar Khorshid, President, Australian Medical Association, *Committee Hansard*, 19 November 2020, pp. 47 and 52.

9 Emeritus Professor Simon Chapman and Emeritus Professor Mike Daube, answer to question on notice QoN015-01, 20 November 2020 (received 25 November 2020).

10 Department of Health, *Submission 167*, p. 10.

> one of the first to ban tobacco advertising and introduce smokefree regulations. Many countries have looked to Australia for leadership.[11]

4.9 Some inquiry participants suggested that Australia should reinvest in a national anti-smoking media campaign, to keep driving progress on smoking reduction:

> Despite clear evidence and the impact of strong media campaigns, we actually haven't had a national campaign for almost a decade, and the current commitment is just $20 million over three years, which is 0.04 per cent of the $45 billion the government will receive in tobacco revenue for that period. So you can do more.[12]

4.10 Dr Omar Khorshid, President, Australian Medical Association (AMA), told the committee the best way to reduce smoking in Australia is a combination of helping people to quit and preventing people from taking it up, and that 'success' on smoking is not turning a smoker into an e-cigarette user, but turning a smoker into a lifelong non-smoker.[13]

4.11 Similarly, Professor Banks argued that '[c]ontinuing progress on smoking means a concerted effort on two things: avoiding having people start to smoke—basically young people—and helping smokers to quit'.[14]

4.12 E-cigarette proponents who provided evidence in support of the legalisation of nicotine e-cigarette products highlighted the harm-reducing potential of e-cigarettes.[15] Many of these submitters put forward the view that e-cigarettes may assist some smokers to move away from using tobacco products towards this alternative form of nicotine delivery, and who may ultimately be able to cease smoking.[16] Some e-cigarette proponents also suggested that the public policy focus should be on reducing harm to combustible cigarette users, rather than eliminating smoking.[17]

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[11] Emeritus Professor Simon Chapman, Emeritus Professor Mike Daube and Professor Matthew Peters, *Submission 195*, pp. 1-2.

[12] Emeritus Professor Simon Chapman, Emeritus Professor Mike Daube and Professor Matthew Peters, *Submission 195*, p. 31; and Emeritus Professor Mike Daube, Private capacity, *Committee Hansard*, 19 November 2020, p. 2.

[13] Dr Omar Khorshid, President, Australian Medical Association, *Committee Hansard*, 19 November 2020, p. 51.

[14] Professor Emily Banks, Professor of Epidemiology and Population Health, ANU, *Committee Hansard*, 13 November 2020, p. 17.

[15] See, for example, Australian Tobacco Harm Reduction Association, *Submission 166*, pp. 5-6 and pp. 23-24; Legalise Vaping Australia, *Submission 173*, pp. 4-5; NSW Users and AIDS Association, *Submission 253*, pp. 2-4 and 6-7; Vaping Trade Association of New Zealand, *Submission 263*, pp. 9-19; and Progressive Public Health Alliance, *Submission 271*, pp. 5-7.

[16] See, for example, Juul Labs, *Submission 242*, p. 2; Nurses' Professional Association of Queensland, *Submission 258*, p. 2; and Vaping Trade Association of New Zealand, *Submission 263*, p. 30.

[17] See, for example, National Retail Association, *Submission 156*, p. 3.

4.13 The Australian Tobacco Harm Reduction Association (ATHRA) explained to the committee that:

> The main purpose of tobacco harm reduction (THR) is to reduce (not necessarily eliminate) the harm from smoking. The aim is not to stop nicotine as nicotine causes little harm. Tobacco harm reduction involves encouraging smokers to switch from high-risk combustible (burnable) cigarettes to a lower-risk nicotine alternative such as vaping.[18]

4.14 Similarly, in their submission, Professor Coral Gartner and Professor Wayne Hall noted that:

> For people who are unable to quit smoking, switching to a less harmful way of obtaining nicotine may enable them to quit sooner and reduce the smoking-related harm they would experience if they continued to smoke. It is arguably unethical and unjust to deny people who have great difficulty ending their nicotine addiction from using less harmful alternatives while they continue to have ready access to tobacco cigarettes.[19]

4.15 The committee notes, however, that currently Australia's precautionary approach does not prohibit smokers from accessing e-cigarettes and nicotine e-liquid as an alternative to combustible cigarettes, as evidenced by the hundreds of submitters who have purchased these products from online retailers or through prescription and reported on their experience of using these products.

4.16 The National Drug and Alcohol Research Centre stated that although it is generally agreed that e-cigarette use is less harmful than smoking combustible cigarettes 'the exact degree of harm reduction is not yet certain'.[20] Furthermore, it is 'likely that long-term use of regular e[-cigarettes] among never smokers will be associated with a degree of health harm, but the degree of such harm is uncertain'.[21]

Personal experience of e-cigarette use

4.17 Individual submitters reported improvements to their health, finances and overall lifestyle from the use of e-cigarettes. The committee notes that the form letters received by the committee recounted similar improvements. The vast majority of personal accounts were from current and former smokers who considered they had experienced significant health improvements as a result of

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[18] Australian Tobacco Harm Reduction Association, *Submission 166*, p. 23.

[19] Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 159*, p. 5.

[20] National Drug and Alcohol Research Centre, University of New South Wales, *Submission 164*, p. 1.

[21] National Drug and Alcohol Research Centre, University of New South Wales, *Submission 164*, p. 1.

transitioning from combustible cigarettes to e-cigarettes or reducing smoking.[22] For example:

> [Two] weeks into vaping and quitting tobacco cigarettes, I no longer felt my breathing was shallow or laboured, my continual coughing stopped, I no longer had phlegm/mucus build-up from my smoking and most definitely now my sense of smell was back (which meant I had to basically throw out the majority of my clothes because I could properly sense how bad they smelled of stale cigarette smoke).[23]

4.18 Mr Tom Morawetz explained that:

> I am vastly healthier, and there is no way anyone who has not undertaken this transformation could understand it, or how grateful I am to have this second chance.
>
> No yellow fingers, no stink breath, fresh clothes, sweet smelling flat and vehicle. No colds or coughs of note, good BP results, eating better now I can taste food and have even lost weight and apart from my non-related other ailments actually feel almost spritely!! Well very almost. My dog Minty and I can now walk 3kms a day, his 12 and my 63 need the exercise, and we enjoy this in the morning together.[24]

4.19 Similarly, Mrs Judith Wolters observed that the health benefits since switching to vaping included:

- Improvement in my mental health. I often slipped into deep depression when smoking and didn't really care if I lived or died but I don't become depressed now since I switched.
- No more regular chest infections.
- I stopped coughing constantly, especially in the mornings when I coughed violently and feared I could break a rib. Now I have to force myself to cough to clear my lungs.
- I could suddenly breathe through my nose and my sleep apnoea stopped. In fact my son was so alarmed when he couldn't hear me snoring he used to check I was still breathing.
- I could walk up my steep 20 metre driveway without wheezing and becoming breathless a few months after I stopped smoking. I needed to drive up to collect my mail before that.
- I did not put on weight.
- My gum disease disappeared and I am hanging onto my last teeth despite my dentist saying they would have to be removed soon years ago because of the gum disease caused by smoking.
- I don't smell like an incinerator.

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[22] See, for example, Mr Tom Morawetz, *Submission 2*, [p. 1]; Mr James Reid, *Submission 4*, [p. 1]; Mr Alan Beard, *Submission 6*, [p. 1]; Ms Maureen Steele, *Submission 10*, [p. 2] and Mr Anthony Barron, *Submission 11*, [p. 1].

[23] Mr Adam Metelmann, *Submission 51*, p. 2.

[24] Mr Tom Morawetz, *Submission 2*, p. 1.

- I don't fear falling asleep with a lit cigarette in my hand and starting a house fire.[25]

4.20 Mrs Linda Foster reported how she overcame her addiction to combustible cigarettes by using e-cigarettes and how now she neither smokes nor vapes:

> A friend introduced me to vaping 6 yrs ago, using PG [Propylene Glycol] and VG [Vegetable Glycerin] with flavouring and nicotine. I used this for around 2 years. One day I ran out of nicotine and just kept on using the vap with just the PG, VG and flavour. After another 1 year I put my vaper down one evening and never picked it up again. That was 3 years ago. To this date I've never wanted to smoke or vape again.[26]

The health impacts of e-cigarettes

4.21 The committee received a range of evidence from submitters regarding the degree of harm posed by e-cigarettes.

4.22 While proponents argue e-cigarettes are significantly less harmful than tobacco use,[27] Professor John Skerritt, Deputy Secretary, Therapeutic Goods Administration, noted that describing a product as less harmful than combustible tobacco does not mean it is inherently safe:

> I believe that smoking is more harmful than vaping but that does not make vaping harmless—in the same way that being hit by a car on the freeway is less harmful than being hit by a truck but it is not desirable.[28]

4.23 Similarly, Dr Michelle Jongenelis informed the committee that '[b]ased on the evidence to date, e-cigarettes are likely to be less harmful than conventional cigarettes, but they are not harmless'.[29] Dr Jongenelis stated:

> They have been found to contain a number of substances known to be harmful to people including formaldehyde, tobacco-specific nitrosamines, nicotine, and heavy metals. The flavourings added to e-liquids have been shown to be unsafe when inhaled directly to the lungs, posing a potential threat to the health of users. This is a particular concern for young adults who have been found to cite the availability of e-liquid flavourings as a major contributor to their initiation and continued use of e-cigarettes. There are significant health risks associated with the use of e-cigarettes,

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[25] Mrs Judith Wolters, *Submission 221*, p. 1.

[26] Mrs Linda Foster, *Submission 282*, [p. 1] (previously had smoked from the age of 10 to 64).

[27] See, for example, Australian Tobacco Harm Reduction Association, *Submission 166*, p. 29.

[28] Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, *Senate Community Affairs Legislation Committee Hansard*, 27 October 2020, p. 11.

[29] Dr Michelle Jongenelis, answer to written question on notice QoN016-01, 20 November 2020 (received 22 November 2020).

> including reduced lung function, stiffness of the arteries, and increased risk of cardiovascular disease.[30]

4.24 Professors Chapman and Daube also raised product ingredients as an area of concern: specifically, 'industrial grade glycols and glycerine that are unsafe for inhalation and food flavourings or other additives that may be safe for ingestion but not for exposure to the huge surface that our lungs represent'.[31]

4.25 The Lung Foundation Australia argued that flavourings posed an under-recognised risk to health:

> Most nicotine e-cigarettes contain flavours, and emerging research suggests that the flavours (such as "green apple") used in non-nicotine e-cigarettes, which are available in Australia as a consumer product, are as addictive as nicotine. The National Health and Medical Research Council advises that flavoured e-cigarettes may expose users to chemicals and toxins such as formaldehyde, heavy metals, particulate matter and flavouring chemicals, at levels much higher than cigarettes, that have the potential to cause adverse health effects.[32]

4.26 The AMA expressed the view that it was inaccurate to characterise e-cigarette use as less harmful than smoking, as the health effects of e-cigarettes may include:

- exposure to nicotine, potentially at higher levels than that included in combustible cigarettes, which can harm adolescent brain development, including functions related to attention, learning, mood and impulse control;
- exposure to toxins that have been classified as cancer-forming agents, such as formaldehyde and various solvents;
- exposure to particulate matter, which may worsen existing illnesses or increase the risk of developing cardiovascular or respiratory disease;
- adverse events ranging from mouth and throat irritation, to life-threatening injuries caused by e-cigarettes overheating or exploding; and
- nicotine poisoning resulting from the accidental ingestion of e-liquids, with symptoms ranging from nausea and vomiting to severe life-threatening illness.[33]

4.27 Other witnesses made the point that the evidence base for any relative difference in harm is constantly evolving. Professor Matthew Peters, Thoracic

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[30] Dr Michelle Jongenelis, answer to written question on notice QoN016-01, 20 November 2020 (received 22 November 2020).

[31] Emeritus Professor Simon Chapman and Emeritus Professor Mike Daube, answer to question on notice QON014-09, 20 November 2020 (received 26 November 2020).

[32] Lung Foundation Australia, *Submission 268*, p. 3.

[33] Australian Medical Association, answers to written question on notice QoN013-01, 19 November 2020 (received 25 November 2020).

Society of Australia and New Zealand, told the committee 'the question about whether they (e-cigarettes) are any safer is now in serious doubt'.[34]

4.28 In a joint submission, the Cancer Council, the National Heart Foundation of Australia and the Australian Council on Smoking and Health also suggested that e-cigarettes may negatively impact health. They stated:

> E-cigarettes expose users to chemicals and toxins at levels that have the potential to cause health effects including solvents such as propylene glycol, glycerol or ethylene glycol, which may form toxic or cancer-causing compounds when vaporised.[35]

4.29 The committee also heard evidence that the use of e-cigarettes by smokers trying to quit 'is likely to lead to greater long-term exposure to nicotine than use of other smoking cessation measures'.[36] However, Professor Ron Borland noted:

> Regardless of dependence, if use of low-toxin nicotine is much less harmful, the public health consequences of long-term use are still going to be much less than for smoking.[37]

4.30 In contrast, a number of submitters argued that e-cigarettes are significantly less harmful than combustible cigarettes.[38]

4.31 Mr Konstantinos Farsalinos submitted that regulation of e-cigarettes should be risk proportionate and that currently 'there is compelling and undisputed evidence on the low risk of electronic cigarettes, especially when compared with the devastating effects of smoking'.[39]

4.32 Professor Hayden McRobbie told the committee that 'based on the current data, the general consensus is that electronic cigarettes are less harmful than combustible tobacco, and therefore represent, in smokers who switch completely to electronic cigarettes, a harm reduction approach'.[40]

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[34] Professor Matthew Peters, former President and Co-Chair of Electronic Cigarettes Working Party, Thoracic Society of Australia and New Zealand, *Committee Hansard*, 19 November 2020, p. 29.

[35] Cancer Council, National Heart Foundation of Australia and Australian Council on Smoking and Health, *Submission 194*, p. 7.

[36] Professor Emily Banks, *Submission 157*, p. 4.

[37] Professor Ron Borland, *Submission 160*, p. 6.

[38] See, for example, factasia, *Submission 45*, pp. 1-3; National Retail Association, *Submission 156*, p. 2; Ampol, *Submission 165*, pp. 1-2; Legalise Vaping Australia, *Submission 173*, pp. 3-5; Tasmanian Small Business Council, *Submission 208*, p. 1; TSG Franchise Management, *Submission 215*, pp. 1-2; UK Vaping Industry Association, *Submission 236*, p. 1 and p. 3; and Juul Labs, *Submission 242*, pp. 1-4.

[39] Mr Konstantinos Farsalinos, *Submission 250*, [p. 2].

[40] Professor Hayden McRobbie, National Drug and Alcohol Research Centre, University of New South Wales, *Committee Hansard*, 13 November 2020, p. 29.

4.33 This view has been broadly adopted across a number of other jurisdictions, including the United Kingdom (UK) and New Zealand. Professor John Britton, University of Notttingham, advised the committee that for many years 'UK policy has therefore been to encourage smokers, so far as possible, to try to quit smoking using current best medical therapy but failing that, to switch from tobacco to electronic cigarettes'.[41]

Claim that e-cigarettes are 95 per cent less harmful than combustible cigarettes

4.34 Many proponents of e-cigarettes claimed that vaping is '95 per cent less harmful' than smoking tobacco. However, this figure was contested due to its source and methodology.

4.35 ATHRA argued that 'vaping is at least 95% less harmful than smoking'.[42] Dr Colin Mendelsohn, Board Member, ATHRA, told the inquiry the figure was also employed in reports by Public Health England and the UK Royal College of Physicians.[43]

4.36 The UK Royal College of Physicians, in its report *Nicotine without smoke: Tobacco harm reduction*, found:

> Although it is not possible to precisely quantify the long-term health risks associated with e-cigarettes, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products and may well be substantially lower than this figure.[44]

4.37 In 2015, Public Health England released its report *E-cigarettes: an evidence update* which stated that 'best estimates show e-cigarettes are 95 per cent less harmful to your health than normal cigarettes, and when supported by a smoking cessation service, help most smokers to quit tobacco altogether'.[45]

4.38 In contrast, the Department of Health argued there was insufficient evidence to quantify the relative degree of harm posed:

> Under typical conditions of use, the number and concentrations of potentially toxic substances emitted from unadulterated e-cigarettes are generally lower than tobacco smoke. 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.[46]

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41 Professor John Britton, *Submission 130*, [p. 1].

42 Australian Tobacco Harm Reduction Association, *Submission 166*, p. 29.

43 Dr Colin Mendelsohn, Board Member, Australian Tobacco Harm Reduction Association, *Committee Hansard*, 13 November 2020, p. 73.

44 UK Royal College of Physicians, *Nicotine without smoke: Tobacco harm reduction*, April 2016, p. 84.

45 Public Health England, *E-cigarettes: an evidence update, A report commissioned by Public Health England*, 2015, p. 5.

46 Department of Health, *Submission 167*, p. 24.

4.39 The committee notes concerns from experts that this 95 per cent figure appears drawn from a single source first published in 2014 and has not been independently verified by later reports which have employed the figure, such as those by Public Health England and the UK Royal College of Physicians.[47] Professors Chapman, Daube and Peters argued that:

> A factoid is "an item of unreliable information that is repeated so often that it becomes accepted as fact." The "95% safer" statement is nothing but an emperor-like factoid with suspiciously few clothes.[48]

4.40 Professors Chapman, Daube and Peters noted that the claim that e-cigarettes are 95 per cent less harmful than combustible cigarettes was first made in a 2014 report, *Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach*, led by Professor David Nutt, and that some authors had 'a history of association with tobacco interests'. Professors Chapman, Daube and Peters argued that although the 95 per cent figure was then employed in the 2014 report by Public Health England, and again in 2015, the health body provided 'no transparent workings of how this figure was actually calculated'.[49]

4.41 A 2018 evidence review of e-cigarettes by Public Health England, which again did not independently assess the claim that vaping is '95 per cent less harmful' than tobacco smoking, stated that this figure is useful for making a point: '[it] remains a good way to communicate the large difference in relative risk unambiguously so that more smokers are encouraged to make the switch from smoking to vaping. It should be noted that this does not mean e-cigarettes are safe'.[50]

4.42 The approach was reiterated by Dr Mendelsohn, who argued that '[t]he fact is this is an estimate; it's not an exact number. It's to give smokers an understanding of the relative risk between vaping and smoking'.[51]

4.43 Professor Borland noted that, while the 95 per cent estimate was a reasonable estimation of the differential risk, '[it] needs to be kept under constant review if new evidence emerges that suggests some of the assumptions are flawed'.[52]

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[47] Emeritus Professor Simon Chapman, Emeritus Professor Mike Daube and Professor Matthew Peters, *Submission 195*, pp. 20-22.

[48] Emeritus Professor Simon Chapman, Emeritus Professor Mike Daube and Professor Matthew Peters, *Submission 195*, p. 22.

[49] Emeritus Professor Simon Chapman, Emeritus Professor Mike Daube and Professor Matthew Peters, *Submission 195*, p. 20.

[50] Public Health England, *Evidence review of e-cigarettes and heated tobacco products 2018: A report commissioned by Public Health England*, February 2018, p. 20.

[51] Dr Colin Mendelsohn, Board Member, Australian Tobacco Harm Reduction Association, *Committee Hansard*, 13 November 2020, p. 72.

[52] Professor Ron Borland, *Submission 160*, p. 2.

4.44 Professor Borland also noted:

> The claim is grounded in good science, which is not the same as direct evidence. Of course there is no direct evidence as to what the effects of vaping will be over a lifetime of use: only the very earliest adopters of this technology could have been vaping for as much as 10 years, or of what benefits shifting to NVPs [nicotine vaping products] from smoking may provide at different ages, and how this compares with quitting nicotine altogether at the same age. It will take decades of use to establish actual outcomes. That is why we need science, the evidence grounded elaboration of mechanisms to help us predict likely outcomes.[53]

4.45 However, Professor Skerritt told the committee that use of the figure was misleading and could give vapers a false sense of security that e-cigarettes are inherently safe:

> …eminent medical journals such as The Lancet have questioned pulling that 95 per cent figure out of the sky. The concern they have is that it may lull people into a false sense of security as to the safety or otherwise of these products. So, we don't endorse the 95 per cent figure. It's probably fruitless to ask whether it's 20 per cent safer, 30 per cent safer or whatever. No-one knows. Clearly smoke tobacco has tars and other things that contribute to lung and other cancers. Nicotine is of course responsible for cardiovascular and other effects, but I think it is actually misleading to keep on quoting the figure of 95 per cent.[54]

Uncertainty about long-term safety of e-cigarette usage

4.46 Submitters highlighted concerns about the potential harms of vaping and a lack of evidence about the long-term safety of e-cigarette use.[55]

4.47 A number of submitters advocated ongoing precaution because of the uncertainty over the long-term impacts from smoking e-cigarettes:

> We know from bitter experience that the consequences of breathing substances into the lungs can be invisible for many, many years—sometimes decades in the case of asbestos or silicosis and other lung conditions. So no-one can say for sure that there is long-term safety in the use of e-cigarettes.[56]

4.48 Similarly, Professor Chapman stated:

> I'm afraid that anyone who tells you that the risks of someone pulling vaporised glycol, nicotine and any number of more than 7,000 flavouring chemicals deep into their lungs an average of 173 times a day, day after

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[53] Professor Ron Borland, *Submission 160*, p. 5.

[54] Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, *Committee Hansard*, 13 November 2020, p. 14.

[55] See, for example, Emeritus Professor Simon Chapman, Emeritus Professor Mike Daube and Professor Matthew Peters, *Submission 195*, p. 3.

[56] Dr Omar Khorshid, President, Australian Medical Association, *Committee Hansard*, 19 November 2020, p. 51.

> day, year after year, are well understood is misleading you about safety. We had no idea for 40 or 50 years after cigarette smoking became widespread that lung cancer would move from being a rare disease to becoming the No. 1 cause of cancer death. We are only in the very early days of understanding the risk profile of e-cigarettes.[57]

4.49 The Royal Australasian College of Physicians (RACP) reiterated that the long-term impact on e-cigarette users remains unknown and that the safest option remains to cease all forms of nicotine consumption:

> The current evidence is unable to quantify the degree of harm reduction and to ascertain, in particular, long-term health impacts to vapers, including long-term health outcomes in their organ systems. What is known for certain at this point in time is that vaping is not without adverse health impacts… Both e-cigarettes and tobacco products pose risks to health. The safest option for the community is not to use either. Thus, the RACP holds that not smoking tobacco or using e-cigarettes remain the safest options for the community; the proven and registered smoking cessation treatments are advised to be used ahead of vaping.[58]

4.50 The AMA likewise submitted:

> The relative novelty of e-cigarette use compared to tobacco smoking means that there is a lack of robust longitudinal studies to confirm what the long-term health effects of e-cigarette use are, *and* whether these effects can be quantified as less harmful than those associated with tobacco smoking [emphasis in original].[59]

4.51 Some submitters, such as Professor Simon Wilson, highlighted the publication of studies around e-cigarettes use and lung injury in the United States as 'why we need a risk mitigation strategy'.[60] Dr Jody Moller, Dr Celine Kelso and Professor Alison Jones told the committee that some ill effects are attributable to contaminants and adulterants:

> E-cigarette or vaping related lung injury (EVALI) which was a lung condition, mostly in young individuals in the US in 2019 which led to 68 deaths and 2,668 hospitalizations, has been linked to contaminated THC (cannabis) vaping cartridges and was not associated with nicotine-containing e-cigarettes or liquids.[61]

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[57] Emeritus Professor Simon Chapman, School of Health, University of Sydney, *Committee Hansard*, 19 November 2020, p. 1.

[58] Royal Australasian College of Physicians, answer to questions on notice QoN013-01, 19 November 2020 (received 25 November 2020), p. 1.

[59] Australian Medical Association, answers to question on notice QoN013-01-Qon013-02, 19 November 2020 (received 25 November 2020).

[60] Professor Simon Wilson, President, Royal Australasian College of Physicians, *Committee Hansard*, 19 November 2020, p. 43.

[61] Dr Jody Moller, Dr Celine Kelso and Professor Alison Jones, *Submission 220*, p. 3.

4.52 Professor John Allan indicated that 'we haven't got the long-term effects of e-cigarettes, but it's likely that those effects are a lot less than those of smoking tobacco'.[62]

4.53 ATHRA submitted that 'the risks of NOT adopting vaping are much greater because cigarettes are substantially more harmful [emphasis in original]'.[63]

4.54 The UK Vaping Industry Association submitted that 'while not risk-free, vaping is a less harmful alternative for adults who would otherwise continue to smoke'.[64]

4.55 The need for more evidence to determine the potential long-term health effects of e-cigarettes was widely acknowledged, including among those advocating for policy change. However, many proponents of e-cigarettes shared the view that 'we [do] know enough to be reassured about long term risk'.[65] Mr Clive Bates submitted:

> The argument that we do not know the long-term risks is a statement of the obvious for a product that has been in the market for about twelve years. It is often claimed that it took decades for the harms of smoking to emerge and therefore that regulators should adopt a 'precautionary' approach. However, this is not the clinching argument many appear to assume it is. Bioscience and toxicology have advanced a immeasurably since the 1950s and we do not generally need to wait decades to determine risks associated with toxic exposures – for example, we would know immediately that cigarettes are highly dangerous if they were introduced today. We would not need to wait decades for smoking-related cancers and heart disease to develop.[66]

Negative impacts

Uptake by youth and non-smokers and the 'gateway effect'

4.56 A key concern frequently raised with the committee was that e-cigarettes may normalise smoking or create nicotine dependency among people who have never smoked—in particular, youth—and introduce them to combustible cigarettes.

4.57 The Department of Health submitted that a number of recent international studies and, most recently, the Commonwealth-commissioned research conducted by the Australian National University's (ANU) National Centre for Epidemiology & Population Health (NCEPH), demonstrated 'strong evidence

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[62] Professor John Allan, President, Royal Australian and New Zealand College of Psychiatrists, *Committee Hansard*, 19 November 2020, 43.

[63] Australian Tobacco Harm Reduction Association, *Submission 166*, p. 27.

[64] UK Vaping Industry Association, *Submission 236*, [p. 1].

[65] Mr Clive Bates, *Submission 158*, p. 3.

[66] Mr Clive Bates, *Submission 158*, p. 3.

that the use of e-cigarettes by non-smokers predicts future smoking'.[67] 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. 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'.[68]

4.58 This finding was repeated by a number of submitters, including The Thoracic Society of Australia and New Zealand and the Australian Council on Smoking and Health.[69]

4.59 Dr Bernie Towler, Principal Medical Officer, Department of Health, argued that the findings of the ANU summary report were reflected in a number of international studies. He stated:

> …other international bodies have reported on just that this year, including the Irish Health Research Board that I just mentioned, which reported in October this year a finding of a gateway effect. It found that adolescents using e-cigarettes are three to five times as likely to start smoking tobacco cigarettes. Again, I could go on and on. The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment in the UK as well as another group that's reported this year, the Scientific Committee on Health, Environmental and Emerging Risks, or SCHEER, which was mandated by the European Commission to look at this issue, found strong evidence for a gateway effect as well. So, there are a range of Australian and international organisations that are finding that this is a real thing.[70]

4.60 Professor Banks, who led the ANU review, emphasised that it is important to avoid widespread availability of e-cigarettes to people who have never smoked to ensure the progress made in reducing rates of tobacco smoking in Australia is protected. Professor Banks stated that:

> …the current evidence, as a summary, is that non-smokers who are exposed to e-cigarettes are on average around three times as likely to take up tobacco smoking. It would be quite a complex equation to say what that would look like at a population level. But certainly from a precautionary

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[67] Department of Health, *Submission 167*, p. 22.

[68] Department of Health, *Submission 167*, p. 22.

[69] The Thoracic Society of Australia and New Zealand, *Submission 162*, p. 5; and Cancer Council, National Heart Foundation of Australia and Australian Council on Smoking and Health, *Submission 194*, p. 5.

[70] Dr Bernie Towler, Principal Medical Officer, Population Health Division, Department of Health, *Committee Hansard*, 19 November 2020, pp. 7-8.

> principle what it really says is that it would be likely to cause harm from the point of view of increasing tobacco smoking.[71]

4.61 Professor Daube expressed concern that, should e-cigarette usage be normalised, Australia may risking losing health gains obtained in the area of youth smoking:

> While progress is always too slow, Australia is a leader in reducing smoking. Having 11 per cent of people smoking daily would have been beyond our expectations even a few years ago. Across the country, there are about 79,000 smokers—just that—in the 12-to-17 age range, and having three per cent among 12- to 15-year-olds is sensational. The tobacco industry has described Australia as 'the darkest market in the world'. So anything that renormalises smoking behaviour would be disastrous.[72]

4.62 Professor Skerritt told the committee that, within Australia and internationally, there is statistical evidence of a rise in youth use of e-cigarettes:

> …as recently as 2016, 2.3 per cent of kids and young adults aged 15 to 24 in Australia were regular vapers. That's now 4.5, almost a doubling. Among US high school students, it's gone in two years from 11.7 per cent in 2017 to 27.5 per cent in 2019 characterising themselves as current e-cigarette users. Among Canadians, it's gone from six per cent in 2017 to 15 per cent.[73]

4.63 In contrast, Professor Hall and Associate Professor Gartner raised the following concerns in relation to evidence claiming that the use of e-cigarettes increases smoking among adolescents:

- these studies over-estimate the association, as any young person who smokes a single puff of a cigarette is classified as a 'smoker';
- adolescents who are most likely to experiment with ENDS [electronic nicotine delivery systems] are those who are already at higher risk of using cigarettes (i.e. more likely to have the traits of sensation seeking and risk-taking);
- these studies were conducted in countries when there were no age restrictions on the purchase of ENDS; and
- epidemiological monitoring studies indicate that ENDS use has not increased regular cigarette smoking among young people, as would be the case if they were a gateway to cigarette smoking.[74]

4.64 The London-based Royal College of Physicians in its report *Nicotine without smoke: Tobacco harm reduction* concluded that while there was concern that

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[71] Professor Emily Banks, Professor of Epidemiology and Population Health, ANU, *Committee Hansard*, 13 November 2020, pp. 27-28.

[72] Emeritus Professor Mike Daube, Private capacity, *Committee Hansard*, 19 November 2020, p. 2.

[73] Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, *Committee Hansard*, 13 November 2020, p. 7.

[74] Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 159*, pp. 9-10.

e-cigarettes could act as a gateway to smoking for young people there was 'no evidence that [this] is occurring to any significant degree in the UK'.[75]

4.65 Similarly, the New Zealand Ministry of Health stated in September 2020 that:

> Despite some experimentation with vaping products among never smokers, vaping products are attracting very few people who have never smoked into regular vaping, including young people.[76]

4.66 A number of submitters expressed similar views.[77] For example, Professor Borland advised that 'these studies are also completely consistent with other possible relationships, most notably that the kinds of adolescents who try vaping would, in the absence of vaping, have tried smoking anyway and perhaps sooner'.[78]

4.67 Professor Borland continued:

> If there is a systematic causal relationship of vaping leading to smoking, then a rise in vaping levels should be associated with a rise in smoking levels at population level within the comparable time period. As the studies typically have one year follow-up, this would mean year to year increases in smoking as vaping increased. This has not been found in the countries where uptake of smoking is assessed regularly (largely the same countries, eg USA from which the observational studies come). Indeed, there is evidence that the rate of decline in smoking actually increased over the period when vaping first become popular in the USA.[79]

4.68 Similarly, ATHRA submitted that a more plausible explanation for the association between youth vaping and smoking is due to shared risk factors:

> This posits that young people who experiment with risky behaviours such as vaping are simply more likely to also later try cigarette smoking because of shared risk factors (confounders) such as peer smoking, a family history of smoking, low socio-economic status and rebelliousness.[80]

4.69 In addition, some submitters referenced the advice of the Surgeon-General of the United States Public Health Service who characterised the increase in

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[75] Royal College of Physicians, *Nicotine without smoke: Tobacco harm reduction*, April 2016, p. 190.

[76] Ministry of Health (NZ), *Position statement on vaping*, 3 September 2020.

[77] See, for example, Professor Chris Bullen and Associate Professor Natalie Walker, *Submission 163*, p. 5; Professor Kenneth Warner, *Submission 129*, p. 2; and Alcohol and Drug Foundation, *Submission 209*, p. 6.

[78] Professor Ron Borland, *Submission 160*, p. 6.

[79] Professor Ron Borland, *Submission 160*, p. 6.

[80] Australian Tobacco Harm Reduction Association, *Submission 166*, p. 17.

e-cigarette use amongst youth in the United States as an 'epidemic'.[81] On this point, Professor McRobbie informed the committee that:

> Certainly in some states in the US they have seen quite a large increase in the use of vaping products. 'Ever used' may not be a particular problem, because 'ever used' is often described as even just one puff. That doesn't necessarily cause ongoing vaping. However, what they have seen in some states with some electronic cigarette products is more regular or daily use in never-smokers. However, I think the data seems to restrict that mainly to the US. If we turn our heads to the EU or particularly England we don't see that same pattern occurring. That might be due to differences in advertising restrictions.[82]

4.70 It is the committee's view that it is appropriate to describe the evidence of the gateway effect as emerging. Dr Towler made the point that the Commonwealth Scientific and Industrial Research Organisation's (CSIRO) finding in a 2018 report, that the evidence for a gateway effect 'does not appear strong',[83] is no longer the case. Dr Towler argued that 'we have moved on from that point in time…we have more recent analysis since then…that've all come to the same conclusion that this is a real thing'.[84]

Nicotine toxicity

4.71 The Department of Health noted that nicotine is a dangerous and highly addictive substance, and that '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'.[85] The department further submitted that:

> Exposure to nicotine via e-cigarette use may pose adverse cardiovascular, respiratory and reproductive effects and negative effects on foetal and adolescent development. 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. Evidence from the International Agency for

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[81] Centers for Disease Control and Prevention, *Surgeon General's Advisory on E-cigarette Use Among Youth*, 9 April 2019, www.cdc.gov/tobacco/basic_information/e-cigarettes/surgeon-general-advisory/index.html (accessed 26 November 2020).

[82] Professor Hayden McRobbie, National Drug and Alcohol Research Centre, University of New South Wales, *Committee Hansard*, 13 November 2020, p. 31.

[83] Stephanie Byrne, Emily Brindal, Gemma Williams, Kim Anastasiou, Anne Tonkin, Samantha Battams and Malcolm Riley, CSIRO, *E-cigarettes, smoking and health: A literature review update*, 22 June 2018, p. 229.

[84] Dr Bernie Towler, Principal Medical Officer, Population Health Division, Department of Health, *Committee Hansard*, 19 November 2020, pp. 8-9.

[85] Department of Health, *Submission 167*, p. 21.

> Research on Cancer also suggests that nicotine is associated with DNA damage and other pathways of carcinogenesis.[86]

4.72 As nicotine for e-cigarettes is not currently available for commercial sale in Australia, many individuals import nicotine and mix it into the e-liquid themselves. Evidence was offered to suggest that nicotine available in liquid form (for use in e-cigarettes) may present a risk of acute nicotine poisoning.[87] Nicotine poisoning can affect users of e-cigarettes directly, but may also occur when children unintentionally access nicotine solutions. The Department of Health submitted that:

> 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. 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), and in 2018, a young child in Victoria died from poisoning after consuming an e-liquid containing nicotine.[88]

4.73 Such unintentional poisonings can be a result of unsafe products, and the committee heard that a lack of regulation 'puts users at risk of unsafe imported products'.[89] For example, the RACP expressed concern about nicotine ingestion in children and infants, noting that 'the risk of accidental exposure or ingestion of nicotine in e-liquid is a growing problem in that there is currently no regulation on child resistant packaging'.[90]

4.74 Many users of e-cigarettes who wrote to the committee requested regulation to improve product safety, noting that the current practice of importing nicotine solutions was leading to substandard products.[91]

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86 Department of Health, *Submission 167*, p. 20.

87 See Australian Tobacco Harm Reduction Association, *Submission 166*, p. 22; The Royal Australasian College of Physicians, *Submission 170*, p. 16; and Dr Jody Moller, Dr Celine Kelso and Professor Alison Jones, *Submission 220*, p. 5.

88 Department of Health, *Submission 167*, p. 20.

89 Australian Tobacco Harm Reduction Association, *Submission 166*, p. 22.

90 The Royal Australasian College of Physicians, *Submission 170,* p. 17.

91 See, for example, Mr James Reid, *Submission 4*, [p. 1]; Mrs Yvette Hopkins, *Submission 9*, [p. 2]; Ms Maureen Steele, *Submission 10*, [p. 2]; Miss Kerri Shannon, *Submission 23*, [p. 2]; Mr Joshua Waters, *Submission 28*, [p. 1]; Dr Richard Watkins, *Submission 31*, [p. 2]; Mr Colin Mannings, *Submission 33* [p. 2]; Mr Chris Hansen, *Submission 46*, [p. 1]; Mr Adam Metelmann, *Submission 51*, [p. 2]; Mr Bill Stewart, *Submission 76*, [p. 1]; Mr Aaron Fisher, *Submission 80*, [p. 1]; Ms Samantha Barratt, *Submission 102*, [p. 2]; Mr Ken McNaughton, *Submission 121*, [p. 1]; Miss Leesa Austin, *Submission 141*, [p. 1]; Ms Deborah Smith, *Submission 144*, [p. 2]; Mr Damien Hackett, *Submission 198*, p. 1; Mr Ben Johnson, *Submission 204*, [p. 1]; Ms Annette Huppatz, *Submission 265*, [p. 1]; Mr Patrick Cameron, *Submission 277*, [p. 2]; Ms Pam Mulholland, *Submission 301*, [p. 1]; Mr Jacent Hipworth, *Submission 316*, [pp. 2-3];

4.75 For adult users of e-cigarettes, avoiding nicotine poisoning can be managed by individuals. E-cigarette users can regulate nicotine dosages by reducing intake based on early symptoms of overdose such as headache, dizziness and nausea.[92]

4.76 In addition, there are in-built protections with some e-cigarette devices. Professor Borland commented that 'most modern devices use thermistors to prevent overheating, further reducing any risk of acutely high intakes of such compounds'.[93]

4.77 In order to ensure that e-cigarette devices have appropriate protections and e-liquids are appropriately packaged to prevent children from accessing them, ATHRA argued that 'a legal supply chain of regulated products will guarantee safer products with accurate labelling, health warnings and child-proof caps'.[94]

4.78 Professor Borland advised the committee:

> Vaping products, very much like cigarettes, don't necessarily deliver a standard dose of nicotine to the user. It depends on how you use them, the power or the strength of the solution and maybe even the make-up of the mix of propylene glycol and vegetable glycerine, which can have an impact on nicotine delivery. So I think there's a nice balance between regulating the product to exclude things that we know are potentially harmful and being flexible over time to be able to adapt and change as we learn more.[95]

4.79 Professor Skerritt informed the committee that, as part of the TGA's current consultation on the scheduling of nicotine and prescription model for e-cigarettes, submitters raised the need for better regulation of e-liquid packaging and ingredients:

> Many of the submissions to the TGA consultation, which only closed yesterday, say, yes, make these products available on prescription through pharmacies but also make sure that there are controls, such as a child-proof cap and controls on composition and all that. No decision has been made. The delegate has not made his or her final decision. It may well be that things such as a child-proof cap or other standards are included in that final decision. Many of the submissions, including from health care professional groups and also from some of the community and vape

Mr Gana Somayanda, *Submission 331*, [p. 1]; Mr John Moore, *Submission 343*, [p. 1]; Mr George Teepa, *Submission 350*, [p. 1]; and Mr Brad Martens, *Submission 376*, [p. 1].

92 See Alcohol and Drug Foundation, *Submission 209*, p. 5; Nurses' Professional Association of Queensland, *Submission 258*, p. 146; and Australian Health Promotion Association, *Submission 274*, p. 4.

93 Professor Ron Borland, *Submission 160*, p. 2.

94 Australian Tobacco Harm Reduction Association, *Submission 166*, p. 22.

95 Professor Ron Borland, Private capacity, *Committee Hansard*, 13 November 2020, p. 35.

groups have emphasised the importance of child-proof caps, so that may well be part of the delegate's final decision.[96]

Dual use

4.80 Approximately 40 per cent of current daily e-cigarette users are dual users who also smoke tobacco, and one-fifth are people who have never smoked tobacco.[97]

4.81 Evidence before the committee suggested that e-cigarettes may be used concurrently with combustible cigarettes (referred to as dual use).[98] The Department of Health stated that this 'calls into question whether [e-cigarettes] will reduce harm among most smokers', and noted that current evidence suggests that dual usage and exclusive use of e-cigarettes may result in prolonged exposure to nicotine, which remains harmful.[99]

4.82 In discussing dual usage, Professors Chapman and Daube directed the committee to a recent paper from the Longitudinal Population Assessment of Tobacco and Health Study,[100] which found that the vast majority of smokers who vape keep using cigarettes: 'one in five exclusive ENDS users quit, and three in five (58%) of dual users (about half of all ENDS users in Australia) drop ENDS and go back to cigarettes after two years'.[101]

4.83 Similarly, The Thoracic Society of Australia and New Zealand submitted that 'no harm reduction is achieved through dual use, and the worst of both worlds is achieved'.[102] Professor Peters also told the committee that 'dual use is a harm

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[96] Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, *Senate Community Affairs Legislation Committee Hansard*, 27 October 2020, p. 2.

[97] Professor Emily Banks, Professor of Epidemiology and Population Health, ANU, *Committee Hansard*, 13 November 2020, p. 17.

[98] See, for example, Cancer Council, *Submission 251*, p. 2; Professor Coral Gartner and Professor Wayne Hall, *Submission 159*, pp. 10-11; The Thoracic Society of Australia and New Zealand, *Submission 162,* p. 5; Department of Health, *Submission 167,* p. 25; The Royal Australasian College of Physicians, *Submission 170*, p. 3; and Asthma Australia, *Submission 273*, p. 4.

[99] Department of Health, *Submission 167,* p. 25.

[100] Andrew F Brouwer, Jihyoun Jeon, Jana L Hirschtick, Evelyn Jimenez-Mendoze, Ritesh Mistry, Irina V Bondarekno, Stephanie R Land, Theodore R Holford, David T Levy, Jeremy M G Taylor, Nancy L Fleischer and Rafael Meza, 'Transitions between cigarette, ENDS and dual use in adults in the PATH study (waves 1–4): multistate transition modelling accounting for complex survey design', *Tobacco Control*, 16 November 2020, dx.doi.org/10.1136/tobaccocontrol-2020-055967 (accessed 17 December 2020).

[101] Emeritus Professor Simon Chapman and Emeritus Professor Mike Daube, answer to question on notice QoN014-04, 20 November 2020 (received 26 November 2020).

[102] The Thoracic Society of Australia and New Zealand, *Submission 162,* p. 5.

accentuation'.[103] The Asthma Society likewise did not view dual use as productive for smoking cessation.[104]

4.84 In contrast, Professors Gartner and Hall noted that there have been issues with past surveys that consider dual use:

> …the fact that many people who use ENDS also smoke cigarettes in cross sectional surveys (i.e. engage in 'dual use') is potentially misleading. These surveys do not distinguish between people who are trialling ENDS, people who are using them to cut down before quitting, and people who are engaging in long term dual use.[105]

4.85 Professors Gartner and Hall also raised the need for further long-term studies in order to determine what percentage of combustible cigarette smokers move to exclusive e-cigarette usage and what number engage in long-term dual use.[106]

4.86 Professor Chris Bullen noted that there may still be some limited benefits to dual usage:

> The scientific evidence points out the fact that there is a lot of dual use that goes on. Having said that, even cutting down the amount of cigarettes you smoke isn't perfect, but it does reduce your risk of long-term respiratory consequences, though probably not the cardiovascular consequences. There are still probably some risks of various forms of cancer, but there's emerging evidence of the risk of respiratory consequences of smoking. If you go to dual use you're smoking fewer cigarettes, and then that's of benefit. So there is some benefit, but it's not perfect.[107]

4.87 Mr Savvas Dimitriou, managing director of Vapoureyes Australia—which designs, manufactures and distributes vaping products—discussed the smoking cessation trends he had observed in his customer base:

> They'll transition to vaping over a period of a week to a month or thereabouts. There'll be a period of dual use and then they'll eventually transition completely to vaping. After that six months they typically drop off and either quit vaping completely or, in some rare cases, end up going back to smoking because they can't find the right device for their needs or whatever it might be. But the vast majority end up on that kind of six-month slide I suppose.[108]

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[103] Professor Matthew Peters, former President and Co-Chair of Electronic Cigarettes Working Party, The Thoracic Society of Australia and New Zealand, *Committee Hansard*, 19 November 2020, p. 28.

[104] Asthma Australia, *Submission 273*, p. 4.

[105] Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 159*, p. 10.

[106] Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 159*, p. 11.

[107] Professor Chris Bullen, Private capacity, *Committee Hansard*, 13 November 2020, p. 46.

[108] Mr Savvas Dimitriou, Managing Director, Vapoureyes Australia, *Committee Hansard*, 19 November 2020, p. 18.

4.88 Submitters who wrote to the committee to share their experience indicated that some e-cigarette users may smoke combustible cigarettes for a short period of time while transitioning solely to e-cigarette use.[109] For instance:

> Before I began vaping I was smoking 50 cigarettes a day. I began vaping in March or April 2014 and duel used before I could stop smoking in September 2014. I still craved tobacco for possibly a year after that but continued to vape. Nicotine is not the only element contributing to the addictive nature of tobacco.[110]

E-cigarettes and smoking cessation

4.89 The inquiry heard the majority of people successfully quit smoking tobacco without any intervention.[111] For example, Professor Chapman argued that '[t]wo-thirds to three-quarters of people who quit smoking do so without any therapeutic agent whatsoever'.[112]

4.90 The committee heard that there is limited and inconclusive evidence that e-cigarettes assist with smoking cessation.

4.91 Professor Banks noted that one study found support for e-cigarettes and cessation, though that was 'within medical quit-smoking services, with smokers also regularly seeing a health professional for behavioural support'.[113]

4.92 Professor Banks' initial review indicated that there was insufficient evidence that e-cigarettes were or were not effective for smoking cessation, and there was some evidence that the use of e-cigarettes by smokers trying to quit was likely to lead to greater long-term exposure to nicotine than the use of approved nicotine replacement therapies.[114]

> One study found that around 80% of successful quitters randomised to e-cigarettes continued to use them at one-year follow up while 9% of those

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[109] See, for example, Name withheld, *Submission 53*, [p. 1]; Mr Luke Oliver, *Submission 142*, [p. 1]; Name withheld, *Submission 191*, [p. 1]; Mr Damien Hackett, *Submission 198*, p. 1; Name withheld, *Submission 201*, [p. 1]; Mr Arthur Wielgosz, *Submission 207*, [p. 2]; Mrs Judith Wolters, *Submission 221*, [pp. 1-3]; Ms Rachael James, *Submission 224*, [p. 1]; Mr Norbert Zillatron Schmidt, *Submission 249*, [p. 1]; Mrs Linda Foster, *Submission 282*, [p. 1]; **N**ame withheld, *Submission 286*, p. 5; Mr Clay Bell, *Submission 351*, [p. 1]; Ms Tara Orr, *Submission 375*, [p. 1]; and Name withheld, *Submission 405*, [p. 2].

[110] Mrs Judith Wolters, *Submission 221*, p. [1].

[111] Professor Emily Banks, Professor of Epidemiology and Population Health, ANU, *Committee Hansard*, 13 November 2020, p. 17; Emeritus Professor Simon Chapman, School of Health, University of Sydney, *Committee Hansard*, 19 November 2020, p. 10.

[112] Emeritus Professor Simon Chapman, School of Health, University of Sydney, *Committee Hansard*, 19 November 2020, p. 10.

[113] Professor Emily Banks, *Submission 157*, p. 5.

[114] Professor Emily Banks, Professor of Epidemiology and Population Health, ANU, *Committee Hansard*, 13 November 2020, p. 18.

> randomised to other nicotine-replacement continued to use these products.[115]

4.93 Professor Skerritt argued that the support of health professionals was key to any cessation outcomes:

> …one of the best people to work with an individual on smoking cessation is their general practitioner, who understands their full health and their medical history. There's a lot of evidence, also, that having a mentor, a coach or another individual involved in smoking cessation discussions will increase the success of smoking cessation, rather than not talking to anyone about it.[116]

4.94 The Department of Health has expressed concern that there is no clear evidence that e-cigarettes assist smoking cessation. Rather, 'some evidence suggests the opposite effect: that overall they may be depressing smoking cessation'.[117] In addition, the department has stated that:

> Health claims for e-cigarettes, such as that they are effective smoking cessation aids or safe alternatives to conventional tobacco products, should be rejected by health authorities in the absence of robust supporting scientific evidence to substantiate these claims.[118]

4.95 The National Health and Medical Research Council's position is that, currently, there is insufficient evidence to conclude whether e-cigarettes can assist smokers to quit combustible cigarettes:

> Experts disagree about whether e-cigarettes may help smokers to quit, or whether they will become 'dual users' of both e-cigarettes and tobacco cigarettes. There is currently insufficient evidence to demonstrate that e-cigarettes are effective in assisting people to quit smoking and no brand of e-cigarette has been approved by the Therapeutic Goods Administration for this purpose.[119]

4.96 The Therapeutic Goods Administration, AMA, Cancer Australia, Cancer Council Australia, National Heart Foundation of Australia and the RACP support the National Health and Medical Research Council's position.[120]

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115 Professor Emily Banks, *Submission 157*, p. 6.

116 Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, *Committee Hansard*, 13 November 2020, p. 11.

117 Australian Government, Department of Health, *Policy and regulatory approach to electronic cigarettes (e-cigarettes) in Australia*, 28 November 2019, p. 2.

118 Australian Government, Department of Health, *Policy and regulatory approach to electronic cigarettes (e-cigarettes) in Australia*, 28 November 2019, p. 2.

119 National Health and Medical Research Council, *CEO Statement: Electronic cigarettes*, 3 April 2017.

120 The Royal Australasian College of Physicians, *Submission 170,* p. 6.

4.97 The RACP advised the committee:

> The current evidence is limited and insufficient in many aspects of e-cigarettes, ranging from its impacts, health risks, to its overall role in public health. In the absence of unequivocal evidence, any recommendation to further relax e-cigarette regulation is associated with potentially grave ramifications, impacting generations to come.[121]

4.98 In 2018, the CSIRO, after reviewing the available evidence on e-cigarettes, concluded that e-cigarette usage by non-smoking youths did predict future smoking and that e-cigarette usage was not proven as an effective smoking cessation method.[122] The CSIRO submitted:

> It is a critical research question to determine the effectiveness of e-cigarettes compared to other smoking cessation methods among Australian smokers generally, and also among specific groups with a high smoking rate. The rate at which young people and adults in Australia start smoking as a result of using e-cigarettes should be assessed and monitored to fill a research gap. On present evidence, it is not possible to determine whether less restrictive access to e-cigarettes would reduce rates of smoking in Australia.[123]

4.99 Similarly, Ms Sharon Appleyard, a representative of the Department of Health, explained that 'while e-cigarettes may be helpful to some smokers individually in relation to smoking cessation, there's no evidence at a population level'.[124]

4.100 In contrast, Professor Warner, Professor Emeritus of Health Management and Policy from the University of Michigan's School of Public Health, submitted that the current evidence 'indicates that vaping nearly doubles the odds of quitting smoking compared to governmentally-approved nicotine replacement therapy products'.[125]

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[121] The Royal Australasian College of Physicians, *Submission 170,* p. 5.

[122] Stephanie Byrne, Emily Brindal, Gemma Williams, Kim Anastasiou, Anne Tonkin, Samantha Battams and Malcolm Riley, CSIRO, *E-cigarettes, smoking and health: A literature review update*, 22 June 2018, p. v.

[123] Stephanie Byrne, Emily Brindal, Gemma Williams, Kim Anastasiou, Anne Tonkin, Samantha Battams and Malcolm Riley, CSIRO, *E-cigarettes, smoking and health: A literature review update*, 22 June 2018, pp. vi-viii.

[124] Ms Sharon Appleyard, First Assistant Secretary, Department of Health, *Committee Hansard*, 13 November 2020, p. 6.

[125] Professor Kenneth Warner, *Submission 129*, p. 2.

The evidence on smoking cessation

4.101 There have been a number of high-level studies into the effectiveness of e-cigarettes as smoking cessation aids. In this section, the committee considers the substantial reviews undertaken by the ANU and Cochrane.[126]

The Australian National University summary report

4.102 In 2018, the Minister for Health, the Hon Greg Hunt MP, commissioned the ANU to conduct an extensive review of the existing evidence on the health effects of e-cigarette use. The final report of this review is due mid-2021. An initial report was provided to the Australian Government on 30 September 2020.[127]

4.103 The 2020 summary report found that 'there was insufficient evidence that nicotine e-cigarette products were a more effective smoking cessation aid than no intervention, non-nicotine e-cigarettes, placebo existing nicotine-replacement therapy or other best-practice interventions'.[128] However, the review noted that 'preliminary evidence highlights the potential for nicotine delivering e-cigarettes to support cessation, and more reliable, large-scale evidence is needed'.[129] Professor Banks submitted that 'our results are consistent with virtually all of the reviews on [the effectiveness of e-cigarettes as a smoking cessation aid] conducted to date'.[130]

4.104 The summary report concluded that:

- Recent declines in smoking were largely driven by very low smoking uptake in younger people with 97 per cent of 14–17 year olds in 2019 having never smoked.
- The large majority of people successfully quitting smoking do so unaided or by going 'cold turkey'.

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[126] Cochrane reviews are internationally acclaimed scientific reviews of evidence which cover a wide range of topics. The Australian Government funds free public access to the Cochrane Library, and the Department of Health notes that '[t]he Cochrane Collaboration is an international, non-profit organisation that produces unbiased analyses of reliable and relevant research studies. Cochrane systematic reviews are widely acknowledged as constituting the highest level of scrutiny of the scientific evidence available.' For further information, see Department of Health, *National Health and Medical Research Council (NHMRC) Program – Cochrane Library*, 12 December 2014, www1.health.gov.au/internet/main/publishing.nsf/Content/health-cochrane.htm (accessed 10 December 2020).

[127] Emily Banks, Katie Beckwith, Grace Joshy, ANU, *Summary report on use of e-cigarettes and relation to tobacco smoking uptake and cessation, relevant to the Australian context*, 24 September 2020.

[128] Emily Banks, Katie Beckwith, Grace Joshy, ANU, *Summary report on use of e-cigarettes and relation to tobacco smoking uptake and cessation, relevant to the Australian context*, 24 September 2020, p. 7.

[129] Emily Banks, Katie Beckwith, Grace Joshy, ANU, *Summary report on use of e-cigarettes and relation to tobacco smoking uptake and cessation, relevant to the Australian context*, 24 September 2020, p. 6.

[130] Professor Emily Banks, *Submission 157*, pp. 5-6.

- Current patterns of use in Australia are largely inconsistent with short term use of e-cigarettes for smoking cessation. Patterns are more consistent with people using e-cigarettes in addition to combustible cigarettes, substitution of combustible cigarettes with e-cigarettes and uptake of e-cigarettes by people who have never smoked.
- Among people who have never smoked or are current non-smokers, those who use e-cigarettes are, on average, around three times as likely to take up smoking of combustible cigarettes as those who have not used e-cigarettes.
- Current evidence suggests that nicotine-delivering e-cigarettes can result in prolonged exposure to nicotine through ongoing exclusive e-cigarette use or dual use with combustible cigarettes.[131]

4.105 In evidence, Professor Banks was questioned about one of the studies in the ANU's review which included a nicotine delivery amount of only 0.01 milligrams per millilitre. In response, Professor Banks explained the rationale for including such a study:

> Because of the remit to consider all types of e-cigarettes, because e-cigarettes are considered to have additional elements that may be supportive of quitting above and beyond nicotine (e.g. hand to mouth movements, taste, simulation of other aspects of the smoking experience) and because the dose of nicotine received by the user depends on the characteristics of the device as well as the nicotine concentration in the e-liquid, the review of e-cigarette efficacy for smoking cessation was inclusive of all doses of nicotine – including the potential to include e-cigarette interventions not delivering nicotine.[132]

4.106 It is the committee's view that, in light of the divergent views regarding the health effects of e-cigarette use, it was appropriate for the Australian Government to commission an extensive independent review of the existing research and evidence. The committee also acknowledges the importance of the ANU's findings and looks forward to the publication of its final report.

The Cochrane reviews

4.107 Proponents of e-cigarettes drew the committee's attention to a series of reviews undertaken by Cochrane,[133] which investigate elements of tobacco addiction, including:

- interventions at the population level;
- interventions to help smokers and other tobacco users to quit;

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[131] Emily Banks, Katie Beckwith, Grace Joshy, ANU, *Summary report on use of e-cigarettes and relation to tobacco smoking uptake and cessation, relevant to the Australian context*, 24 September 2020, p. 7.

[132] Professor Emily Banks, Professor of Epidemiology and Population Health, ANU, answer to written question on notice, QoN 19-01, 25 November 2020 (received on 30 November 2020).

[133] See, for example, Dr McRobbie, Committee Hansard, 13 November 2020, p. 29, Dr Mendelsohn, Committee Hansard, 13 November 2020, p. 71.

- interventions to prevent tobacco use;
- interventions to reduce harm in people who use tobacco; and
- other reviews on related matters.[134]

4.108 The 2014 Cochrane review of e-cigarettes as a smoking cessation tool found that e-cigarettes helped some people to stop smoking.[135] Based largely on the combined results of two randomised controlled trials, involving over 600 people, the review found that using e-cigarettes containing nicotine increased the chances of stopping smoking combustible cigarettes long-term, compared to using e-cigarettes without nicotine. However, the review also noted that the quality of the evidence was low, because it was based on a small number of studies.[136]

4.109 These findings were affirmed in the results of an updated Cochrane review, which was published in 2016.[137] This review included an examination of 24 completed studies, three of which were randomised controlled trials and 21 of which were cohort studies. The updated review incorporated 11 new observational studies. However, the review's authors again noted that the quality of the evidence overall was low because it was based on a small number of studies.

4.110 In 2020, the Cochrane review was updated once again, with the results published on 14 October 2020. The latest version of the review included 50 completed studies, representing 12 430 participants, of which 26 studies were randomised controlled trials.[138] On the basis of their analysis, the review's authors determined that there was:

> Moderate-certainty evidence that [e-cigarettes] with nicotine increase quit rates compared to [e-cigarettes] without nicotine and compared to

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134 All of Cochrane's reviews can be found on the organisation's website.

135 Jamie Hartmann-Boyce, Hayden McRobbie, Chris Bullen, Rachna Begh, Lindsay F Stead and Peter Hajek, 'Electronic cigarettes for smoking cessation', *Cochrane Database of Systematic Reviews*, vol. 12, no. CD010216, 2014. This was the first review of e-cigarettes to pool data and to conduct a meta-analysis.

136 The review included randomised controlled trials, cohort follow-up studies and randomised cross-over trials each of which measured abstinence rates of current smokers (who were motivated or not motivated to quit) at six months or longer.

137 Jamie Hartmann-Boyce, Hayden McRobbie, Chris Bullen, Rachna Begh, Lindsay F Stead and Peter Hajek, 'Electronic cigarettes for smoking cessation', *Cochrane Database of Systematic Reviews*, vol. 9, no. CD010216, 2016.

138 Jamie Hartmann-Boyce, Hayden McRobbie, Nicola Lindson, Chris Bullen, Rachna Begh, Annika Theodolou, Caitlin Notley, Nancy A Rogott, Tari Turner, Ailsa R Butler and Peter Hajek, Electronic cigarettes for smoking cessation, *Cochrane Database of Systematic Reviews*, vol. 10, no. CD010216, 2016.

> [nicotine replacement therapy]. Evidence comparing nicotine [e-cigarettes] with usual care/no treatment also suggests benefit, but is less certain.[139]

4.111 The review observed that more studies were needed to confirm the degree to which e-cigarettes assisted with harm reduction. While the review's authors did not detect any clear evidence of harm from nicotine e-cigarettes, they noted that 'the longest follow-up was two years and the overall number of studies was small'.[140]

4.112 The 2020 Cochrane review noted that further randomised controlled trials of the effectiveness of e-cigarettes as cessation aids are underway and that their review will be updated as relevant new evidence becomes available.

Impact of e-cigarettes on smoking prevalence

4.113 Evidence on the impact of e-cigarettes on smoking cessation and tobacco consumption is beginning to accumulate. However, the committee received submissions which call for further research in this area.

4.114 The evidence that is currently available suggests that e-cigarettes can be at least as effective as other nicotine replacement therapies as aids to quitting smoking. The impact of legalising e-cigarettes on rates of smoking, was noted by Professor Borland in the context of declining smoking rates abroad:

> The countries we tend to compare ourselves with most: New Zealand, Canada, the UK, US, and Europe all have much more liberal policies around vaping, indeed in the case of NZ and Canada, both have moved in the last few years from the same historical position Australia began with to explicitly legalize vaping in various forms and have put in place (or are putting in place) regulatory frameworks to minimize the risk. As far as we can tell, from those countries with enough data, smoking rates are declining at least as fast, probably faster in those other countries than in Australia.[141]

4.115 International studies have been undertaken to model and better understand the long term impacts of e-cigarettes on smoking prevalence. For example, in the United States,[142] New Zealand,[143] and Singapore.[144] However, as Dr Elizabeth Greenhalgh and Dr Michelle Scollo observed:

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[139] Jamie Hartmann-Boyce, Hayden McRobbie, Nicola Lindson, Chris Bullen, Rachna Begh, Annika Theodolou, Caitlin Notley, Nancy A Rogott, Tari Turner, Ailsa R Butler and Peter Hajek, Electronic cigarettes for smoking cessation, *Cochrane Database of Systematic Reviews*, vol. 10, no. CD010216, 2016.

[140] Jamie Hartmann-Boyce, Hayden McRobbie, Nicola Lindson, Chris Bullen, Rachna Begh, Annika Theodolou, Caitlin Notley, Nancy A Rogott, Tari Turner, Ailsa R Butler and Peter Hajek, Electronic cigarettes for smoking cessation, *Cochrane Database of Systematic Reviews*, vol. 10, no. CD010216, 2016.

[141] Professor Ron Borland, *Submission 160*, p. 7.

[142] David T Levy, Ron Borland, Eric N Lindblom, Maciej L Goniewicz, Rafael Meza, Theodore R Holford, Zhe Yuan, Yuying Luo, Richard J O'Connor, Raymond Niaura and

> Such modelling is limited by a lack of understanding of long-term health effects, effects on smoking uptake, and effectiveness for cessation, and conclusions subsequently vary substantially depending on the assumptions and parameters used by researchers.[145]

The role of the tobacco industry

4.116 A key concern for submitters, particularly those in the health community, was that major tobacco companies are increasingly directly involved in the e-cigarette industry. For example, the Cancer Council, the National Heart Foundation of Australia and the Australian Council on Smoking and Health submitted that '[t]he tobacco industry is by far the dominant player in the global e-cigarette and other novel tobacco products market worth USD$11.73 billion in 2019'.[146]

4.117 This concern was heighted by the publication, during the inquiry, of content sponsored by Phillip Morris International in *The Australian* titled 'Follow science to the moon'.[147] This content called for Australia's regulatory stance on e-cigarettes to replicate that of the UK, the United States, New Zealand and the European Union. The committee considers the timing of this publication was determined in an attempt to influence the deliberations of this committee.

4.118 Dr Jongenelis submitted that '[e]-cigarettes are part of Big Tobacco's product diversification strategy to deliver new and novel nicotine delivery devices'.[148]

David B Adams, 'Potential deaths averted in USA by replacing cigarettes with e-cigarettes', *Tobacco Control*, 27(1), 2018, pp. 18-25. See also this study's predecessor: David T Levy, Ron Borland, Andrea C Villanti, Raymond Niaura, Zhe Yuan, Rafael Meza, Theodore R Holford, Geoffrey Fong, Cummings K Michael and David B Adrams, 'The application of a decision-theoretic model to estimate the public health impact of vaporized nicotine product initiation in the United States', *Nicotine and Tobacco Research*, 19(2), 2017, pp. 149-59. For further information see National Academies of Sciences Engineering and Medicine, *Public health consequences of e-cigarettes*, The National Academies Press, Washington, DC, 2018.

143 Frederieke S Petrovic-van der Deen, Nick Wilson, Anna Crothers, Christine L Cleghorn, Coral Gartner and Tony Blakely, 'Potential country-level health and cost impacts of legalizing domestic sale of vaporized nicotine products', *Epidemiology*, 30(3), 2019, pp. 396-404.

144 Thi Thanh Tra Doan, Ken Wei Tan, Borame Sue Lee Dickens, Yin Ai Lean, Qianyu Yang and Alex R Cook, 'Evaluating smoking control policies in the e-cigarette era: a modelling study', *Tobacco Control 29.5*, 2019.

145 Dr Elizabeth Greenhalgh and Dr Michelle Scollo, Chapter 18, Potential for harm reduction in tobacco control in Elizabeth Greenhalgh, Michelle Scollo and Margaret Winstanley (eds), *Tobacco in Australia: facts and issues*, Cancer Council Victoria, Melbourne, 2020.

146 Cancer Council, the National Heart Foundation of Australia and the Australian Council on Smoking and Health, *Submission 194*, p. 9.

147 The Australian (content produced in partnership with Philip Morris International), 'Follow science to the moon', *The Weekend Australian*, www.theaustralian.com.au/sponsored/rp9Rxv493P9nQTUOkEni/follow-science-to-the-moon/ (accessed 12 December 2020).

148 Dr Michelle Jongenelis, *Submission 66*, p. 6.

In particular, Dr Jongenelis suggested that the vaping industry targets adolescents and young adults to drive their profits through the development and promotion of youth-orientated e-juice flavours and the use of appealing packaging and product design.[149]

4.119 Mr Maurice Swanson, Chief Executive Officer, Australian Council on Smoking and Health, commented that the involvement of Big Tobacco is motivated by profitability:

> Their objective…is to provide a range of nicotine delivery devices, from traditional cigarettes to e-cigarettes through to heated tobacco products, and their reason for doing so is that they know that in many Western countries the prevalence of smoking is falling and they need to maintain profitability. If they can dress up their alternative nicotine delivery products as being safer—that's what they're promoting—then they can maintain both their share value and their profitability. That's the bottom line here.[150]

4.120 In contrast, Professor David Sweanor, Chair, Advisory Board for the Centre for Health Law, Policy and Ethics, University of Ottawa, told the committee that '[vaping] completely destroys [Big Tobacco's] business model'.[151] Professor Sweanor submitted:

> The most important point to make is that vaping is absolutely not a strategy hatched by Big Tobacco to somehow create gains for their shareholders. Vaping is a classic example of disruptive technology that was developed independently of Big Tobacco, has been spurred on by consumers and entrepreneurs, and is an existential threat to the longstanding business model of Big Tobacco.[152]

4.121 Professor Sweanor went on to state that:

> The five-year stock charts of transnational tobacco companies show that they have been devastated since the advent of viable safer alternatives to cigarettes…Overall, these companies have lost over US$300 billion of collective market value.[153]

4.122 This point was also reiterated by Mr Dimitriou who told the committee he believed that legalising e-cigarette use would disrupt the business model of the

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149 Dr Michelle Jongenelis, *Submission 66*, p. 6.

150 Mr Maurice Swanson OAM, Chief Executive Officer, Australian Council on Smoking and Health *Committee Hansard*, 19 November 2020, p. 34.

151 Professor David Sweanor, Chair, Advisory Board for the Centre for Health Law, Policy and Ethics, University of Ottawa, *Committee Hansard*, 19 November 2020, p. 21.

152 Professor David Sweanor, *Submission 161*, p. 2.

153 Professor David Sweanor, Chair, Advisory Board for the Centre for Health Law, Policy and Ethics, University of Ottawa, *Committee Hansard*, 19 November 2020, p. 21.

Big Tobacco industry.[154] Mr Dimitriou presented on the personal and business aspects of the vaping industry as an e-cigarette user and Chairman of the Smoke-free Traders Association. In his view, the e-cigarette industry is a consumer-driven industry and '[o]ur entire business is about stealing Big Tobacco's customers'.[155] Mr Dimitriou also emphasised his desire to distance himself and the e-cigarette industry from the tobacco industry.[156]

[154] Mr Savvas Dimitriou, Managing Director, Vapoureyes Australia, *Committee Hansard*, 19 November 2020, p. 14.

[155] Vapoureyes Australia, *Submission 197*, p. 6.

[156] Mr Savvas Dimitriou, Managing Director, Vapoureyes Australia, *Committee Hansard*, 19 November 2020, pp. 13-14.

Chapter 5
Regulatory approaches

5.1 A variety of views were provided to the committee on the relative strengths and weaknesses of a prescription-based model in comparison to other regulatory approaches.

5.2 E-cigarette proponents mainly argued for e-cigarettes to be treated as a consumer product. They argued that the liberalisation of e-cigarettes may form part of a harm reduction strategy and may lead to a decrease in smoking prevalence.

5.3 Many other submitters advocated for a continued precautionary approach by the Therapeutic Goods Administration (TGA). For example, Professors Simon Chapman, Mike Daube and Matthew Peters argued that:

> Any weak system of regulation in Australia would release a Trojan horse which could attract new cohorts of young people into nicotine dependency; popularise a highly addictive and potentially unhealthy fad in young people with all the promises of owning the latest and most prestigious vaping apparatus and peer-kudos from vape clouding displays; lure some long-term quitters back into nicotine dependency; hold many smokers in smoking, in the erroneous belief that smoking reduction (not quitting) confers risk reduction; renormalise smoking behaviour; and distract attention and focus from proven evidence-based action to reduce smoking.[1]

Evidence received on the prescription-based model

5.4 As previously noted, the Australian regulatory approach favours a prescription-based model. At the time of writing, the possession of nicotine for use in e-cigarettes without a prescription is illegal in all states and territories except South Australia.[2] E-cigarette users have, however, been able to source products online without a prescription.

5.5 If made final, the TGA's interim decision on nicotine scheduling would clarify the entry of nicotine in the Standard for the Uniform Scheduling of Medicines and Poisons (the Poisons Standard) with the principal effect that certain nicotine containing products for human use would require a prescription.[3]

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1 Emeritus Professor Simon Chapman, Emeritus Professor Mike Daube and Professor Matthew Peters, *Submission 195*, p. 3.

2 Department of Health, *Submission 167*, p. 8.

3 Therapeutic Goods Administration, *Notice of an interim decision to amend the current Poisons Standard*, 23 September 2020, www.tga.gov.au/resource/notice-interim-decision-amend-current-poisons-standard (accessed 17 December 2020).

5.6 The Australian Government's proposal to prohibit the importation of e-cigarettes containing nicotine would impose penalties (of up to $222 000 for the most serious breaches) on persons who import nicotine for use in e-cigarettes directly from an overseas supplier without a valid import permit.[4] Instead, individuals may obtain e-cigarette products containing nicotine via a permit granted by the Department of Health to a doctor or medical supplier who would be able to import the goods using a courier service or by cargo service.[5]

5.7 The committee heard evidence that a prescription-based model appropriately restricts access to e-cigarettes containing nicotine, given that the long-term impacts of e-cigarette use are unknown. For example, the Queensland Nurses and Midwives' Union favoured a continued ban on the basis of the precautionary approach (like the Australian Association for Adolescent Health Ltd) until long-term research is able to rule out any long-term health consequences.[6]

5.8 A representative from the Department of Health noted that the proposed prescription-based scheme was part of a broader plan to reduce harm at the population level:

> …basically, there's really no evidence that e-cigarettes at a population level will lead to smoking cessation. Evidence at a population level is different to evidence at an individual level. So, while e-cigarettes may be helpful to some smokers individually in relation to smoking cessation, there's no evidence at a population level.[7]

5.9 The Royal Australasian College of Physicians (RACP) supported the view that e-cigarette usage should remain strictly regulated, noting that the long-term impacts of e-cigarettes and related products remained unclear at an aggregate level:

> …the current data [is] inadequate to inform the unequivocal impact of nicotine e-cigarettes on smoking rates, or the impact on the aggregate population health, including amongst populations who experience negative impacts across the social determinants, in that the effectiveness of e-cigarettes in smoking cessation is unclear.[8]

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4 Therapeutic Goods Administration, *Prohibition in importing e-cigarettes containing vaporiser nicotine*, 17 November 2020, www.tga.gov.au/behind-news/prohibition-importing-e-cigarettes-containing-vaporiser-nicotine (25 November 2020).

5 Therapeutic Goods Administration, *Prohibition in importing e-cigarettes containing vaporiser nicotine*, 17 November 2020.

6 Queensland Nurses and Midwives' Union, *Submission 210*, p. 3; and Australian Association for Adolescent Health Ltd, *Submission 264*, [p. 3].

7 Ms Sharon Appleyard, First Assistant Secretary, Department of Health, *Senate Community Affairs Legislation Committee Hansard*, 27 October 2020, p. 6.

8 The Royal Australasian College of Physicians, *Submission 170*, p. 7.

5.10 The Australian Medical Association (AMA) agreed with this approach, noting that it 'strongly advocates for and supports a precautionary approach to the regulation of nicotine vaping products, and believes that the international experience supports this approach'.[9]

5.11 Professors Chapman, Daube and Peters advised the committee that 'the current access de facto free-for-all nicotine in Australia is allowing children easy access to vapable nicotine and carries significant quality and safety risks'.[10] They wrote in support of the prescription-based model and argued that it should remain in place until such time as 'sufficient long term, high quality data may have accumulated to show that vapable nicotine poses an acceptable risk profile to allow it to be sold without prescription'.[11]

5.12 Professor Chapman suggested that the process of meeting with a health professional was an effective method of quitting smoking.[12]

5.13 Similarly, Dr Omar Khorshid advised the committee that:

> Really, the best part of a GP or prescription related model is that the prescription of the e-cigarette liquid would be accompanied by a conversation between the GP and the patient about their smoking, about other ways to quit and about the impacts of nicotine addiction on life and on their health.[13]

5.14 Additionally, the committee recognises that the only random control trial demonstrating significant benefit of e-cigarettes as a method of smoking cessation identified by Professor Emily Banks, in her initial review, was one in which 'smokers used the e-cigarettes within medical quit-smoking survives, with smokers also regularly seeing a health professional for behavioural support'.[14]

5.15 It was also argued that 'the obvious umpire in this matter should be the TGA'.[15] The George Institute for Global Health recommended that e-cigarette products be subject to the same rigorous assessments that the TGA applies to all other

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[9] Australian Medical Association, *Submission 183*, p. 2.

[10] Emeritus Professor Simon Chapman, Emeritus Professor Mike Daube and Professor Matthew Peters, *Submission 195*, p. 30.

[11] Emeritus Professor Simon Chapman, Emeritus Professor Mike Daube and Professor Matthew Peters, *Submission 195*, p. 30.

[12] Emeritus Professor Simon Chapman, School of Health, University of Sydney, *Committee Hansard*, 19 November 2020, p. 9.

[13] Dr Omar Khorshid, President, Australian Medical Association, *Committee Hansard*, 19 November 2020, p. 48.

[14] Professor Emily Banks, *Submission 157*, p. 6.

[15] The George Institute for Global Health, *Submission 267*, [p. 1]; and Emeritus Professor Simon Chapman, Emeritus Professor Mike Daube and Professor Matthew Peters, *Submission 195*, p. 29.

therapeutic products before they are made available to the Australian public, while the Lung Foundation Australia submitted that 'all nicotine products for use as smoking cessation aids should be submitted to the TGA to review their safety and efficacy before they can be prescribed to Australians'.[16]

5.16 Many e-cigarette proponents argued that the prescription-based model for nicotine e-cigarette products was not evidence-based and was actually counterproductive.[17] For example, Legalise Vaping Australia argued:

> Australia's health system is not prepared to prescribe nicotine, with GPs not knowing how to prescribe nicotine and pharmacies against stocking it. Australian vapers will go back to smoking cigarettes if vaping is only available as a prescription.[18]

5.17 Professor John Skerritt informed the committee that the TGA had received a written statement from both the Royal Australian College of General Practitioners (RACGP) and the AMA which indicated their support for a prescription model, and, if the proposed prescription model is introduced in 2021, 'there will be a very significant education program, which has already been budgeted for, for doctors on how to go about it'.[19]

5.18 It was also argued that a prescription-based model is not proportionate to the risks associated with e-cigarette use.[20] Some submitters suggested that regulation as a consumer product would be a risk-proportionate approach.[21]

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16 Lung Foundation Australia, *Submission 268*, p. 9.

17 See, for example, factasia, *Submission 45*, [p. 2]; National Retail Association, *Submission 156*, p. 2; Australian Tobacco Harm Reduction Association, *Submission 166*, pp. 23-24; Vapoureyes, *Submission 197*; p. 5; European Tobacco Harm Reduction Advocates, *Submission 202*, p. 1 and p. 9; TSG Franchise Management, *Submission 215*, [pp. 1-2]; International Network of Nicotine Consumer Organisations, *Submission 243*, p. 3; and Master Grocers Australia Independent Retailers, *Submission 276*, p. 3.

18 Legalise Vaping Australia, *Submission 173*, p. 3.

19 Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, *Committee Hansard*, 13 November 2020, p. 5.

20 See, for example, Coalition of Asia Pacific Tobacco Harm Reduction Advocates, *Submission 38*, pp. 7-8; Australian Tobacco Harm Reduction Association, *Submission 166*, p. 7; Legalise Vaping Australia, *Submission 173*, pp. 9-8; Aotearoa Vapers' Community Advocacy, *Submission 178*, p. 2; Juul Labs, *Submission 242*, pp. 3-4; International Network of Nicotine Consumer Organisations, *Submission 243*, p. 4; Mr Konstantinos Farsalino, *Submission 250*, [p. 2]; NSW Users and AIDS Association, *Submission 253*, pp. 2-6; and Vaping Trade Association of New Zealand, *Submission 263*, p. 5.

21 See, for example, factasia, *Submission 45*, pp. 2-3; National Retail Association, *Submission 156*, p. 3; Mr Clive Bates, *Submission 158*, pp. 6-7; Australian Tobacco Harm Reduction Association, *Submission 166*, pp. 3 and 5-6; Legalise Vaping Australia, *Submission 173*, p. 3; Vapoureyes, *Submission 197*, p. 2; Juddy Corp Pty Ltd, *Submission 227*, p. 2; NSW Users and AIDS Association, *Submission 253*, pp. 3-4; Vaping Trade Association of New Zealand, *Submission 263*, p. 5; and Progressive Public Health Alliance, *Submission 271*, p. 4.

5.19 E-cigarette users expressed the following reasons for their opposition to the prescription-based model:

- E-cigarettes have better health outcomes than smoking cigarettes and are an important strategy for harm minimisation.
- E-cigarettes provide a safer alternative to smoking tobacco, especially for those who are socially or economically disadvantaged or suffer from anxiety-related mental health issues.
- A prescription-based model would increase the burden on doctors' surgeries and pharmacies.
- Prohibition or increased restrictions on e-cigarettes are an infringement on freedom of choice.
- The prescription-based model would destroy the Australian e-cigarette industry, which encompasses a sizeable network of small and family-owned businesses across the country.
- Some expressed a fear that if a prescription model was introduced, they would return to combustible cigarettes.[22]

5.20 For example, Mr Justin Fowler submitted:

> I am also deeply concerned that if vaping was further restricted that I would be definitely [sic] forced back to smoking poisonous tobacco products again as I have done in the past time and time again. I have finally beaten the grasp of tobacco products and rid them from my life for the benefit of myself, my family and all the others around me and this thought genuinely terrifies me.[23]

5.21 One submitter expressed concern that being located in a regional area would make it more difficult to access a prescription, as accessing a general practitioner was not simple:

> I live in a regional area of New South Wales where there is no guarantee that a doctor will issue such a prescription nor that such a product will be available in a local pharmacy. Given that a visit to the doctor currently costs me: over $50 in taxi fares; plus doctors fees (variable but increasing); plus additional expense should I be required to travel to a pharmacy; plus the unknown cost of such a purchase at the pharmacy (I suspect considerably more than I currently spend on e-liquid), I think it may be cheaper (certainly a lot easier) to purchase cigarettes.[24]

5.22 In contrast, e-cigarette user Mr Reid described the relative ease of the process of obtaining a prescription for nicotine in e-cigarette use:

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[22] See, for example, Name withheld, *Submission 7*, [p. 2]; Mrs Yvette Hopkins, *Submission 9*, [p. 2]; Mr Stuart Bowermann, *Submission 55*, [p. 1]; Name withheld *Submission 60*, [p. 1]; Name withheld, *Submission 201*, [p. 2]; Mrs Judith Wolters, *Submission 221*, [p. 1]; Ms Paula Foley, *Submission 332*, [p. 2]; and Mr Shaun Drew, *Submission 362*, [p. 1].

[23] Mr Justin Fowler, *Submission 203*, [p. 2] (34 years of age, previously a smoker from the age of 12).

[24] Name withheld, *Submission 50*, [p. 1] (age unknown, previously a smoker for over 30 years).

> I've got a very, very supportive GP. I suggested it to him, and we then started to investigate. He did as much research as I did. Eventually, we started to discuss the prescription model… You need to put your medical number in to even access it. That then explains how to go about writing a prescription. I sat in his surgery. He logged on, opened that section, read through it and said, 'Not a problem,' and handed me my first prescription. It was not cumbersome; for me, it was quite easy.[25]

5.23 Some submitters noted that the enforcement of a prescription-based model through a prohibition on the importation of vaporiser nicotine could result in a black market in nicotine e-cigarette products.[26] The Australian Tobacco Harm Reduction Association (ATHRA) advised the committee that the 'requirement for a prescription makes it far harder and more costly to access a much less harmful product' and 'the restricted access to legal vaping products has led to increasing black market sales which put users at risk from unsafe products'.[27] On this point, Professor David Sweanor explained that limiting the availability of e-cigarette products is 'putting the safer alternative at a huge disadvantage'.[28]

5.24 While Lung Foundation Australia did not support the use of e-cigarettes as a 'harm reduction smoking cessation method', it spoke out against the proposed rescheduling of nicotine under the Poisons Standard on the basis that this approach does not require the prescribed products to be assessed for safety, toxicity and health impacts. The Lung Foundation Australia stated that the proposed rescheduling would provide 'implicit approval to the manufacturers and consumers of nicotine products' and that it would transfer 'responsibility for the safety, efficacy and physical impact of these products to the medical professionals prescribing, and possibly, dispensing the unapproved therapeutic nicotine products'.[29]

Obtaining a prescription

5.25 Most vapers who use e-nicotine import the liquid from overseas retailers.[30] As a result, there are only a handful of doctors who currently prescribe it.[31]

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[25] Mr James Reid, Private capacity, *Committee Hansard*, 13 November 2020, p. 60.

[26] See, for example, Australian Tobacco Harm Reduction Association, *Submission 166*, p. 5 and p. 24; Legalise Vaping Australia, *Submission 173*, p. 4; Vapora, *Submission 226*, p. 2; Mr Konstantinos Farsalinos, *Submission 250*, p. 2; Liberal Democratic Party, *Submission 266*, p. 4; and Master Grocers Australia Independent Retailers, *Submission 276*, p. 3.

[27] Australian Tobacco Harm Reduction Association, *Submission 166*, pp. 5 and 24.

[28] Professor David Sweanor, Chair, Advisory Board for the Centre for Health Law, Policy and Ethics, University of Ottawa, *Committee Hansard*, 19 November 2020, p. 22.

[29] Lung Foundation Australia, *Submission 268*, p. 9.

[30] See, for example, Ms Dianne Gorman, Private capacity, *Committee Hansard*, 13 November 2020, p. 62; Dr Colin Mendelsohn, Board Member, Australian Tobacco Harm Reduction Association, *Committee Hansard*, 13 November 2020, p. 77.

Professor Skerritt advised the committee that '[i]t's about 10 [general practitioners] at the moment'.[32]

5.26 Professor Skerritt explained:

> It's minuscule, because at the moment there's this massive loophole whereby I could go online today and have it delivered to my home here in Canberra and not go to a GP.[33]

5.27 The Department of Health later clarified that, as at 27 November 2020, there were 14 medical practitioners prescribing nicotine containing e-cigarettes for smoking cessation. In addition:

> From receipt of the first application for approval for Special Access Scheme B access to nicotine for inhalation products for smoking cessation on 22 June 2020 to date, the TGA has approved 15 applications by 12 separate medical practitioners. This represents supply on 15 separate occasions. As noted in evidence to the committee, these numbers reflect the fact that many individuals are importing nicotine products without medical oversight.[34]

5.28 Professor Skerritt explained that support information would be made available for doctors applying to be an authorised prescriber for nicotine and a consumer community-level campaign would be run.[35] Professor Skerritt described what such a campaign could entail:

> …the typical approaches that are used are working in partnership with consumer groups, whether it is a consumer health forum, whether it is other groups that have a reach into the target demographics. It will involve working together with mass media. It will also involve social media. Whether it will involve any paid media is a question still to be resolved.[36]

5.29 Further addressing concerns regarding the prescription model, a representative of the Department of Health made it clear that a prescription pathway would allow prospective e-cigarette users seeking to quit smoking to access a prescription through a general practitioner, as well as through

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[31] Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, *Committee Hansard*, 13 November 2020, p. 5.

[32] Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, *Senate Community Affairs Legislation Committee Hansard*, 27 October 2020, p. 13.

[33] Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, *Senate Community Affairs Legislation Committee Hansard*, 27 October 2020, p. 13.

[34] Department of Health, answer to question on notice, 13 November 2020 (received 27 November 2020).

[35] Adjunct Professor John Skerritt, Deputy Secretary, Department of Health *Committee Hansard*, 13 November 2020, p. 6.

[36] Adjunct Professor John Skerritt, Deputy Secretary, Department of Health *Committee Hansard*, 13 November 2020, p. 6.

telehealth services and stop smoking clinics.[37] Professor Skerritt also argued that the process for a doctor to become authorised to prescribe nicotine for e-cigarette use would be 'almost trivial', consisting of an easy online registration process that would be valid for five years at no cost.[38]

5.30 A number of inquiry participants raised an additional critique of this scheme: namely, that a prescription pathway would create a detrimental toll on Australia's health care system. The National Retail Association submitted they believe such a model would 'result in at a minimum extra two million GP visits occurring annually, costing the health budget more than $300 million across the forward estimates in funded short consultation fees paid to GPs'.[39] In contrast, a representative of the Department of Health advised the committee that it expects the number of additional visits to be in the order of between 70 000 to 180 000.[40] This figure was drawn from a regulatory impact statement currently being finalised with the Office of Best Practice Regulation. As smokers tend to visit doctors more often than non-smokers, it is expected that many would seek a prescription bundled in with the already occurring visits.[41]

5.31 A further concern raised in relation to the prescription-based model is the willingness of doctors to prescribe, and pharmacists to dispense, nicotine e-cigarette products. For example, the RACP submitted:

> There are potential medico-legal, ethical and professional responsibilities for the medical profession in taking on the prescribing role for a product unapproved by the TGA as a therapeutic product for smoking cessation, taking essentially a 'gatekeeper role' in lieu of regulation. The RACP contends that further consideration of the TGA's proposed regulatory changes in relation to the scheduling of nicotine is warranted, mainly around the mechanism of prescribing unapproved nicotine e-cigarette products and the need for development of evidence-based prescribing guidelines for such products. We suggest that further time is taken by the TGA to address these important concerns before implementation commences.[42]

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[37] Adjunct Professor John Skerritt, Deputy Secretary, Department of Health *Committee Hansard*, 13 November 2020, p. 5.

[38] Adjunct Professor John Skerritt, Deputy Secretary, Department of Health *Committee Hansard*, 13 November 2020, p. 5.

[39] National Retail Association, *Submission 156*, p. 7.

[40] Adjunct Professor John Skerritt, Deputy Secretary, Department of Health *Committee Hansard*, 13 November 2020, p. 3.

[41] Adjunct Professor John Skerritt, Deputy Secretary, Department of Health *Committee Hansard*, 13 November 2020, p. 5.

[42] The Royal Australasian College of Physicians, *Submission 170,* p. 4.

5.32 Professor John Wilson expanded on this position:

> For doctors, there are risks in prescribing a wide range of commercial products outside usual standards of required scientific evidence of safety and effectiveness. Prescribing must align with the principles of evidence-based quality or the quality use of medicines framework. As doctors do not prescribe cigarettes, as they once did, it is most appropriate that the RACP recommends a do-no-harm approach to e-cigarettes. There are potential medico-legal, ethical and professional responsibilities for the medical profession in taking on the prescribing role for a product unapproved by the TGA as a therapeutic product for smoking cessation that contains what is still a highly addictive poison.[43]

5.33 Despite these concerns, Professor Skerritt advised that:

> It's fair to say the AMA still oppose and do oppose the use of vaping products, except as an absolute last resort. But, in writing to us—and these submissions will be published on our website—the RACGP supports the proposed amendments. In other words, it supports the provision or the prescription-only model. The AMA accepts a proposal to down schedule nicotine to S4. The AMA regards this as an important move to ensure that patients see their doctor for advice on the most reliable and safe smoking cessation methods.[44]

5.34 Dr Omar Khorshid, President, AMA, told the committee that the AMA supports the prescription model as an effective way to reduce access to e-cigarettes. However, Dr Khorshid acknowledged that 'doctors in general may be a little reticent to prescribe products that are not TGA approved'. To address this, he suggested that doctors be educated about how e-cigarettes may be used as well as product ingredients.[45]

Regulation as a consumer good

5.35 A number of e-cigarette proponents called for e-cigarette products to be regulated as consumer goods.[46] It was argued that regulation as a consumer product would offer important consumer protections.[47] These submitters

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[43] Professor John Wilson, President, The Royal Australasian College of Physicians, *Committee Hansard*, 19 November 2020, pp. 38-39.

[44] Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, *Committee Hansard*, 13 November 2020, p. 6.

[45] Dr Omar Khorshid, President, Australian Medical Association, *Committee Hansard*, 19 November 2020, pp. 48-49.

[46] See, for example, factasia, *Submission 45*, pp. 2-3; National Retail Association, *Submission 156*, p. 3; Mr Clive Bates, *Submission 158*, pp. 6-7; Australian Tobacco Harm Reduction Association, *Submission 166*, pp. 3 and 5-6; Legalise Vaping Australia, *Submission 173*, p. 3; Vapoureyes, *Submission 197*, p. 2; Juddy Corp Pty Ltd, *Submission 227*, p. 2; NSW Users and AIDS Association, *Submission 253*, pp. 3-4; Vaping Trade Association of New Zealand, *Submission 263*, p. 5; and Progressive Public Health Alliance, *Submission 271*, p. 4.

[47] See, for example, National Retail Association, *Submission 156*, p. 3; Australian Tobacco Harm Reduction Association, *Submission 166*, p. 24; and Legalise Vaping Australia, *Submission 173*, p. 3.

particularly highlighted that treatment of nicotine containing e-cigarettes as a consumer product in other regulatory regimes (such as the United Kingdom and Canada) has led to a decrease in smoking prevalence.[48]

5.36 However, there was also concern expressed that regulating e-cigarettes as consumer goods would be serving a vested interest. The committee notes that the Tobacco Industry has made submissions to the TGA calling for nicotine-containing e-cigarettes to be treated as a consumer product. Professor Skerritt noted:

> There are two public submissions from big tobacco on the TGA proposal for rescheduling nicotine to prescription-only. Both of those big tobacco companies strongly oppose the prescription-only model for tobacco and advocate that e-cigarettes should be available as a broader consumer product. You draw your own conclusions on why they may have advocated for that… British American Tobacco and Imperial Brands have both made submissions, and they have indicated their preference for e-cigarettes containing nicotine to be widely available consumer products.[49]

5.37 The Thoracic Society of Australia and New Zealand stated that '[e]-cigarettes, whether containing nicotine or not, are not suitable consumer products'.[50]

5.38 The Australian Competition and Consumer Commission (ACCC) also submitted that:

> The ACCC is aware that some stakeholders regard the ACL [Australian Consumer Law] as an appropriate mechanism to regulate e-cigarettes. However, the ACL's product safety provisions are limited in their application as they only provide for the restriction of supply in certain circumstances related to the physical safety of consumer goods, such as requirements regarding their design, construction or composition. They do not provide for health controls and cannot regulate user behaviour, nor provide for the enforcement of mandatory age restrictions to reduce uptake by children and young people.[51]

5.39 In discussing whether it would be more appropriate for the regulation of nicotine to fall under health legislation, as opposed to consumer legislation, Professor Chris Bullen stated:

> If the goal in Australia is also to improve public health, then the various regulatory levers available, such as taxation, packaging, contents,

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[48] See, for example, National Retail Association, *Submission 156*, p. 3; Australian Tobacco Harm Reduction Association, *Submission 166*, p. 2 and p. 9; and Legalise Vaping Australia, *Submission 173*, p. 5.

[49] Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, *Committee Hansard*, 13 November 2020, p. 8.

[50] The Thoracic Society of Australia and New Zealand, *Submission 162*, p. 1.

[51] Australian Competition & Consumer Commission, *Submission 182*, p. 5.

> advertising, sales to minors, flavours, standards and so on, are in common with many consumer products, and could be invoked that way.[52]

5.40 However, Dr Rob Grenfell, Director, Health and Biosecurity, Commonwealth Scientific Industrial Research Organisation stated that '[i]f [e-cigarettes] were available freely to the community, that would mean that utilisation of that product would occur at higher rates'.[53]

5.41 Similarly, Professor Banks told the committee:

> One characteristic of consumer products is that they tend to be widely available. Even when we look at, say, tobacco or alcohol, where those products are widely available, and we try to target them to specific groups to avoid young people being exposed to them, we still have quite widespread exposure. If we want to avoid widespread exposure of people who are non-smokers to something, we probably need to avoid it being available as a consumer product. Even under current circumstances, in 2016 around 18 per cent of current daily e-cigarette users were in fact people who had never smoked. If you think of that broad view where we have actually restricted access now, we're already finding substantial use among people who have never smoked.[54]

5.42 The National Retail Association submitted that 'our economy could benefit substantially from government tax revenue, local economic activity and a reduction in the overall health bill'.[55] It was also argued that this revenue could be used to fund further harm reduction measures, such as education campaigns, research and enforcement.[56]

5.43 The National Retail Association further claimed that, as more of Australia's 2.3 million smokers transition to e-cigarette products,[57] 'the domestic market has the potential to grow to over $4 billion over the next decade'.[58]

5.44 ATHRA outlined three main strategies to minimise youth access. These include access control, marketing control and public information.[59] Specific measures proposed by submitters included:

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[52] Professor Chris Bullen, answer to written question on notice QoN002-02, 18 November 2020 (received 20 November 2020).

[53] Dr Rob Grenfell, Director, Health and Biosecurity, Commonwealth Scientific Industrial Research Organisation, *Committee Hansard*, 13 November 2020, p. 27.

[54] Professor Emily Banks, Epidemiology and Population Health, ANU, *Committee Hansard*, 13 November 2020, p. 27.

[55] National Retail Association, *Submission 156*, p. 9.

[56] See, for example, Mr Andrew Thompson, *Submission 133*, [p. 4].

[57] Australian Institute of Health and Welfare, *Data tables: National Drug Strategy Household Survey 2019 – 2 Tobacco smoking supplementary tables*, 16 July 2020, Table 2.3.

[58] National Retail Association, *Submission 156*, p. 9.

[59] Australian Tobacco Harm Reduction Association, *Submission 166*, pp. 20-21.

- restricting sale of e-cigarette products to specialist vape shops, tobacconists, pharmacies, adult stores and other suitable outlets;[60]
- maintaining the current minimum age of sale for vaping products and e-liquids at 18 years, require strict proof of age at purchase points and via internet sales and improve enforcement;[61]
- responsible advertising to adult smokers, avoiding any appeal to youth and non-smokers;[62]
- packaging to restrict appeal to young people;[63] and
- restricting e-liquid brand and flavour names which appeal to youth.[64]

5.45 Professor Wayne Hall and Associate Professor Coral Gartner suggested a similar approach, whereby e-cigarettes and related products would be allowed to be sold as a tightly regulated consumer good:

> We believe that the sale of ENDS [electronic nicotine delivery systems] that meet consumer safety standards to adults should be allowed under tight regulation. Nicotine would be supplied in child-resistant containers, promotions would be banned except at points of sale, such as specialist vape stores, tobacconists and/or pharmacies.[65]

5.46 Similarly, the RACP recommended regulatory controls on the sale, supply, use and promotion of e-cigarette devices to prevent an uptake in e-cigarette usage amongst youth. Specifically, the RACP recommended:

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[60] See, for example, Mr Robert Adams, *Submission 65*, pp. 1-2; Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 159*, p. 12; Australian Tobacco Harm Reduction Association, *Submission 166*, p. 21; Legalise Vaping Australia, *Submission 173*, pp. 5 and 7; Mr Charles McCracken, *Submission 211*, [pp. 1-2].

[61] See, for example, Mr Andrew Thompson, *Submission 133*, [p. 3]; National Retail Association, *Submission 156*, p. 4; Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 159*, p. 12; Australian Tobacco Harm Reduction Association, *Submission 166*, p. 5; Legalise Vaping Australia, *Submission 173*, p. 9; and Australian Institute of Health and Welfare, *Submission 214*, p. 6. The Thoracic Society of Australia and New Zealand viewed this as ineffective, stating that that 'age restrictions are little deterrent in a retail environment'. For further information see The Thoracic Society of Australia and New Zealand, *Submission 162*, p. 5.

[62] See, for example, National Retail Association, *Submission 156*, p. 2 and p. 4; Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 159*, p. 4; and Australian Tobacco Harm Reduction Association, *Submission 166*, p. 7 and p. 21.

[63] See, for example, National Retail Association, *Submission 156*, p. 2; Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 159*, p. 13; Australian Tobacco Harm Reduction Association, *Submission 166*, p. 21; and Emeritus Professor Simon Chapman, Emeritus Professor Mike Daube and Professor Matthew Peters, *Submission 195*, p. 31.

[64] See, for example, the Coalition Asia Pacific Tobacco Harm Reduction Advocates, *Submission 38*, pp. 1 and 6; Dr Michelle Jongenelis, *Submission 66*, p. 5; and UK Vaping Industry Association, *Submission 236*, pp. 3-4.

[65] Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 159*, p. 7.

- The sale and supply of e-cigarettes (with or without nicotine) to minors, including access through personal importation scheme, must be prohibited and stringently enforced in all Australian states and territories.
- E-cigarettes must not be allowed to be promoted in a way that encourages their uptake or smoking initiation. Their sale and supply to minors must be prohibited in all Australian states and territories.
- The use of e-cigarettes should be banned in all areas that are designated to be smoke-free by all Australia's state and territory laws.[66]

Restrictions

5.47 The committee heard evidence from harm reduction proponents and e-cigarette critics that appropriate regulatory measures are required to protect Australian youth and non-smokers, and also to ensure product quality and safety for e-cigarette users. Broadly, these included:

- restrictions on sale and distribution;
- restrictions on promotion and advertising;
- packaging and product information;
- product quality and safety; and
- restrictions on the use of flavours and ingredients.

Restrictions on sale and distribution

5.48 Submitters proposed a number of restrictions on how and where e-cigarettes should be sold, including age restrictions on sales and limits on maximum volumes of e-liquid that can be sold.[67] In particular, the committee heard strong support for a minimum age of 18 years and strict age verification and enforcement.[68]

5.49 However, others acknowledged that this approach has not proven successful with regards to other widely available and regulated consumer products such as tobacco and alcohol.[69]

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66 The Royal Australasian College of Physicians, *Submission 170,* p. 14.

67 See, for example, Mr Andrew Thompson, *Submission 133*, [p. 3]; National Retail Association, *Submission 156*, p. 4; Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 159*, p. 12; Australian Tobacco Harm Reduction Association, *Submission 166*, p. 5; Legalise Vaping Australia, *Submission 173*, p. 9; Australian Institute of Health and Welfare, *Submission 214*, p. 6; Dr Judy Moller, Dr Celine Kelso and Professor Alison Jones, *Submission 220*, pp. 1 and 3-4; and Vaping Trade Association of New Zealand, *Submission 263*, p. 30.

68 See, for example, Mr Andrew Thompson, *Submission 133*, [p. 3]; National Retail Association, *Submission 156*, p. 4; Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 159*, p. 12; Australian Tobacco Harm Reduction Association, *Submission 166*, pp. 4-5; Legalise Vaping Austalia, *Submission 173*, p. 9; and Australian Institute of Health and Welfare, *Submission 214*, p. 6.

69 Professor Emily Banks, Professor of Epidemiology and Population Health, ANU, *Committee Hansard*, 13 November 2020, p. 27.

5.50 It was also argued that limits should be set on maximum concentrations of nicotine in e-liquid.[70] The committee heard that 'importation of high concentration nicotine is an increased risk to the individual due to the potential for accidental exposure to high doses of nicotine'.[71]

5.51 Dr Jody Moller, Dr Celine Kelso and Professor Alison Jones proposed restricting the maximum concentration of nicotine to 36 mg/mL (3.6 per cent) and limiting the maximum container volume to 50ml.[72]

5.52 As discussed earlier, the European Union regulates e-cigarettes that do not make therapeutic claims as consumer products, subject to a nicotine concentration limit of 20mg/ml and a bottle capacity of 10ml.[73] However, one submitter posited that 'by limiting the level of nicotine concentration available in e-cigarettes, the product became less efficacious for smokers as a smoking cessation aid, and more accessible to never-smokers'.[74]

5.53 Professor Hall and Associate Professor Gartner cautioned that nicotine e-cigarette products should not be sold by generalist retailers:

> Nicotine solutions should be supplied in child-resistant containers and no promotion allowed except at licensed points of sale. These should be restricted to specialist vape stores, tobacconists, adult stores and/or pharmacies to minimise youth access. All nicotine products should be stored behind the counter.[75]

5.54 Professor Bullen and Associate Professor Natalie Walker highlighted the model used by New Zealand as 'an example of sensible regulation around vaping'.[76] In particular, general stores and other businesses which do not specialise in e-cigarettes can sell e-cigarette products, but are restricted to tobacco, mint, menthol flavours only, while specialist vape shops are exempt from a number of these restrictions.

5.55 Professor Robert Beaglehole also commended the New Zealand model. He stated:

> The New Zealand Government treats vaping as a consumer issue with the potential to reduce the harm from smoked cigarettes by encouraging

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70 See, for example, Dr Jody Moller, Dr Celine Kelso and Professor Alison Jones, *Submission 220*; and Miss Dianna Nguyen, *Submission 232*, p. 4.

71 Dr Jody Moller, Dr Celine Kelso and Professor Alison Jones, *Submission 220*, p. 3.

72 Dr Jody Moller, Dr Celine Kelso and Professor Alison Jones, *Submission 220*, p. 1.

73 See Medicines and Healthcare products Regulatory Agency, *E-cigarettes: regulation for consumer products*, 25 November 2020, www.gov.uk/guidance/e-cigarettes-regulations-for-consumer-products (accessed 30 November 2020).

74 Nicovape Pty Ltd, *Submission 283*, p. 8.

75 Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 159*, p. 12.

76 Professor Chris Bullen and Associate Professor Natalie Walker, *Submission 163*, [p. 2].

> switching to less harmful products. From a public health perspective this is a sensible approach, given the enormity of the burden of death and disease caused in New Zealand by smoked cigarettes. The legislation attempts to balance the aims of encouraging adult cigarette smokers to switch while protecting young people from vaping.[77]

5.56 The National Retail Association put forward a draft Responsible Retailers Code of Conduct for Smoke-Free Products to guide retailers in relation to age verification, product information and promotion. The code proposed that retailers:

- Never sell vape products to anyone under the age of 18 or anyone purchasing on their behalf. Proof of age is to be requested if a customer is perceived to be under 25 years old.
- Ensure any nicotine components are clearly labelled or available for the product.
- Avoid claiming any health benefits from the use of vape products.[78]

Restrictions on promotion and advertising

5.57 A number of submitters argued in favour of restricting advertising of e-cigarette products to adult smokers.[79] In addition, it was argued that vendors should be prohibited from making claims about the safety and efficacy of e-cigarettes as a smoking cessation method.[80]

5.58 The Department of Health highlighted its concern that the widespread advertising and promotion of products via digital media and other communication platforms was being used to increase the appeal of e-cigarettes to youth.[81]

5.59 Dr Jongenelis expressed concern that widespread advertising and availability of e-cigarettes in the United States 'led to substantial increases in youth use'.[82] She advised the committee that 'Australia can very much avoid having to

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[77] Professor Robert Beaglehole, answer to written question on notice QoN001-02, 18 November 2020 (received 22 November 2020).

[78] National Retail Association, *Submission 156*, p. 5.

[79] See, for example, The Royal Australasian College of Physicians, *Submission 170*, p. 3; National Retail Association, *Submission 156*, pp. 2 and 4; Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 159*, p. 4; and Australian Tobacco Harm Reduction Association, *Submission 166*,
pp. 7 and 21.

[80] Mr Andrew Thompson, *Submission 133*, [p. 4].

[81] Department of Health, *Submission 167*, p. 19.

[82] Dr Michelle Jongenelis, Private capacity, *Committee Hansard*, 19 November 2020, p. 51.

throw that money at intervention later on by just taking the right steps now to prevent that from even happening in the first place'.[83]

5.60 Associate Professor Gartner also expressed her opposition to 'any kind of replication of the US situation which allowed aggressive marketing or advertising of these products, because it could increase vaping amongst young people'.[84]

5.61 While ATHRA was supportive of restrictions on marketing specifically targeted at young people, it submitted that 'blanket bans on advertising prevent responsible, targeting [of] advertising to adult smokers to educate them about these products'.[85]

5.62 Mr Ben Youdan also advised that, in his opinion, there was a need to strike a balance between 'clear, directed messages to adult smokers about switching, without it necessarily being over-medicalised, and ensuring that they have good information about the products'.[86]

5.63 Similarly, Dr Mendelsohn commented that the 'promotion should be about switching from smoking to vaping'. He likened advertising for e-cigarettes to that used for alcohol:

> We need to learn from that in developing a policy for the advertising of vaping. But if we think vaping is a life-saving alternative for people who can't quit, we need to make sure that adult smokers are aware of it and that we provide the information and target any messaging to them.[87]

[83] Dr Michelle Jongenelis, Private capacity, *Committee Hansard*, 19 November 2020, p. 51.

[84] Dr Coral Gartner, Private capacity, *Committee Hansard*, 13 November 2020, p. 32.

[85] Australian Tobacco Harm Reduction Association, *Submission 166*, pp. 8 and 20.

[86] Mr Ben Youdan, Private capacity, *Committee Hansard*, 13 November 2020, p. 45.

[87] Dr Colin Mendelsohn, Board Member, Australian Tobacco Harm Reduction Association, *Committee Hansard*, 13 November 2020, p. 78.

Packaging and product information

5.64 The committee heard evidence that 'regulations such as child-proof packaging and appropriate labelling of e-liquids should be put in place'.[88] A number of jurisdictions, including Canada, the European Union, the United Kingdom and the United States, have introduced measures to include child resistant requirements for e-liquids, such as the requirement for:

- labelling to include risk-proportionate health messages regarding toxicity and addictiveness;
- a full list of e-liquid ingredients;
- advice to keep out of the reach of children; and
- advice on overdose management.

5.65 Dr Moller, Dr Kelso and Professor Jones advised that 'packaging should avoid cartoon-style imagery and be required to contain warnings about nicotine and the unknown health risks of flavouring molecules'.[89]

Product quality and safety

5.66 As discussed earlier, e-liquids contain a wide range of substances of varying concentration and, at present, there is very little to guarantee the accuracy of any ingredients listed on their labels. The committee heard evidence that a number of measures should be put in place to ensure product safety and quality.[90] These included establishing quality and safety standards in relation to the devices, electrical safety and e-liquids. One submitter called for the committee to '[r]egulate THR [tobacco harm reduction] product quality and safety standards in-line with consumer product guidelines'.[91]

5.67 Mr Konstantinos Farsalino proposed a number of principles that should be followed to create a regulatory framework for e-cigarettes. In particular, he submitted that regulation should be realistic and ensure product quality. However, he warned against setting unreasonably high quality standards as

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[88] Ms Diane Gorman, *Submission 100*, p. 2. See also Professor Coral Gartner and Professor Wayne Hall, *Submission 159*, p. 4; Australian Tobacco Harm Reduction Association, *Submission 166*, p. 21; Australian Competition & Consumer Commission, *Submission 182*, p. 2; Dr Jody Moller, Dr Celine Kelso and Professor Alison Jones, *Submission 220*, pp. 1 and 3-4; and Australian Capital Territory Government, *Submission 288*, p. 1.

[89] Dr Jody Moller, Dr Celine Kelso and Professor Alison Jones, *Submission 220*, p. 2.

[90] See, for example, factasia, *Submission 45*, [p. 2]; Mr Keith Riseley, *Submission 92*, p. 2; National Retail Association, *Submission 156*, p. 4; Professor Coral Gartner and Professor Wayne Hall, *Submission 159*, p. 12; Australian Tobacco Harm Reduction Association, *Submission 166*, p. 5; Legalise Vaping Australia, *Submission 173*, p. 9; Australian Institute of Health and Welfare, *Submission 214*, p. 6; Dr Jody Moller, Dr Celine Kelso and Professor Alison Jones, *Submission 220*, pp. 1 and 3–4; Vaping Trade Association of New Zealand, *Submission 263*, p. 30.

[91] Name withheld, *Submission 286*, p. 2.

this 'creates a competitive advantage for tobacco cigarettes, while the regulation should aim for the opposite'.[92]

5.68 The RACP recommended that e-cigarette product packaging and labelling requirements should be implemented, including disclosure of all ingredients and their concentrations in e-liquid, child-resistant packaging, plain packaging rules and health warning labels.[93]

5.69 In addition, Dr Khorshid discussed the need for the regulation of product quality and safety standards in order to strengthen the prescription-based model:

> Any process that was designed to make nicotine based e-cigarette products available on prescription would ideally include some further regulation to ensure that the products are reliable, that their sources are reliable, that you can believe the quantities of nicotine and whatever other products are within their products so that both the consumer and the doctor know what's actually being ingested.[94]

Restrictions on the use of flavours and other ingredients

5.70 The National Health and Medical Research Council has advised that e-cigarette flavourings may expose users to chemicals and toxins such as formaldehyde, heavy metals, particulate matter and flavouring chemicals 'at levels that have the potential to cause adverse health effects'.[95]

5.71 This general view was supported by a number of witnesses, including Professor Chapman and Dr Jongenelis.[96] Harm reduction advocates, such as Dr Mendelsohn and Mr Bates, accepted in principle that some flavours carry with them potential risks, have not been approved for inhalation and would require ongoing monitoring for harmful effects.[97]

5.72 Despite the popularity of such flavours, the RACP was concerned that the health impacts of inhaling heated flavoured chemicals is unknown and has not

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92 Mr Konstantinos Farsalino, *Submission 250*, [p. 2].

93 The Royal Australasian College of Physicians, *Submission 170*, p. 4.

94 Dr Omar Khorshid, President, Australian Medical Association, *Committee Hansard*, 19 November 2020, p. 49.

95 National Health & Medical Research Council, *CEO Statement: Electronic cigarettes*, www.nhmrc.gov.au/about-us/resources/ceo-statement-electronic-cigarettes (accessed 17 December 2020).

96 Emeritus Professor Simon Chapman, School of Health, University of Sydney, *Committee Hansard*, 19 November 2020, p. 7; Dr Michelle Jogenelis, Private capacity, *Committee Hansard*, 19 November 2020, p. 50.

97 Dr Colin Mendelsohn, Board Member, Australian Tobacco Harm Reduction Association, *Committee Hansard*, 13 November 2020, p. 72; and Mr Clive Bates, Private capacity, *Committee Hansard*, 19 November 2020, p. 62.

been well studied and may pose a risk to health.[98] The ACCC noted that '[c]hildren are vulnerable and may be attracted to e-liquids marketed, scented, and flavoured as novelty scents and flavours', which could lead to accidental nicotine poisoning.[99]

5.73 Other submitters were also concerned that novelty flavours and targeted marketing could lead to an uptake in e-cigarette usage among young people.[100] Dr Moller, Dr Kelso and Professor Jones noted that many e-juices had flavours and associated name titles that seemed deliberately marketed to youth:

> There are a wide variety of e-liquid brands and flavours available to individuals. A recent study analysing flavours available on the Dutch market examined 20,000 differently named e-liquids and identified 213 different flavouring molecules… Amongst the many thousands of flavouring names available some, for example, Oba Oba, Unicorn Vomit, Beast, and Drgn Spit etc do not clearly identify or even suggest a flavour. It is likely that these e-liquids are deliberately designed to entice young individuals and all names which do not clearly indicate a flavour-type should be banned in Australia.[101]

5.74 It is noted that the UK Vaping Industry Association has guidelines around its members' sale of flavours, which limit such marketing towards youth:

> The UKVIA [UK Vaping Industry Association] has issued guidance to members which aims to strike the right balance between innovative and appealing products which support adult smokers in the transition to a less harmful alternative, whilst not appealing to anyone who does not already smoke or vape or anyone who is under 18. These guidelines state that members must not use flavour names or descriptors that are particularly appealing to youths, or are associated with youth culture, including popular language or expressions, or names which are reminiscent of confectionary disproportionally appealing to children.[102]

5.75 In concluding their analysis of the role of flavoured e-liquids on youth uptake of e-cigarettes, Professor Hall and Associate Professor Gartner argued that this issue should be monitored by government and health bodies into the future:

> We should monitor sales and ENDS [electronic nicotine delivery systems] use among young people. If certain types of flavours are associated with increased use among non-smoking youth, then we should restrict the use

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98 The Royal Australasian College of Physicians, *Submission 170*, p. 17.

99 Australian Competition & Consumer Commission, *Submission 182*, p. 2.

100 See, for example Professor Coral Gartner and Professor Wayne Hall, *Submission 159*, p. 11, Department of Health, *Submission 167*, pp. 18-19; New South Wales Government, *Submission 171*, p. 2; Cancer Council, National Heart Foundation of Australia and Australian Council on Smoking and Health, *Submission 194*, p. 5; and Dr Jody Moller, Dr Celine Kelso and Professor Alison Jones, *Submission 220*, p. 2.

101 Dr Jody Moller, Dr Celine Kelso and Professor Alison Jones, *Submission 220*, p. 2.

102 UK Vaping Industry Association, *Submission 236*, p. 3.

of these flavoured products to minimise their attractiveness to non-smoking young people.[103]

[103] Professor Coral Gartner and Professor Wayne Hall, *Submission 159*, p. 12.

Chapter 6
Committee view

6.1 Australia's success in driving down smoking rates hinges not only on helping smokers to quit but also in avoiding people starting to smoke, particularly younger generations. As Professor Emily Banks stated, Australia's progress 'is increasingly driven by our younger generations not taking up smoking'[1] and, given the strong evidence of a gateway effect, it is important that Australia avoid widespread availability of e-cigarettes if it is to maintain its progress against smoking uptake.

6.2 The committee heard repeatedly that the best way to reduce smoking in Australia is a combination of helping people to quit and preventing people from taking up smoking in the first place.

6.3 The committee also heard Australia has been a world leader in driving down smoking rates through strong and innovative approaches such as plain packaging.

6.4 While daily adult smoking levels have fallen across Australia, the rates of decline have slowed over the period from 2013 to 2019[2] and there remain increased smoking rates across remote communities and people living in the lowest socioeconomic areas.[3] In these circumstances, the Australian Government must renew its efforts to reduce smoking prevalence. The committee recognises the evidence that Australia has not had a national campaign to reduce rates of smoking in almost a decade and existing campaigns receive very little funding from revenue raised in relation to taxes on tobacco.[4]

6.5 The Australian Government is currently consulting on a prescription model for e-cigarettes in Australia. On 23 September 2020, the Therapeutic Goods Administration announced an interim decision that would clarify the

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1 Professor Emily Banks, Professor of Epidemiology and Population Health, ANU, *Committee Hansard*, 13 November 2020, p. 17.

2 Australian Institute of Health and Welfare, *National Drug Strategy Household Survey 2019*, 16 July 2020, p. 6.

3 For example, the *National Drug Strategy Household Survey 2019* reported that people in remote and very remote areas were twice as likely as those in major cities to smoke daily (19.2 per cent compared with 9.8 per cent) and people living in the lowest socioeconomic areas were about 3.7 times as likely as those in the highest socioeconomic areas to smoke daily (19.0 per cent compared with 5.1 per cent).

4 Emeritus Professor Mike Daube, Faculty of Health Sciences, Curtin University, *Committee Hansard*, 19 November 2020, p. 2.

scheduling of nicotine in the Standard for the Uniform Scheduling of Medicines and Poisons (the Poisons Standard). The proposed changes, if finalised, would mean that e-cigarette products containing nicotine could only be supplied with a doctor's prescription.

6.6 The Australian Government has previously flagged its intention to make regulations prohibiting the importation of nicotine e-cigarettes products, except where permission is granted by the Department of Health to a doctor or medical supplier to import the goods using courier or cargo services. The committee notes that the Australian Government has deferred a decision on these regulations to 2021.

6.7 The committee understands that, if implemented, the effect of the import regulations and rescheduling of nicotine in the Poisons Standard will require individuals to source nicotine e-cigarette products via a medical practitioner. The proposed changes would also impose harsh penalties of up to $222 000 for those who import nicotine for use in e-cigarettes directly from an overseas supplier without a valid import permit.

6.8 The committee is concerned that there appears to be significant mounting evidence that e-cigarettes have some 'gateway' effect, that is, introducing smoking to non-smokers. Research also suggests that any cessation effect using e-cigarettes is more short-lived than for other nicotine replacement therapy techniques and that former smokers using e-cigarettes have over twice the odds of relapse as non-e-cigarettes users.[5]

6.9 Rates of smoking and e-cigarette use amongst young people are particularly concerning have been given significant consideration during senators' deliberations.

6.10 Approximately 40 per cent of current daily e-cigarette users are dual users who also smoke tobacco, and one-fifth are people who have never smoked tobacco.

6.11 While users and promoters of e-cigarettes often argued that they should be treated as a consumer product, the committee's view is that commercialisation of e-cigarettes or other novel nicotine products poses a significant revenue opportunity for the tobacco companies who have a business model that cannot be reconciled with the public interests.

6.12 A frequent argument advanced by vaping proponents is one of convenience and ease of access (as opposed to requiring a prescription). In the committee's view, that consideration does not balance sufficiently against the potential broad public harms of 'opening the gates' by treating e-cigarettes containing liquid nicotine as a consumer product. Given the high take-up of vaping among youth and concerns over the gateway effect, coupled with the lack of

[5] Professor Emily Banks, *Submission 157*, p. 6.

conclusive evidence regarding cessation effectiveness and safety, it would be unwise for Australia to make e-nicotine freely available for domestic sale. The committee heard evidence that suggests e-cigarettes may be able to play a harm-reduction role under tight policy settings. However, even if sale was prohibited to under-18s, experience with cigarettes and alcohol show prohibition of sale is not an effective barrier to access for the under-aged.

6.13 The committee agrees there should be stringent regulation of flavourings used in e-cigarettes, as many of the chemicals used in them were never intended for inhalation. The Lung Foundation Australia submitted that it may be the case that even the flavoured, non-nicotine vaping liquids currently permitted for domestic sale may be harmful and even addictive. The committee is also deeply concerned that flavoured products may act as a real inducement to young people to take up e-cigarettes.

6.14 As much as individual smokers may feel vaping has helped them to quit, there is not yet sufficient evidence to support e-cigarettes containing nicotine as a cessation tool, nor have the health effects of e-cigarettes containing liquid nicotine been conclusively established. It is this lack of conclusive clinical evidence that lays the foundation for the TGA's position: until and unless the evidence shifts demonstrating safety and effectiveness of e-cigarettes—including the long-term evidence regarding safety—there is no reason to weaken Australia's sensible approach to the regulation of liquid nicotine.

6.15 The committee recognises the evidence that the most effective method of quitting smoking is through the assistance of a trained health professional. It stands to reason that providing access to nicotine for e-cigarettes within a health or medical framework can only improve the chances that they quit.

6.16 The committee appreciates and respects the submissions made by many individuals who have stated that vaping has been helpful in their efforts to quit smoking. While this may be persuasive, the public health impacts of e-cigarettes containing nicotine have yet to be conclusively established. The committee heard considerable evidence as to the health risks of vaping nicotine which gives rise to significant cause for concern. While the tobacco industry and the vaping sector are advocating that Australia should move to what would be, effectively, an unregulated or deregulated market for liquid nicotine and e-cigarettes, the science does not support this approach.

6.17 Consistent with the TGA's position, the absence of conclusive clinical evidence as to both the health effects of e-cigarettes and the efficacy of e-cigarettes as a smoking cessation tool supports the conclusion that there is no case to weaken Australia's precautionary approach to the regulation of liquid nicotine. It is the committee's view that unless the evidence shifts such that the safety and effectiveness of e-cigarettes can be conclusively demonstrated including over

the longer term, Australia's sensible approach to the regulation of liquid nicotine should not be compromised.

6.18 The committee is cognisant that it is highly addictive nicotine which sustains the tobacco industry's business model. It is therefore not surprising that the tobacco industry would be seeking to move into, and dominate the global liquid nicotine market by ensuring that e-cigarettes with nicotine become widely accessible and available to consumers in Australia and around the world, irrespective of the consequences. There are many billions of dollars of profits to be made from addiction to nicotine and, in disingenuously advocating for a so-called 'smoke free' future, the tobacco industry's brazen attempts to foster a new nicotine market are there for all to see. The committee further noted Philip Morris' attempts to influence this committee by way of the publication of a thinly veiled advertisement in support of a deregulated e-cigarette market under the guise of 'science' in *The Australian* newspaper.[6]

Renewed efforts to reduce smoking prevalence

6.19 The committee recognises that there is no international consensus on the most efficient regulatory framework for nicotine e-cigarettes nicotine or other novel nicotine products. Notably, Australia is the only country to propose a prescription-based model for the supply of e-cigarette products containing nicotine.[7] This is in contrast to the steps taken by New Zealand, United Kingdom and the United States where the harm reduction benefits of e-cigarette use have been acknowledged and e-cigarettes are legislated as consumer goods.[8] That the rest of the world has not adopted a prescription pathway is not an argument against doing it—Australia is a world leader in tobacco harm reduction and control—and on this we would be a world leader too.

6.20 Moreover, a prescription approach provides Australia with the necessary policy freedom to respond to developments in clinical evidence. If sufficient clinical evidence emerges that there are no long-term harms from e-cigarette use, these settings could be eased. If instead sufficient clinical evidence emerges that there are long-term harms, these settings can continue or be tightened.

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6 The Australian (content produced in partnership with Philip Morris International), 'Follow science to the moon', *The Weekend Australian*, www.theaustralian.com.au/sponsored/rp9Rxv493P9nQTUOkEni/follow-science-to-the-moon/ (accessed 16 December 2020).

7 Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, *Committee Hansard*, 13 November 2020, p. 10.

8 E-cigarette products that make therapeutic claims are regulated separately in both jurisdictions.

6.21 The committee supports the Australian Government's current goal of 10 per cent smoking prevalence by 2025. To achieve this target, daily smoking prevalence must fall to minimal levels; tobacco access and supply must be significantly reduced and accordingly Australia must renew its efforts in evidence-based strategies to reduce smoking prevalence.

6.22 Australia has been a global leader in tobacco control for decades and had achieved significant, long term reductions in smoking prevalence. However, these achievements are at risk if smoking rates do not continue to fall. The costs of smoking—estimated to be $137 billion—require a more ambitious target, such as those adopted by comparable countries such as New Zealand and United Kingdom and renewed investment in evidence-based strategies that are proven to reduce tobacco use and take-up, including a new national smoking campaign. In Australia, the current regulatory framework draws on existing laws that may apply to tobacco products, poisons, therapeutic goods, consumer goods and industrial chemicals. However, there are variations between states and territories in regulatory approaches to e-cigarettes. The committee believes that this inconsistency should be addressed through the development of a nationally consistent approach to the regulation of e-cigarettes, and it acknowledges this is a key motivation behind the TGA's proposed prescription model.

6.23 As previously stated, the committee acknowledges the best way to reduce smoking prevalence in Australia is a combination of helping people to quit and preventing people from taking it up in the first place. Australia's approach to e-cigarettes should not neglect one objective in pursuit of the other. The committee has carefully considered the evidence provided and proposes seven recommendations which aim to renew our efforts to reduce smoking prevalence, support evidence-based approaches to tobacco control and provide new avenues for smokers to quit.

Recommendation 1

6.24 The committee recommends that the Australian Government outline concrete measures to meet the target of reducing smoking rates to below 10 per cent by 2025 and beyond.

Recommendation 2

6.25 The committee recommends that the Australia Government continue to invest in evidence-based strategies that are proven to reduce tobacco use and take-up, and in particular, consider renewed investment in a new national anti-smoking campaign.

Recommendation 3

6.26 The committee recommends that the Therapeutic Goods Administration continue to oversee the classification of nicotine, and the assessment of any e-cigarette product as a therapeutic good, and that the Australian Government and Parliament accept the Therapeutic Goods Administration's advice.

Recommendation 4

6.27 The committee recommends that the Australian Government support the implementation of any prescription pathway as recommend by the Therapeutic Goods Administration by measures such as the provision of appropriate information and evidence to medical professionals and the public, ensure a smooth process by which a medical professional can become a prescribing authority and address any issues which may arise regarding access to and for pharmacies and medical professionals.

Recommendation 5

6.28 The committee recommends that the Australian Government implement national evidence-based regulations regarding nicotine and e-liquids and e-cigarette devices with respect to: minimum standards for manufacture and safety, child-resistant containers, appropriate health warnings, prohibited access for youth, appropriate restrictions on advertising, mandatory standards for labelling, clear guidelines about public vaping, a notification scheme for pre-market registration, a system for reporting harmful effects and recall of unsafe products and other related issues.

Recommendation 6

6.29 The committee recommends that the Australian Government implement an evidence-based regulatory process, involving the appropriate statutory body, to assess, regulate, and if necessary, restrict the use of colourings and flavouring in e-cigarettes.

Recommendation 7

6.30 The committee recommends that the Australian Government continue to support independent research into e-cigarette use and related products, particularly in relation to the:

- **health impacts of long term e-cigarette use;**
- **impact of Australia's tobacco control measures on smoking rates and patterns and use of e-cigarettes by adults and young people;**
- **effectiveness of e-cigarettes as an aid to help people quit smoking combustible cigarettes;**
- **short and long term health effects of ingredients commonly used in e- liquids, including but not limited to: vaporiser nicotine, propylene glycol and vegetal glycerine; and**
- **safety of e-liquid flavours for inhalation.**

Senator Tony Sheldon
Deputy Chair

Senator Anne Urquhart
Member

Senator the Hon Sarah Henderson
Member

Senator Stirling Griff
Member

Senator the Hon Sarah Henderson's additional comments

Summary

1.1 As noted in the majority report, a prescription based model provides the best pathway to strike an appropriate balance between providing treatment options for long term smokers under medical supervision while protecting against the legitimate risk of uptake of e-cigarette use from non-smokers, particularly young Australians (teenagers and young adults).

1.2 It is also appropriate that decisions around regulation and access to medicines and poisons are made by an independent health regulator, on public health grounds, such as the Therapeutic Goods Administration (TGA).

1.3 The current limited evidence regarding efficacy of e-cigarettes, the unknown long term risk of e-cigarettes and legitimate concerns around the uptake of e-cigarettes amongst non-smokers warrant a precautionary approach to this issue.

1.4 Such an approach is entirely consistent with other nicotine replacement therapies which make health claims. Nicotine gums and patches were initially registered as prescription medicines owing to the fact they were new and the long term risks were not fully known. Over time, as the risk profile of these products was better understood (risk of side effects and unintended public health consequences was deemed low), the restrictions on such products were gradually relaxed to the point where they are now available in supermarkets and general retail stores.

1.5 Adopting, initially, a conservative approach to the availability of new products making therapeutic claims (where restricted or supervised availability can be gradually relaxed over time) appears to be a far more sensible approach. Allowing a product such as e-cigarettes to be sold, essentially, without restriction from the start increases the risk of regulators having to intervene 'to put the genie back in the bottle' when serious health issues appear in the general population, as has been observed in other countries such as the United States and Canada.

1.6 While the committee heard from several independent health witnesses advocating for widespread availability of e-cigarettes from the perspective of public health, many appeared to place an almost exclusive emphasis on what is in the interests of current smokers.

1.7 While assisting current smokers to quit is critically important, a number of witnesses explained to the committee that, from a public health perspective, it

was equally or even more important to prevent non-smokers from ever taking up smoking.

1.8 As Professor Emily Banks noted:

> Continuing progress on smoking means a concerted effort on two things: avoiding having people start to smoke—basically young people—and helping smokers to quit. Our progress is increasingly driven by our younger generations not taking up smoking.[1]

1.9 This sentiment was also shared by Professor John Wilson:

> Australia's smoking rate continues to decline, and this is primarily due to the very low rate of young people taking up smoking. In 2019, 97 per cent of young people aged 14 to 17 were never smokers, and it's testimony to the great efforts of health policymakers. It is therefore essential that concerted efforts remain focused on maintaining very low smoking uptake rates by young people in Australia and any gateway effect of e-cigarettes is neutralised and reversed.[2]

1.10 It was also outlined to the committee that Australia is a world leader in tobacco cessation policies and its smoking rates are some of the lowest in the world. This was achieved without the widespread availability and promotion of e-cigarettes in Australia. Professor Mathew Peters told the committee:

> In recent times, a small group of vaping advocates has sought to denigrate Australia's achievements in tobacco control. International comparisons are important. Based on unifying OECD data, the rates of reduction in adult smoking between 2010 and 2016—or 2012 and 2018 for New Zealand—in the United States, the United Kingdom, Canada and Australia, as well as New Zealand, were similar: all of us lost about 20 per cent of our smokers. We had a different range of policy options and our approach to electronic cigarettes was highly discordant. So we encourage and reassure the Senate select committee that Australia can remain a world leader in tobacco control whilst charting its own course, implementing and enhancing evidence based measures that we know will reduce smoking rates.[3]

Assisting smokers in their attempts to quit

1.11 Despite Australia's success in reducing smoking rates, tobacco use still contributes to an estimated 21,000 deaths or more than one in eight fatalities every year.[4]

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1 Professor Emily Banks, Professor of Epidemiology and Population Health, ANU, *Proof Committee Hansard*, 13 November 2020, p. 17.

2 Professor John Wilson, President, Royal Australasian College of Physicians, *Proof Committee Hansard*, 19 November 2020, p. 38.

3 Professor Matthew Peters, former President and Co-Chair of Electronic Cigarettes Working Party, Thoracic Society of Australia and New Zealand, *Proof Committee Hansard*, 19 November 2020, p. 29.

4 Australian Institute of Health and Welfare, 'Tobacco use linked to more than 1 in 8 deaths, but burden easing', *Media Release*, 24 October 2019.

1.12 As noted in the majority report, Commonwealth, State and Territory Governments need to outline specific measures on how Australia will meet a 10 per cent smoking target by 2025.

1.13 Further to this, there is an opportunity for Government to explore how to improve access to a medical practitioner for smoking cessation.

1.14 The widespread uptake of telehealth consultations during the COVID-19 pandemic has shown that both medical practitioners and consumers are keen to embrace new forms of technology to manage health. The Government has already signalled that telehealth will be permanently embedded into Australia's health system. To this extent, smoking cessation needs to be considered as a high priority for access via telehealth.

1.15 Individuals, particularly those living in regional and remote areas, often have difficulty accessing particular health services and finding medical practitioners who have a particular expertise in certain areas of health management.

1.16 Several witnesses, including the Department of Health and the Australian Medical Association, provided evidence that having the support of others such as a GP increases the chances of successfully quitting.[5]

> We know that brief advice—and we've known this for donkey's years—from a GP about quitting smoking is a really important factor, so if the TGA process encourages vapers or anybody else to go to their GP for advice on smoking cessation then that's going to be immensely beneficial.[6]

1.17 Giving the above and the fact that smoking rates are higher in regional areas,[7] it is imperative that telehealth services are available to facilitate improved access to medical practitioners.

1.18 The Government should also review and assess the affordability of nicotine replacement therapies, particularly those which are currently listed on the Pharmaceutical Benefits Scheme. Affordability of suitable treatment is of paramount importance in assisting smokers to quit.

1.19 Finally, while a prescription based model, initially at least, is a sensible first step particularly to best manage the risks of uptake of e-cigarettes amongst non-smokers, consideration should be given in due course to allowing smokers (where use of an e-cigarette has initially been deemed suitable to be used by a medical practitioner) to access liquid nicotine without a prescription via their local pharmacy.

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[5] Adjunct Professor John Skerritt, Deputy Secretary, Department of Health *Committee Hansard*, 13 November 2020, p. 11.

[6] Emeritus Professor Mike Daube, Private capacity, *Committee Hansard*, 19 November 2020, p. 10.

[7] Australian Institute of Health and Welfare, 'Smoking and drinking rates higher in regional and remote Australia', *Media Release*, 16 July 2020.

1.20 Pharmacists are trained in the supply of Pharmacist Only medicines which can be accessed over-the-counter by a consumer if deemed appropriate by a pharmacist.

1.21 Ensuring that liquid nicotine is available without a script and supplied in pharmacies is entirely consistent with a medical model. It would enable greater, easier and more affordable access for consumers attempting to quit smoking in a health supervised environment while still safeguarding against the risk of rapid uptake of e-cigarettes by non-smokers including young Australians.

Recommendation 1

1.22 The Commonwealth Government should ensure that telehealth under Medicare is universally accessible for smoking cessation to assist smokers to quit.

Recommendation 2

1.23 The Commonwealth Government should immediately review the affordability of nicotine replacement products and move to list more of these products on the Pharmaceutical Benefits Scheme in line with medical evidence.

Recommendation 3

1.24 Upon application and subject to the usual public health assessment processes, the TGA should consider reviewing the classification of liquid nicotine to enable it to be sold in pharmacies without a prescription.

Role of the Tobacco Industry

1.25 The tobacco industry has an infamous history of trying to stymie genuine evidence-based initiatives for smoking cessation. Whether it be, over many decades, denying the link between smoking and adverse health outcomes, falsely promoting alternate tobacco products as 'safer' alternatives or aggressively opposing (through lobbying and litigation) public health regulations, the industry has shown time and time again its wholly disingenuous regard for the public health impacts of its products.

1.26 As noted in the majority report, several large tobacco companies are on the public record as advocating for e-cigarettes to be regulated as a consumer product. Philip Morris International (PMI) has recently published advertorials in Australian media advocating for the widespread availability of e-cigarettes.

PMI has also launched a campaign around a 'smoke free future', with the condition that e-cigarette products are made widely available.[8]

1.27 For the industry to claim with this latest lobbying effort around e-cigarettes that it now has the public interest and the health of all Australians at front of centre of its priorities is frankly laughable if it were not so serious.

1.28 With respect to the arguments that e-cigarettes should have the same level of accessibility as regular tobacco products purely on principle or on the basis of ensuring individual rights, it is worth remembering the health impact caused by the failure of governments around the world to properly assess, and then appropriately act upon, the catastrophic health impacts of traditional cigarettes.

1.29 As explained by Professor Simon Chapman:

> Yes, cigarettes are consumer goods, and look at the absolute disaster that status has caused the world. We have made every conceivable mistake in failing to properly regulate tobacco. Those who argue that we should treat e-cigarettes in exactly the same way appear to know nothing of the history of the release of the smoking genie from the bottle at the beginning of last century and the 70-year struggle to get it back in. So let's not make the same catastrophic errors again.[9]

1.30 As noted by several witnesses, the decline in smoking rates in Australia did not occur by chance. Such declines were due to a range of policy and regulatory measures which, in combination, have led to this decline.

1.31 Allowing the general sale of e-cigarettes risks a repetition of the mistakes of the past and further risks renormalising smoking behaviour, undoing decades of public health gains.

1.32 The tobacco industry is still a major player in global lobbying efforts around tobacco policies, hence its policy positions and actions to implement these measures cannot be ignored: to downplay or deny the involvement of the tobacco industry in the discussion around e-cigarettes is simply denying reality.

1.33 The tobacco industry is also becoming more sophisticated in its lobbying efforts, often using fronts such as 'grass root' consumer organisations, specialist lobbying firms and providing support to 'independent' think tanks.[10] It is often difficult to uncover these specific links and relationships.

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[8] PMI, *Delivering a smoke-free future*, 31 July 2019, https://www.pmi.com/our-transformation/delivering-a-smoke-free-future (accessed 18 December 2020).

[9] Professor John Allan, President, Royal Australian and New Zealand College of Psychiatrists, *Committee Hansard*, 19 November 2020, p. 1.

[10] National Center for Chronic Disease Prevention and Health Promotion (US), Office on Smoking and Health, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*, 2012; and B. Freeman, A. Vittiglia and Margaret Winstanley, 'Section 10A.3 Mechanisms of

1.34 In a number of countries such as Canada, New Zealand, the European Union and the United States, tobacco companies are required by law to disclose details of expenditure including on tobacco advertising, promotion and sales volume. In the case of the United States, such legal requirements have been in place since the 1960s.[11]

1.35 Currently no such legislation exists in Australia. The Commonwealth should urgently consider implementing similar measures in an Australian context (noting that tobacco advertising is prohibited in Australia).

1.36 Such measures would be an important strategy in forcing transparency which would assist in revealing, and ultimately curtailing, tobacco industry influence in the development of public policy.

Recommendation 4

1.37 The Commonwealth Government should introduce legislation consistent with other countries which requires tobacco companies to mandatorily disclose details of expenditure including on tobacco and nicotine marketing, lobbying activities and sales volume.

Senator the Hon Sarah Henderson

influence—Industry-funded research' in Michelle Scollo and Margaret Winstanley (eds), *Tobacco in Australia: Facts and issues*, Cancer Council Victoria, 2019.

11 Federal Trade Commission, 'FTC Releases Reports on Cigarette and Smokeless Tobacco Sales and Marketing Expenditures for 2018', *Media Release*, 30 December 2019.

Senator Griff's additional comments

1.1 I absolutely understand and appreciate that vaping has proven effective for some smokers and has helped them switch from combustible cigarettes which users feel has significantly improved their health. But I also note the evidence from witnesses that personal anecdotes and individual experience isn't a proxy for population-level evidence.[1]

1.2 The safety of e-cigarettes—particularly the long-term safety—has not been established. Neither has their effectiveness as a cessation tool. While that is the case, a prescription model for nicotine e-cigarettes, as proposed by the Therapeutic Goods Administration (TGA), strikes the right balance between protecting the community and making available a tool which assists some smokers to stop smoking tobacco (even if vaping doesn't help them quit nicotine altogether).

1.3 A joint submission from the Cancer Council, the National Heart Foundation of Australia and the Australian Council on Smoking and Health stated they could support vaping if there was conclusive evidence that e-cigarettes offered a broad public health benefit:

> The evidence, where reviewed and presented systematically by independent health authorities, has consistently shown that use of e-cigarettes and other novel products poses significant health harms and risks to the Australian population, with no conclusive evidence of a health benefit.[2]

1.4 The Australian National University (ANU) research led by Professor Emily Banks and commissioned by the Federal Government showed that former smokers who use e-cigarettes had twice the odds of relapse as former smokers who do not use e-cigarettes.[3]

1.5 It found that only one study demonstrated e-cigarettes were effective for quitting—and that was if vaping was accompanied by face-to-face support from health professionals.[4]

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1 Ms Sharon Appleyard, Department of Health, *Committee Hansard,* 13 November 2020, p. 6; Dr Omar Khorshid, President, Australian Medical Association, *Committee Hansard*, 19 November 2020, p. 47; Emeritus Professor Simon Chapman, Emeritus Professor Mike Daube and Professor Matthew Peters, S*ubmission 195*, p. 8.

2 Cancer Council, the National Heart Foundation of Australia and the Australian Council on Smoking and Health, *Submission 194*, p.1.

3 Professor Emily Banks, Australian National University, *Submission 157*, p. 6.

4 Professor Emily Banks, Australian National University, *Submission 157*, p. 6. (citing Hajek P, Phillips-Waller A, Przulj D, et al. A randomized trial of e-cigarettes versus nicotine-replacement therapy. *New England Journal of Medicine* 2019; 380(7): 629-37).

1.6 This shows that a prescription model for e-nicotine is well-placed to assist smokers as it means smokers can speak with their GP about nicotine replacement therapies, but if they land on vaping as their preferred option, they can access a prescription for liquid nicotine for up to 12 months. Ongoing contact with their GP, including for prescription renewals if needed, would provide an opportunity for smokers/vapers to speak with a medical professional about their cessation progress, or any concerns regarding their ongoing use of nicotine.

1.7 A number of persuasive concerns were put to the inquiry by various witnesses and submitters[5] who argued against weakened regulation of e-cigarettes and liquid nicotine. These concerns can be summarised by the opening statement of the Australian Medical Association's President, Dr Omar Khorshid:

> Tobacco companies have a vested interest in keeping consumers addicted to their products through the use of highly addictive nicotine and have clearly invested considerable resources in undermining the views of the health industry throughout the world. The AMA is disturbed by the repeated claims by the industry that nicotine-containing e-cigarettes are an effective way to reduce the harm caused by tobacco, because the evidence to support these claims is, at the very best, inconclusive. What we do know is that they cause specific harms on their own in the short term. We don't know about the long-term risks of e-cigarette use. We also know that they are a gateway for young Australians to become addicted to nicotine and, potentially, to start smoking tobacco as well.[6]

1.8 Vaping nicotine is not a risk-free activity. That needs to be stressed. Nicotine is a dangerous and addictive poison and its availability must be regulated.

1.9 And, as Dr Khorshid told the committee, the ultimate "harm reduction" goal must be to reduce nicotine addiction altogether by helping people to permanently quit smoking, or to never take up nicotine — in any form — in the first place:[7]

> It is not a success to turn a smoker into an e-cigarette user; the success is turning the smoker into a non-smoker, and a lifelong non-smoker.[8]

1.10 While vaping proponents argue e-cigarettes are significantly safer than combustible cigarettes, health experts warned the committee that vaping liquids contain substances such as food flavourings that were never intended

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5 See for example, Thoracic Society of Australian and New Zealand, S*ubmission 162;* Cancer Council, the National Heart Foundation of Australia and the Australian Council on Smoking and Health, *Submission 194.*

6 Dr Omar Khorshid, President, Australian Medical Association, *Committee Hansard*, 19 November 2020, p. 47.

7 Dr Omar Khorshid, Australian Medical Association, *Committee Hansard*, 19 November 2020, p. 52.

8 Dr Omar Khorshid, Australian Medical Association, *Committee Hansard*, 19 November 2020, p. 51.

to be heated and inhaled, and a long list of toxic substances which pose a risk to health.

1.11 Dr Bernie Towler, from the Department of Health's Population Health Division, told the inquiry that there was growing evidence of potentially 'very nasty health effects' ranging from lung injuries to fatal poisonings, and studies which show 'cardiovascular and respiratory effects in human and animal studies, which are projected to show long-term health effects'.[9]

1.12 The Department of Health stated that e-cigarette aerosol contains harmful substances such as 'ultrafine particles, flavourings, volatile organic compounds, cancer-causing chemicals, heavy metals, propylene glycol, vegetable glycerine, cannabinoids and vitamin E acetate' and that, irrespective of the ingredients, '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'. [10]

1.13 Even the nicotine-free flavoured liquids freely available in vape shops contain toxic substances that should not be inhaled, including formaldehyde, and substances that may be addictive, according to research presented by the Lung Foundation. It said:

> …emerging research suggests that the flavours (such as "green apple") used in non-nicotine e-cigarettes, which are available in Australia as a consumer product, are as addictive as nicotine.[11]

1.14 So while vaping may be deemed 'less worse' than smoking tobacco, it doesn't make e-cigarettes inherently safe.

> I'm afraid that anyone who tells you that the risks of someone pulling vaporised glycol, nicotine and any number of more than 7,000 flavouring chemicals deep into their lungs an average of 173 times a day, day after day, year after year, are well understood is misleading you about safety. We had no idea for 40 or 50 years after cigarette smoking became widespread that lung cancer would move from being a rare disease to becoming the No. 1 cause of cancer death. We are only in the very early days of understanding the risk profile of e-cigarettes.[12]

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[9] Dr Bernie Towler, Principal Medical Officer, Population Health Division, Department of Health, *Committee Hansard*, 13 November 2019, p. 7.

[10] Department of Health, S*ubmission 167,* p. 20.

[11] Lung Foundation Australia, S*ubmission 268*, p. 3.

[12] Emeritus Professor Simon Chapman, *Committee Hansard*, 19 November 2020, p. 1.

1.15 The committee also heard that, because e-cigarettes are a relatively new product, there was little research that had looked at their health effects beyond two years. [13]

1.16 Given all this, the question is why would Australia want to make e-cigarettes more readily available to more people, as vaping proponents want?

1.17 The main argument advanced for relaxing regulation around e-cigarettes containing nicotine is one of convenience. Proponents argue that Australia should treat e-cigarettes as a consumer product, a restricted one just like cigarettes and tobacco. That is a utopian and self-serving view. If nicotine liquids are available to any adult entering a vape shop, under-18s will of course find ways to access this just as they do alcohol and cigarettes.

1.18 Professor Banks told the inquiry it was important to 'avoid widespread availability of e-cigarettes to people who have never smoked or who are non-smokers', and the experience with trying to restrict youth access to alcohol and tobacco demonstrated that 'if we want to avoid widespread exposure of people who are non-smokers to something we probably need to avoid it being available as a consumer product'.[14]

> Experience with alcohol and tobacco indicates that there is extensive and harmful use in young people if products are widely available, even with regulatory controls and recommendations about age limits. Hence, avoidance of use in non-smokers would include measures that avoid widespread availability of e-cigarettes.[15]

1.19 Professor Chapman who, in common with professors Daube and Peters, has worked for decades to reduce smoking prevalence and smoking harms, is strongly opposed to liberalisation and told the committee that the weak regulatory approach taken with cigarettes decades ago should not be repeated with e-cigarettes:

> Cigarettes are consumer goods and look at the absolute disaster that status has caused the world. We have made every conceivable mistake in failing to properly regulate tobacco. Those who argue that we should treat e-cigarettes in exactly the same way appear to know nothing of the history of the release of the smoking genie from the bottle at the beginning of last century and the 70-year struggle to get it back in. So, let's not make the same catastrophic errors again. We strongly support the proposal for the TGA to regulate e-cigarettes and for personal importation to be banned.[16]

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[13] Dr Bernie Towler, Principal Medical Officer, Population Health Division, Department of Health, *Committee Hansard*, 13 November 2020, p. 7.

[14] Professor Emily Banks, ANU, *Committee Hansard*, 13 November 2020, p. 27.

[15] Professor Emily Banks, ANU, *Submission 157*, p. 7.

[16] Emeritus Professor Simon Chapman, *Committee Hansard*, 19 November 2020, p. 1.

1.20 Since 2001, the fall in Australia's smoking rate has been driven mostly by younger people not taking up smoking.[17] However, a growing number of e-cigarette users are teenagers and young adults. Between 2016 and 2019, the proportion of 18 to 24-year-olds who had vaped increased from 19 per cent to 26 per cent, and the number of non-smokers who had tried e-cigarettes climbed from just over 13.6 per cent to 19.6 per cent[18]. According to the Australian Institute of Health and Welfare, the majority of teenagers and young adults who tried vaping were non-smokers and a key reason for doing so was curiosity.

1.21 There is considerable concern – and evidence – of a 'gateway effect' where vaping may normalise smoking and encourage youth to try or take-up combustible cigarettes.[19]

> When we surveyed [young never-smokers], over half of them were saying that they would actually prefer to use a nicotine-containing e-cigarette, and the vast majority were really drawn to the flavours that are available. Because they're non-smokers, their primary reason for using these is enjoyment and fun. So certainly, if we are going to even consider the option of legalising e-cigarettes, it is worth noting that the risk of having a bunch of non-smokers who are then taking up the use for enjoyment and fun really has the potential to undermine the incredible public health response of Australia over decades to ensure the health of Australians, especially our youth.[20]

1.22 The ANU study led by Professor Banks indicated that e-cigarette users who had never smoked were, on average, **three times more likely** to try smoking conventional cigarettes and transition to regular tobacco smoking than non-vapers. This was based on a meta-analysis of 25 studies and, to varying degrees, 'all 25 studies found an increased risk of taking up smoking with use of e-cigarettes'.[21]

1.23 Because of all these concerns, a number of health experts and researchers warned the committee about the potential harms of opening the gates to another nicotine delivery system. For instance:

> Any weak system of regulation in Australia would release a Trojan horse which could attract new cohorts of young people into nicotine dependency; popularise a highly addictive and potentially unhealthy fad in young people with all the promises of owning the latest and most prestigious vaping apparatus and peer-kudos from vape clouding displays; lure some long-term quitters back into nicotine dependency; hold

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17 Australian Institute of Health and Welfare, S*ubmission 214*, p. 4.

18 Australian Institute of Health and Welfare, *Submission 214*, p. 4.

19 See, for example, Department of Health, *Submission 167*, pp. 22–23.

20 Dr Michelle Jongenelis, *Committee Hansard*, 19 November 2020, p. 51.

21 Professor Emily Banks, ANU, *Submission 157*, p. 6.

> many smokers in smoking, in the erroneous belief that smoking reduction (not quitting) confers risk reduction; renormalise smoking behaviour; and distract attention and focus from proven evidence-based action to reduce smoking.[22]

1.24 And:

> There is growing evidence that e-cigarette usage is increasing amongst youth and young people and is seen as socially acceptable, reversing decades of tobacco control success. This is especially so in countries where the regulatory environment is more liberalised. E-cigarette use amongst young people who have never smoked is damaging to health, and it may be the gateway effect to tobacco smoking for young people who use e-cigarettes, as this has been shown across multiple studies. The assumption that e-cigarettes are harmless is entirely incorrect. They are associated with lung injury and nicotine dependence.[23]

1.25 Nonetheless, vaping proponents pointed to New Zealand's relatively loosely-regulated consumer approach to vaping as one that Australia should emulate – but the NZ Cancer Society has urged the committee to do the opposite saying 'we advise a very cautious approach to any liberalisation of these products'.[24]

> For the first time in 20 years, smoking prevalence in school-aged New Zealand children has increased rather than decreased, and this reversal occurred over the last few years, alongside a rapid increase in vaping among young New Zealanders.[25]

1.26 University of Melbourne researcher Dr Jongenelis stated that the United States (US) was "quite envious" of Australia's precautionary approach, as it battled what the US surgeon general has labelled an 'epidemic' of youth vaping driven by widespread advertising and availability of e-cigarettes. She further stated:

> They've now had to spend millions of dollars on mass media campaigns targeting youth to get them to stop using e-cigarettes. Australia can very much avoid having to throw that money at intervention later on by just taking the right steps now to prevent that from even happening in the first place.[26]

1.27 Of a lesser note are the economic arguments put forward by vested interest such as retailers – including jobs and business growth – which ignore that this is predominantly a public health issue. Policymakers should not be seduced into trading off questionable economic benefits for a more relaxed approach to

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[22] Emeritus Professor Simon Chapman, Emeritus Professor Mike Daube and Professor Matthew Peters, S*ubmission 195*, p. 3.

[23] Professor John Wilson, President, Royal Australasian College of Physicians, *Committee Hansard*, 19 November 2020, p. 38.

[24] Cancer Society of New Zealand, S*ubmission 289*, p. 1.

[25] Cancer Society of New Zealand, *Submission 289*, p. 3.

[26] Dr Michelle Jongenelis, *Committee Hansard*, 19 November 2020, p. 51.

a nicotine alternative, especially in an environment where the potential health harms and risks – if realised – constitute an economic burden in themselves.

1.28 Australia has been driving down smoking prevalence since the early 1990s, through innovations such as plain packaging and effective strategies such as tobacco excise and national anti-smoking campaigns[27]. Our success has been progressive and hard-won.

1.29 As witnesses submitted, Australia cannot afford to 'rest on its laurels'[28] and we must continue to invest in **proven** measures that work to reduce smoking rates[29] — and a number of submitters advocated for more or renewed spending on anti-smoking media campaigns which are 'highly effective at driving cessation activity'.[30]

1.30 Tobacco remains a leading cause of preventable death and disease in Australia[31], but vaping is not the 'cure'. Instead it poses a real risk to public health and, given the lack of evidence on safety alone, it would be foolish to open the door to e-cigarettes only to risk paying high health and economic costs in decades to come.

1.31 The key issue for policymakers isn't the degree to which e-cigarettes are 'safer' than combustible cigarettes; it's the degree to which e-cigarettes are safe, full stop.

1.32 As such, the TGA's precautionary approach to the regulation of liquid nicotine (and related products that seek to make therapeutic claims) must be supported, and any ongoing attempts by the pro-vaping lobby to promote e-cigarettes — or to weaken their regulation — must be resisted.

Senator Stirling Griff

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27 Department of Health, *Submission 167,* pp. 10–11.

28 Dr Omar Khorshid, President, Australian Medical Association, *Committee Hansard*, 19 November 2020, p. 52.

29 See, for example, Stroke Foundation, S*ubmission 278*; and Emeritus Professor Simon Chapman and Emeritus Professor Mike Daube, answers to written question on notice QoN 015-01, 20 November 2020 (received 25 November).

30 Thoracic Society of Australia and New Zealand, S*ubmission 162*, p. 7. Also Stroke Foundation, *Submission 278,* pp. 4—5; Emeritus Professor Mike Daube, *Committee Hansard*, 19 November 2020, p. 2.

31 Department of Health, S*ubmission 167*, p. 10.

Australian Greens' additional comments

1.1 The Australian Greens support the findings and recommendations of the Majority Report.

1.2 The Australian Greens acknowledge the potential harm reduction role for nicotine containing e-cigarettes in a suite of smoking cessation tools available to consumers.

1.3 Evidence provided by e-cigarette users, some researchers and public health officials indicate that e-cigarettes have been found to be beneficial for *some* individuals, as a less risky alternative to combustible cigarettes, to assist smokers in reducing harm.

1.4 Notwithstanding this, the Australian Greens share the view of many academics and public health officials in this space that there is not enough evidence at a population level to claim that nicotine containing e-cigarettes have, on average, a positive benefit for all.

1.5 The Australian Greens support calls to take a precautionary approach in the regulations of e-cigarettes to ensure we do not undo many years of outstanding public health campaigns to reduce the levels of tobacco smoking in Australia.

Taking a precautionary approach

1.6 The Australian Greens recognise that e-cigarettes are considered safer than combustible cigarettes but also recognise research demonstrates a range of short-term risks exist, and there is a lack of long-term evidence available for scrutiny.

1.7 In his evidence to the committee, Dr Bernie Towler, Principal Medical Officer, Population Health Division, Department of Health, noted that research from the Health Research Board of Ireland released this year acknowledged that long-term health impacts beyond 24 months had not yet been researched, and that e-cigarettes are known to present a range of short-term risks including burns, poisonings, lung injuries, exacerbation of asthma, and cardiovascular and respiratory effects.[1]

1.8 In particular, the Australian Greens note the industry claim that e-cigarettes were substantially less harmful than combustible cigarettes—by around 95 per cent—was, as pointed out by Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, a consensus view of 13 academics coordinated by Public Health England in 2015, and has since been rebuked by

[1] Dr Bernie Towler, Principal Medical Officer, Population Health Division, Department of Health, *Proof Committee Hansard,* 13 November 2020, p. 7.

eminent medical journals such as *The Lancet* as lacking scientific credibility. The figure is not endorsed by the Department of Health. Professor Skerritt noted:

> It's probably fruitless to ask whether it's 20 per cent safer, 30 per cent safer or whatever. No-one knows. Clearly smoke tobacco has tars and other things that contribute to lung and other cancers. Nicotine is of course responsible for cardiovascular and other effects, but I think it is actually misleading to keep on quoting the figure of 95 per cent.[2]

1.9 Notwithstanding the above, the Australian Greens recognise that potentially e-cigarettes have a role to play as a harm reduction measure against combustible cigarettes and as a potential smoking cessation tool for those seeking to quit smoking. Evidence heard by the committee demonstrates that e-cigarettes containing nicotine are significantly lower in risk than traditional combustible cigarettes, and accordingly have a role to play in tobacco harm reduction strategies. As Dr Colin Mendelsohn, Board Member, Australian Tobacco Harm Reduction Association, noted:

> It's designed for adult smokers who are unable to quit with other methods, or on their own, as a second-line treatment, and these people would continue to smoke otherwise. I think we've got to always consider it in that context. The reality is, and I've treated smokers for over 40 years, smoking is incredibly difficult to quit, and many Australians simply are not able to quit. Vaping's not risk-free, but it's a far safer alternative to continuing to smoke.[3]

1.10 Dr Alex Wodak, Director, Australian Tobacco Harm Reduction Association, further noted:

> Harm reduction is accepted as the third pillar of our National Tobacco Strategy, but it was largely neglected in the past because harm-reduction options weren't very good. In the last decade, we've had good harm-reduction options, but it's now neglected because the options are extremely good. A major advance in public health in recent decades has been the development of a growing range of effective, relatively safe tobacco harm-reduction options… When people have a choice between dangerous or low-risk nicotine options, they rush to the low-risk options.[4]

1.11 However, as a smoking cessation tool, the Australian Greens share the concerns of the Department of Health and Professor Banks, Professor of Epidemiology and Population Health, Australian National University, that there remains an insufficient level of evidence across a population level to

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[2] Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, *Proof Committee Hansard*, 13 November 2020, p. 14.

[3] Dr Colin Mendelsohn, Australian Tobacco Harm Reduction Association, *Proof Committee Hansard*, 13 November 2020, p. 66.

[4] Dr Alex Wodak, Australian Tobacco Harm Reduction Association, *Proof Committee Hansard*, 13 November 2020, p. 67.

claim that e-cigarettes, on average, have a net-positive benefit. It is recognised that e-cigarettes can assist some to quit, but can also prolong smoking in others, and that further research of the benefits across a population, rather than on an individual-to-individual basis, is required. Accordingly, a precautionary approach to the regulation of nicotine containing e-cigarettes is warranted until we can better understand the population-wide effects of its use in harm reduction strategies and as a cessation tool.

1.12 Consistent with other smoking cessation tools such as sprays and lozenges that also commenced as prescription-only goods, the Australian Greens support a prescription-based model for e-cigarettes containing nicotine until further research on the long-term impacts are completed. Despite the actions of other countries in this space, Australia should continue to be a leader in smoking harm reduction policy and take a precautionary approach to e-cigarettes. Supporting the use of a precautionary approach, Professor Emily Banks noted:

> Tobacco came upon us before we had the ability to assess its health effects and before we had good systems to ensure that products used by our community were safe. In making tobacco widely available, we made a grave mistake—a mistake that costs us eight million lives a year worldwide. It is important that we address the harms of tobacco at the same time as protecting the community from further harm.[5]

1.13 A prescription-based model would allow individuals to have a discussion with their GP about the range of smoking cessation options available to them and make an informed decision about the approach to smoking cessation they wish to pursue. A number of witnesses appearing before the Committee noted this interaction with a GP as a beneficial step for anyone considering smoking cessation. As Emeritus Professor Mike Daube, AO, Faculty of Health Sciences, Curtin University noted:

> …I would be more than happy to see far more people going to their GPs specifically for advice on smoking cessation. We know that brief advice – and we've known this for donkey's years – from a GP about quitting smoking is a really important factor, so if the TGA process encourages vapers or anybody else to go to their GP for advice on smoking cessation then that's going to be immensely beneficial.[6]

1.14 The Australian Greens acknowledge the concerns raised by the committee that some GPs are reluctant to issue nicotine e-cigarette prescriptions to patients due to a lack of information or training on the role of e-cigarettes as a smoking cessation tool. The Australian Greens recognise that the RACGP and the AMA

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[5] Professor Emily Banks, Australian National University, *Proof Committee Hansard*, 13 November 2020, p. 17.

[6] Emeritus Professor Mike Daube, Curtin University, *Proof Committee Hansard*, 19 November 2020, p. 10.

support the prescription-based model and patients speaking with their GPs for advice on the most appropriate smoking cessation tool for their circumstances.

1.15 The Australian Greens recommend that GPs be urgently provided with opportunities to upskill in smoking cessation options, including the use of e-cigarettes, to ensure they are fully informed of all options when assisting patients.

1.16 The Australian Greens strongly believe that vaping retailers or any other non-health practitioner should not be providing individuals with health advice about smoking cessation. This is fundamentally a public health issue. Consideration of regulation should be made using a public health lens, and not take into consideration commercial implications.

1.17 In summary, the Australian Greens consider that the Therapeutic Goods Administration (TGA) scheduling process of nicotine containing e-cigarettes and nicotine liquids for use in e-cigarettes should be allowed to be completed.

1.18 Should the TGA recommend that nicotine containing e-cigarettes and nicotine liquids for use in e-cigarettes be available only via prescription, the Australian Greens recommend that that decision be implemented by the Australian Government and that the TGA and the Australian Government commit to reviewing the effectiveness of the process in two years' time as more research and data becomes available.

Gateway effect and the impact on young people

1.19 The Australian Greens support the view of the majority of the Committee and public health officials that we must act to ensure that people who have never smoked—and in particular young people—avoid using e-cigarettes.

1.20 The committee heard evidence from Professor Banks that there was, on average, a 300 per cent increased risk in non-smokers becoming regular smokers of tobacco after using e-cigarettes. This association between e-cigarette users who had never smoked cigarettes before, and then go on to become regular tobacco smoking users, is known as the 'gateway effect'.

1.21 As Dr Bernie Towler noted:

> I think there's really quite compelling evidence that the gateway effect is a real thing. The ANU research, which has been referred to already today, shows that e-cigarette users who've never smoked or are current non-smokers are on average three times as likely to take up smoking or combustible cigarettes as those who have not used e-cigarettes.[7]

[7] Dr Bernie Towler, Principal Medical Officer, Population Health Division, Department of Health, *Proof Committee Hansard*, 13 November 2020, p. 11.

1.22 Currently over 95 per cent of people aged 14 to 17 in Australia have never smoked—a statistic Australia should be proud of.[8] However, the Australian Greens are concerned e-cigarettes and the 'gateway effect' have the ability to undermine the preventative work undertaken in Australia to date that has allowed us to achieve such low levels of tobacco smoking uptake in young people.

1.23 Adjunct Professor John Skerritt noted:

> …as recently as 2016, 2.3 per cent of kids and young adults aged 15 to 24 in Australia were regular vapers. That's now 4.5, almost doubling. Among US high school students, it's gone in two years from 11.7 per cent in 2017 to 27.5 per cent in 2019 characterising themselves as current e-cigarette users. Among Canadians, it's gone from six per cent in 2017 to 15 per cent. So there are concerns that some of the hard-won gains may be counteracted by young people taking up vaping, and many people who take up vaping, as Dr Banks will testify, also then move to combustible cigarettes.[9]

1.24 There is a real concern that the increasing use of e-cigarettes in young people will result in the normalisation of, and increased uptake in, regular tobacco smoking, bringing along with it the potential lifelong health implications.

1.25 Evidence provided to the committee strongly supported the claim that young people who use e-cigarettes were significantly more likely to start tobacco smoking. As an example, the committee was advised of a study released by the Irish Health Research Board in October 2020 reporting that adolescents using e-cigarettes were three to five times as likely to start smoking tobacco cigarettes.

1.26 Implementing a prescription-based model for e-cigarettes would assist in stemming the uptake of e-cigarette use in young people before we fully understand their long-term health implications.

Big tobacco companies

1.27 The Australian Greens hold significant concerns about the active involvement of the big tobacco industry in the debate around regulatory reform of e-cigarettes in Australia.

1.28 The motivations of the industry were articulated in a Philip Morris International sponsored article on the website of The Australian newspaper, where it was claimed that Government regulation was prohibiting Australian smokers from accessing e-cigarettes which, in their view, are a viable and safer alternative for combustible cigarette smokers. The article concludes with:

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[8] Professor Emily Banks, Australian National University, *Proof Committee Hansard*, 13 November 2020, p. 17.

[9] Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, *Proof Committee Hansard*, 13 November 2020, p. 11.

> It's time for the policy makers, regulators and health authorities in Australia to be guided by facts and evidence and support science-based alternatives that can help smokers leave cigarettes behind.[10]

1.29 Research presented to the committee clearly articulated that the use of e-cigarettes would increase the likelihood of non-smokers taking up smoking on a regular basis. It is clear that e-cigarettes present an emerging market to the big tobacco industry, and subsequently they have an obvious interest in any regulatory reform that may restrict access and consumption.

1.30 As Professor Banks stated:

> Interestingly, there are two public submissions from big tobacco on the TGA proposal for rescheduling nicotine to prescription-only. Both of those big tobacco companies strongly oppose the prescription-only model for tobacco and advocate that e-cigarettes should be available as a broader consumer product. You draw your own conclusions on why they may have advocated for that.[11]

1.31 Professor Daube further noted:

> What we are seeing from the tobacco industry is what we've seen before – promotion of all kinds of different products. I've got no doubt whatsoever that it is in their interests to see these products on the market so they can sell as many addictive products as possible.[12]

1.32 It was made clear throughout the committee's hearings that public health officials have significant reservations about the tobacco industry's claims that e-cigarettes and other 'science-based alternatives can help smokers leave cigarettes behind'.[13]

1.33 Emeritus Professor Simon Chapman AO, School of Health, University of Sydney, noted:

> They're trying to intrigue people with this new product, bring them into the market and hold them in it with a highly addictive product.[14]

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[10] Philip Morris International. 'Follow science to the moon', *The Australian*, https://www.theaustralian.com.au/sponsored/rp9Rxv493P9nQTUOkEni/follow-science-to-the-moon/ (accessed 17 December 2020).

[11] Professor Emily Banks, Australian National University, *Proof Committee Hansard*, 13 November 2020, p. 12.

[12] Emeritus Professor Mike Daube, Curtin University, *Proof Committee Hansard*, 19 November 2020, p. 8.

[13] Philip Morris International. 'Follow science to the moon', *The Australian*, https://www.theaustralian.com.au/sponsored/rp9Rxv493P9nQTUOkEni/follow-science-to-the-moon/ (accessed 17 December 2020).

[14] Emeritus Professor Simon Chapman, University of Sydney, *Proof Committee Hansard*, 19 November 2020, p. 8.

1.34 It is clear the big tobacco industry holds the view that vaping and e-cigarettes offer new profit-making opportunities as traditional combustible smoking rates continue to reach record lows in Australia. This is a very clear conflict of interest.

1.35 This is a public health issue, and regulations should be considered and enacted without the influence of the big tobacco industry or any other commercial interests.

1.36 The Australian Greens caution the Government not to allow the influence of the big tobacco industry to affect its decision-making on this important public health issue and recommend taking a precautionary approach to regulating e-cigarettes.

Recommendations

1.37 The Australian Greens support the recommendations of the Majority Report and further recommend:

Recommendation 1

1.38 That any decision-making on e-cigarettes by the Australian Government be based on public health principles as part of a harm reduction approach, rather than commercial considerations.

Recommendation 2

1.39 The Australian Government continue to invest in evidence-based harm reduction strategies, incorporating new approaches as evidence of their long-term effectiveness becomes available.

Recommendation 3

1.40 Should the TGA recommend that nicotine containing e-cigarettes and nicotine liquids for use in e-cigarettes be available only via prescription, the Australian Government implement that decision and commit to reviewing that decision in two years' time as more research and data becomes available.

Recommendation 4

1.41 General Practitioners urgently upskill in smoking harm reduction and cessation options, including the use of nicotine containing e-cigarettes, to ensure they are fully informed of all options when assisting patients.

Recommendation 5

1.42 Prohibit the sale of nicotine containing e-cigarettes and nicotine liquids for use in e-cigarettes in convenience stores.

Senator Rachel Siewert

Chair's report

Chair's foreword

The committee received a wide range of evidence examining issues associated with tobacco harm reduction strategies and the safety and efficacy of e-cigarettes. Senators reached differing conclusions on the issues raised and potential improvements to the current regulation of, and the policy framework underpinning, the sale, use and promotion of e-cigarette products in Australia.

Senator the Hon Canavan and myself do not agree with the conclusions and recommendations contained in the majority report of the committee. We consider the majority report does not fairly or accurately convey the evidence about the comparative lesser harm of e-cigarettes, nor the level of opposition to the proposed prescription-based model.

Chapters 4, 5 and 6 of this Chair's report present the extensive evidence received from experts, individuals and organisations in relation to the safety and efficacy of e-cigarettes that was not included in the majority report. Our views and recommendations are set out in Chapter 7 of this Chair's report.

Finally, we thank the thousands of individuals who contributed to this inquiry. Your testimony is deeply appreciated and, on behalf of Senator the Hon Canavan and myself, we thank you for your active participation.

Chapter 1 - Introduction

1.1 On 6 October 2020, the Senate established the Select Committee on Tobacco Harm Reduction (the committee) to inquire and report on tobacco reduction strategies, with particular reference to:

(a) the treatment of nicotine vaping products (electronic cigarettes and smokeless tobacco) in developed countries similar to Australia (such as the United Kingdom, New Zealand, the European Union and United States), including but not limited to legislative and regulatory frameworks;
(b) the impact nicotine vaping products have had on smoking rates in these countries, and the aggregate population health impacts of these changes in nicotine consumption;
(c) the established evidence on the effectiveness of e-cigarettes as a smoking cessation treatment;
(d) the established evidence on the uptake of e-cigarettes amongst non-smokers and the potential gateway effect onto traditional tobacco products;
(e) evidence of the impact of legalising nicotine vaping products on youth smoking and vaping rates and measures that Australia could adopt to minimise youth smoking and vaping;
(f) access to e-cigarette products under Australia's current regulatory frameworks;
(g) tobacco industry involvement in the selling and marketing of e-cigarettes; and
(h) any other related matter.[1]

1.2 The committee was required to present its final report on or before 1 December 2020. Following a resolution of the committee on 2 November 2020, and in accordance with the motion agreed by the Senate on 23 March 2020,[2] the reporting date for the inquiry was extended to 18 December 2020.

Conduct of the inquiry

1.3 The committee advertised the inquiry on its webpage and invited submissions from a range of relevant stakeholders, including interest groups, government

[1] *Senate Journals*, No. 67, 6 October 2020, pp. 2341–2342.

[2] *Senate Journals*, No. 47, 23 March 2020, p. 1545.

agencies, public health organisations, industry, universities and research bodies.

1.4 The committee received over 13 000 documents, comprised of submissions, form letters and correspondence. This included 900 public and name withheld submissions, which are detailed in Appendix 1. Further to this, the inquiry received over 30 confidential submissions.

1.5 The committee also received 8 324 form letters, with substantially similar content, from ex, current and non-smokers across three email campaigns.[3] A summary of the main points made by individuals is available on the committee's website.

1.6 In addition, the committee received approximately 362 pieces of correspondence.

1.7 The committee held public hearings in Canberra on 13 November 2020 and in Sydney on 19 November 2020. The list of witnesses who participated in the public hearings is at Appendix 2.

1.8 The committee undertook the inquiry following established parliamentary practices and procedures and sought the views of a wide range of organisations and individuals. Public hearings were accessible to members of the public: proceedings were broadcast online and transcripts of the hearings are available on the inquiry webpage.[4]

What are electronic cigarettes?

1.9 Smoke-free products deliver nicotine in the absence of both combustion and smoke. The term covers a broad range of products including electronic cigarettes, heat-not-burn tobacco products, chewing tobacco, snuff and other novel nicotine products.

1.10 Electronic cigarettes (also known as e-cigarettes, e-cigs, electronic nicotine delivery systems, electronic non-nicotine delivery systems, alternative nicotine delivery systems, personal vaporisers, e-hookahs, vape pens or vapes) are battery powered devices that deliver an aerosol by heating a solution that users breathe in.[5] For the purpose of this report, electronic cigarettes are referred to as e-cigarettes.

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3 An additional 3 597 duplicates have not been included in this figure.

4 Throughout the conduct of the inquiry, we were aware of Australia's obligations under the *World Health Organisation Framework Convention on Tobacco Control* (WHO FCTC). 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.

5 Department of Health, *About e-cigarettes*, 17 March 2020, https://www.health.gov.au/health-topics/smoking-and-tobacco/about-smoking-and-tobacco/about-e-cigarettes (accessed 30 November 2020).

1.11 Heat-not-burn tobacco products are also battery-powered electronic devices, however, they differ from e-cigarettes in that they heat tobacco up to 350 degrees celsius to produce aerosols containing nicotine and other chemicals, which are inhaled by users.[6] Other smokeless tobacco products, including chewing tobacco and snuff, involve oromucosal nicotine delivery.

1.12 E-cigarette devices consist of three parts: a battery (usually rechargeable); a tank or 'pod' for the e-liquid; and a 'coil' or heating element.[7] E-cigarettes have evolved as a product since first entering the market, with products now ranging from early 'first generation' devices that resemble cigarettes, to second and third generation devices that enable users to modify characteristics of the device, such as adjusting the voltage.[8]

1.13 E-cigarettes and combustible cigarettes are substantially different products. A combustible cigarette burns tobacco at around 600 degrees celsius and produces smoke which contains high levels of harmful and potentially harmful constituents, including carbon monoxide and tar, whereas e-cigarettes deliver nicotine without smoke.[9] E-cigarettes do not contain tobacco and heat nicotine liquid, rather than burning it.[10] The absence of burning and its by-product, smoke, is significant because '[b]urning tobacco causes almost all the harm from smoking. It releases over 7,000 chemicals, tars, carbon monoxide, other toxic gases and solid particles'.[11]

1.14 The solution used in e-cigarettes is e-liquid (also known as 'e-juice' or 'vape juice'). E-liquids may contain propylene glycol, vegetable glycerine or glycerol, flavouring, colour additives and, in some cases, water. E-liquids may or may not contain nicotine.[12] Vapourised e-liquid is often

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6 World Health Organisation, *Heat-Not-Burn tobacco products information sheet*, https://apps.who.int/tobacco/publications/prod_regulation/heat-not-burn-products-information-sheet/en/index.html (accessed 7 December 2020).

7 Australian Tobacco Harm Reduction Association, *Switching to vaping in 5 easy steps*, 27 December 2019, https://athra.org.au/wp-content/uploads/2019/12/Switch-to-Vaping-in-5-easy-steps-flyer26Dec2019.pdf (accessed 30 November 2020).

8 National Health and Medical Research Council, *CEO Statement: Electronic cigarettes*, 3 April 2017, https://www.nhmrc.gov.au/about-us/resources/ceo-statement-electronic-cigarettes (accessed 1 December 2020).

9 United States Food & Drug Administration, *Harmful and Potentially Harmful Constituents (HPHCs)*, content current as of 10 July 2019, https://www.fda.gov/tobacco-products/products-ingredients-components/harmful-and-potentially-harmful-constituents-hphcs (accessed 7 December 2020).

10 Department of Health, *About e-cigarettes*, https://www.health.gov.au/health-topics/smoking-and-tobacco/about-smoking-and-tobacco/about-e-cigarettes (accessed 3 December 2020).

11 Australian Tobacco Harm Reduction Association, *Submission 166*, p. 23.

12 BetterHealth Cannel, *E-liquids for use in e-cigarettes*, July 2019, https://www.betterhealth.vic.gov.au/health/healthyliving/e-liquids-for-use-in-e-cigarettes (accessed 30 November 2020).

referred to as 'vapour', while the action of inhaling this aerosol is referred to as 'vaping'.[13]

1.15 E-liquids can be purchased pre-mixed or made by mixing together separate ingredients. Commercial e-liquids often come in nicotine concentrations of 0mg/mL (no nicotine), 3mg/mL, 6mg/mL and 12mg/mL, although higher concentrations may reach up to 50mg/mL.[14] These values represent the amount of nicotine in each 1mL of e-liquid. For contrast, the nicotine content in a cigarette is generally between 13mg and 30mg.[15]

Previous inquiries

1.16 In recent years, there have been a number of parliamentary committees which have inquired into various aspects of e-cigarettes, including a House of Representatives standing committee in the 45th Parliament and Senate committees in the 44th and 45th Parliaments.[16]

Acknowledgements

1.17 We thank the individuals and organisations who contributed to this inquiry. While committee members do not have the power to intervene in, or investigate, personal circumstances, we sincerely appreciate the time and effort taken by individuals, as well as their friends and family, to participate in the inquiry. We thank everyone who took the time to contact the committee and recount their personal experiences with e-cigarette use. Their contributions have been an invaluable resource to the inquiry.

References to Hansard

1.18 In this report, references to *Committee Hansard* are to proof transcripts. Page numbers may vary between proof and official transcripts.

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[13] Department of Health, *About e-cigarettes*, 17 March 2020, https://www.health.gov.au/health-topics/smoking-and-tobacco/about-smoking-and-tobacco/about-e-cigarettes (accessed 30 November 2020).

[14] E-liquids ranging in nicotine concentration from 0mg/mL to 50mg/mL are advertised for commercial sale through a number of websites.

[15] Therapeutic Goods Administration, *Scheduling delegate's interim decisions and invitation for further comment: ACCS/ACMS, November 2016*, 2 February 2017, https://www.tga.gov.au/book-page/21-nicotine (accessed 4 December 2020).

[16] House of Representatives Standing Committee on Health, Aged Care and Sport, *Report on the inquiry into the use and marketing of electronic cigarettes and personal vaporisers in Australia*, March 2018; Senate Community Affairs Legislation Committee, *Vaporised Nicotine Products Bill 2017*, September 2017; Senate Select Committee on Red Tape *Effect of red tape on tobacco retail: Interim report*, June 2017; and Senate Economics References Committee, *Personal choice and community impacts. Interim report: the sale and use of tobacco, tobacco products, nicotine products and e-cigarettes (term of reference a)*, May 2016.

Structure of the report

1.19 This report is structured as follows:

- Chapter 1 provides information about the context and administrative details of the inquiry.
- Chapter 2 discusses Australia's regulatory approach to e-cigarettes, including the prevalence of tobacco smoking and e-cigarette use in Australia.
- Chapter 3 sets out international approaches to regulating e-cigarettes.
- Chapter 4 explores personal accounts of e-cigarette use.
- Chapter 5 considers the health impacts of e-cigarettes.
- Chapter 6 examines the relative strengths and weaknesses of a prescription-based model in comparison to other regulatory approaches.
- Chapter 7 concludes with our view and recommendations.

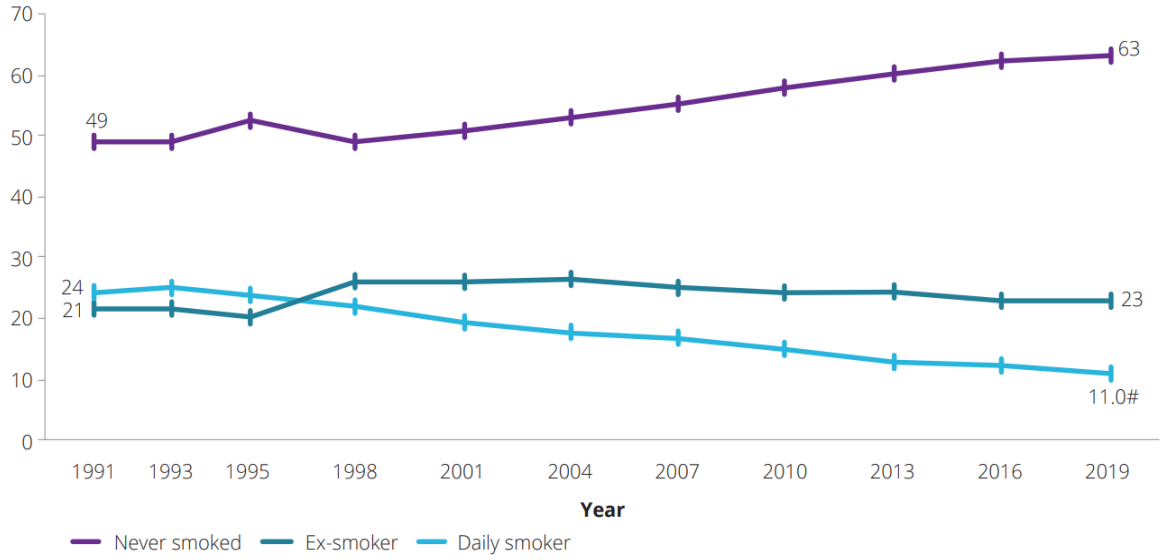
Chapter 2 - The Australian context

Introduction Between 2016 and 2019, smoking prevalence decreased in Australia by 1.2 per cent amongst adults who smoke combustible cigarettes on a daily basis.[1] Concurrently, however, there was an increase in e-cigarette use. This chapter discusses tobacco smoking and e-cigarette use in Australia, before going on to summarise the Australian Government's approach to e-cigarette products and their regulation as a therapeutic good.

Tobacco smoking in Australia

2.2 The rates of daily smoking in Australia have reduced from 12.2 per cent (2.4 million people) in 2016 to 11.0 per cent (2.3 million) in 2019. This compares with 24 per cent of Australians smoking tobacco daily in 1991.[2]

Figure 1 Tobacco smoking status, people aged 14 and over, 1991–2019



Source: Australian Institute of Health and Welfare, National Drug Strategy Household Survey 2019, 16 July 2020, p. 6.

2.3 The number of Australians (aged 14 and older) who have never smoked has increased from 55.4 percent in 2007 to 63.1 per cent in 2019.[3] In particular, the

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1 Australian Institute of Health and Welfare, *National Drug Strategy Household Survey 2019*, 16 July 2020, p. vii.

2 Australian Institute of Health and Welfare, *Submission 214*, p. 4.

3 Australian Institute of Health and Welfare, *Submission 214*, p. 8.

Australian Institute of Health and Welfare reported that the 14–17 year age group was the most likely of all age demographics to have never smoked.[4]

2.4 The *National Drug Strategy Household Survey 2019* estimated that tobacco smoking accounts for 22 per cent of the total cancer burden in Australia.[5] The committee also heard that tobacco smoking remains a leading cause of preventable death and disability in Australia, estimated to have killed almost 21 000 Australians in 2015.[6] It was also noted that tobacco smoking compounds health and social inequalities and is a major contributor to poorer health status in socioeconomically disadvantaged populations.[7]

2.5 The Department of Health estimated 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.[8]

2.6 The Australian Government has set a national target for the rate of daily smoking amongst adults of '10 per cent by 2025'.[9] This new target was announced after the previous target set under the National Healthcare Agreement of '10 per cent by 2018' was not met.[10] Other countries have set more ambitious targets, including New Zealand, which aims to be smoke-free (defined as achieving a smoking rate of less than 5 per cent) by 2025.[11]

Use of e-cigarettes

2.7 While there has been a decline in tobacco smoking, there has been an increase in e-cigarette use in Australia. In 2019, the *National Drug Strategy Household Survey* found that the proportion of people who have ever used e-cigarettes rose from 8.8 per cent (1.7 million people) to 11.3 per cent (2.4 million people)

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4 In 2007, 93 per cent of those aged 14-17 years had never smoked, while in 2019 96.6 per cent had never smoked.

5 Australian Institute of Health and Welfare, *National Drug Strategy Household Survey 2019*, 16 July 2020, p. 1.

6 Department of Health, *Submission 167*, p. 10.

7 Department of Health, *Submission 167*, p. 10.

8 Department of Health, *Submission 167*, p. 10.

9 The Hon Greg Hunt MP, Minister for Health, 'National Press Club address—Long Term National Health Plan', *Media Release*, 15 August 2019.

10 Productivity Commission, *National Healthcare Agreement—Performance Reporting Dashboard*, https://performancedashboard.d61.io/healthcare (accessed 7 December 2020).

11 Health Promotion Agency, *Smokefree Aotearoa 2025*, content current as of 9 June 2019, https://www.smokefree.org.nz/smokefree-in-action/smokefree-aotearoa-2025 (accessed 7 December 2020).

and the proportion of people who used e-cigarettes rose from 1.2 per cent (200 000 people) to 2.5 per cent (500 000 people).[12]

2.8 The committee notes that the *National Drug Strategy Household Survey 2019* does not distinguish between e-cigarette products containing nicotine and those without nicotine.[13]

2.9 The Department of Health commented that:

> 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 in 2020. 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.[14]

The Australian Government's position on e-cigarettes

2.10 Australia has led the world in implementing tobacco control measures including:

- substantial increases in excise on tobacco products;
- education programmes and campaigns;
- bans on smoking in public places;
- plain packaging of tobacco products;
- bans on retail displays of tobacco products;
- labelling with updated and larger graphic health warnings;
- prohibiting tobacco advertising, promotion and sponsorship; and
- providing support for smokers to quit, including through nicotine replacement therapies on the Pharmaceutical Benefits Scheme.[15]

2.11 In respect to e-cigarettes, the Australian Government has adopted a precautionary approach:

> The precautionary approach encourages action to prevent harm when there is scientific uncertainty and until a body of evidence establishes the requirement for alternative regulation. This includes the lack of conclusive evidence around the safety risks posed to users by the unknown inhalation toxicity of nicotine and other chemicals used with e-cigarettes, passive exposure to e-cigarette vapour, risks associated with child poisoning, and issues around quality control and efficacy. The precautionary approach also takes into account the broader risks that e-cigarettes may pose to

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[12] Australian Institute of Health and Welfare, *National Drug Strategy Household Survey 2019*, 16 July 2020, p. 9.

[13] Australian Institute of Health and Welfare, *Submission 214*, p. 2.

[14] Department of Health, *Submission 167*, p. 13.

[15] Department of Health, *Submission 167*, p. 10.

> population health, namely their potential to disrupt the decline in tobacco use in Australia.[16]

2.12 In June 2020, the Australian Government responded to a report by the House of Representatives Standing Committee on Health, Aged Care and Sport on the use and marketing of e-cigarettes and personal vaporisers in Australia. The response noted evidence linking e-cigarettes to tobacco use and nicotine addiction, and the risks of e-cigarette use leading to future smoking in the young adult population. The response concluded:

> The Government will continue to monitor the impact of e-cigarettes on smoking cessation. However, at a population level, there is currently insufficient evidence to promote the use of e-cigarettes for smoking cessation. The Government will also continue to monitor emerging evidence regarding the direct harms e-cigarettes pose to human health, their impacts on smoking initiation, uptake among youth and dual use with conventional tobacco products.[17]

2.13 In September 2019, Australia's Chief Medical Officer and the state and territory Chief Health Officers presented a joint statement about the emerging link between e-cigarette use and lung disease. The statement reported that:

> All Australian governments are united in maintaining a precautionary approach to the marketing and use of e-cigarettes. There is growing evidence implicating e-cigarettes in a range of harms to individual and population health. E-cigarettes are relatively new products and the long-term safety and health effects associated with their use and exposure to second-hand vapour are unknown.[18]

2.14 Similarly, Commonwealth and state and territory ministers discussed the growing amount of evidence in relation to 'the direct harms e-cigarettes pose to human health, their impact on smoking initiation and cessation, uptake among youth and dual use with conventional tobacco products' at a meeting of the Ministerial Drug and Alcohol Forum.[19]

2.15 The Ministerial Drug and Alcohol Forum agreed to a set of updated national guiding principles for e-cigarettes. The principles, released by the Department of Health in November 2019, reaffirm the precautionary approach to e-cigarettes being taken by all Australian governments and note that any change

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[16] Australian Government, Department of Health, *Policy and regulatory approach to electronic cigarettes (e-cigarettes) in Australia*, 28 November 2019.

[17] Australian Government, *Australian Government response to the Standing Committee on Health, Aged Care and Sport Report on the Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia*, 17 June 2020, p. 9.

[18] Chief Medical Officer and State and Territory Chief Health Officers, 'E-cigarettes linked to severe lung illness', *Media Release*, 13 September 2019.

[19] Ministerial Drug and Alcohol Forum, *Ministerial Drug and Alcohol Forum Communiqué*, 28 November 2019, p. 1.

to the regulation of e-cigarettes in Australia will have the protection of the health of children and young people as its primary focus and goal.[20]

2.16 In addition, the Department of Health stated that any change to the regulation of e-cigarettes should:

- place protecting the health of existing adult cigarette smokers as its second key goal;
- take into account the conclusions reached by credible health and scientific agencies in relation to the interpretation and advice of evidence;
- be precautionary in nature;
- minimise the proliferation of e-cigarette marketing and use, particularly among young people while maximising the impact of effective tobacco control measures; and
- complement jurisdictional legislation and take into account the approaches taken by Australian and state and territory governments and other countries to e-cigarettes.[21]

Regulation as a therapeutic good

2.17 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 a prescription.[22] Australia's regulatory treatment of e-cigarettes containing nicotine is a shared responsibility between the Commonwealth and state and territory governments.[23] The current regulatory framework draws on existing legislation and regulations that apply to tobacco products, poisons, therapeutic goods and consumer goods. E-cigarettes containing nicotine are regulated differently from those that do not contain nicotine.[24]

2.18 In Australia, it is illegal to import or sell products that make therapeutic claims, unless they have received market authorisation by the Therapeutic Goods Administration (TGA) or they are otherwise exempt or subject to an approval or authority granted by the TGA.[25]

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[20] Australian Government, Department of Health, *Policy and regulatory approach to electronic cigarettes (e-cigarettes) in Australia*, 28 November 2019.

[21] Australian Government, Department of Health, *Policy and regulatory approach to electronic cigarettes (e-cigarettes) in Australia*, 28 November 2019, pp. 1-4.

[22] The possession of nicotine for use in e-cigarettes without a prescription is illegal in all states and territories except South Australia. See Department of Health, *Submission 167*, p. 8.

[23] Department of Health, *Submission 167*, p. 6.

[24] E-cigarette devices and e-liquid refills that do not contain nicotine are generally classified as legal consumer goods and can be sold legally in all Australian states and territories, except for Western Australia.

[25] Department of Health, *Submission 167*, p. 6.

2.19 Nicotine is currently classified as a dangerous poison under Schedule 7 of the Standard for the Uniform Scheduling of Medicines and Poisons (the Poisons Standard) except in preparations for human therapeutic use, tobacco prepared and packed for smoking, and when labelled and packed for the treatment of animals.[26]

2.20 Part 4 of the Poisons Standard is a record of decisions regarding the classification of medicines and chemicals into schedules. Decisions regarding the scheduling of substances for inclusion in the Poisons Standard are made by the Secretary of the Department of Health. In practice, decisions for medicines scheduling are made by their delegate who is a senior medical officer in the Department of Health.[27]

2.21 The Poisons Standard is a legislative instrument under the *Therapeutic Goods Act 1989* (Cth) and is given legal effect through relevant state and territory drugs, poisons and controlled substances legislation.[28]

2.22 States and territories can adopt the current Poisons Standard as made, or adopt it subject to variations. In addition, each state and territory has its own laws that determine where consumers can buy a particular drug or poison, how it is to be packaged and labelled and penalties for possession, use and supply.[29]

2.23 Although each Australian jurisdiction may make its own laws to determine the availability of poisons and medicines, they have classified nicotine consistently with the Poisons Standard.[30]

2.24 There is a general prohibition on the commercial supply of nicotine e-cigarette products in every Australian jurisdiction. Other dealings with nicotine (such as possession, manufacturing and use) may also be prohibited and each state and territory has its own set of nicotine-related offences. States and territories have amended their tobacco control laws to treat the advertising, sale and use of e-cigarettes in a similar manner as tobacco products.[31]

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[26] Poisons Standard October 2020 (Cth).

[27] Department of Health, *Submission 167*, p. 7.

[28] TGA, *Contacts for State/Territory medicines & poisons regulation units*, 18 February 2020, https://www.tga.gov.au/contacts-stateterritory-medicines-poisons-regulation-units (accessed 8 December 2020),

[29] Department of Health, *Submission 167*, p. 7. For state and territory legislation regulating e-cigarettes, please see Heather Douglas, Wayne Hall and Coral Gartner, 'E-cigarettes and the law in Australia', *Australian Family Physician*, vol. 44, no. 6, 2015, Appendix 1.

[30] As at 9 October 2018, only the Australian Capital Territory, Tasmania and Western Australia had adopted Part 4 of the Poisons Standard subject to variations. See TGA, *Australian State & Territory variations from Part 4 of the Poisons Standard*, 31 May 2019, https://www.tga.gov.au/australian-state-territory-variations-part-4-poisons-standard (accessed 3 November 2020).

[31] TGA, *Electronic cigarettes*, 25 October 2019, https://www.tga.gov.au/community-qa/electronic-cigarettes (accessed on 29 October 2020).

Access to unapproved therapeutic goods

2.25 E-cigarettes containing nicotine can be legally imported by individuals through the Personal Importation Scheme under the *Therapeutic Goods Act 1989* (Cth), provided that appropriate rules are followed, including:

- the product is for personal use to quit smoking;[32]
- the importer must have a current valid prescription from an Australian-registered medical practitioner; and
- the importer cannot import more than 3 months' supply at one time under the Personal Importation Scheme, unless a doctor has applied to the TGA for approval for a longer duration of supply.[33]

2.26 The committee received a number of personal accounts detailing difficulties in obtaining a prescription for nicotine for e-cigarettes due to a refusal of doctors to write prescriptions.[34] These personal accounts are explored further in Chapter 4.

2.27 In addition to the Personal Importation Scheme, two further pathways to access unapproved therapeutic goods exist: the Special Access Scheme and the Authorised Prescriber Scheme.

2.28 Under the Authorised Prescriber pathway, the TGA is able to grant a medical practitioner authority to prescribe a specified unapproved nicotine product to a class of patients in their immediate care. Whereas, the Special Access Scheme provides for the import and/or supply of an unapproved therapeutic good for a single patient, on a case by case basis.

2.29 In addition, the Department of Health submitted that:

> 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.[35]

Pathway for approval

2.30 Chemicals with a therapeutic use (such as a chemical that aids in the cessation of cigarette smoking by influencing, inhibiting or modifying a physiological process) must be authorised for use by the TGA. As indicated in Schedule 7 of the Poisons Standard, nicotine may legally be used for human use in tobacco

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[32] An individual may also import these products for immediate family members, provided that family member holds a valid prescription.

[33] TGA, *Electronic cigarettes*, 25 October 2019, https://www.tga.gov.au/community-qa/electronic-cigarettes, (accessed on 29 October 2020).

[34] See, for example, Name withheld, *Submission 151*, [p. 1]; Name withheld, *Submission 193*, [p. 1]; Name withheld, *Submission 201*, [p. 2].

[35] Department of Health, *Submission 167*, p. 7.

prepared and packed for smoking and for therapeutic purposes where appropriate approvals and licences have been granted.[36]

2.31 Registered (TGA-approved) smoking cessation medicines in Australia include nicotine replacement therapies (such as sprays, patches, lozenges and chews) available without prescription either over-the-counter in pharmacies or, in some cases, from other retailers.

2.32 There is no legal impediment to submitting e-cigarette products that contain nicotine for TGA approval. An application for registration on the Australian Register of Therapeutic Goods could be made, which would involve an assessment of safety, efficacy and quality by the TGA, consistent with the requirements for existing nicotine replacement products.

2.33 However, the committee heard that product registration is 'enormously costly and onerous'.[37] The National Retail Association explained that 'there are many suppliers that would look to move their manufacturing on-shore should smoke-free nicotine products be made legal'.[38] However:

> What would make this untenable is for the product to be regulated by the TGA. Every product, including every flavour or composition, would have to be approved by the TGA which would incur huge costs to the supplier. This is why the regulation should be carried out by the ACCC who can ensure principles and standards of the product instead.[39]

2.34 At the time of reporting, no e-cigarette products have been approved by the TGA as a therapeutic good for smoking cessation.[40]

Relevant decisions of the Therapeutic Goods Administration

Proposal to exempt nicotine from Schedule 7 at 36mg/mL

2.35 On 23 March 2017, the TGA ruled against a proposal to exempt nicotine for use in e-cigarettes from Schedule 7 of the Poisons Standard. The proposed amendment would have allowed for a maximum nicotine concentration of 3.6 per cent in e-cigarettes, a maximum container size of 900 milligrams and required safety and labelling standards for packaging.[41]

2.36 The TGA ruled that the current scheduling of nicotine, which restricts access to the substance under the Poisons Standard, was appropriate. The TGA's

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36 Department of Health, *Submission 167*, p. 6.

37 Australian Tobacco Harm Reduction Association, *Submission 166*, p. 23.

38 National Retail Association, *Submission 156*, p. 6.

39 National Retail Association, *Submission 156*, p. 6.

40 Department of Health, *Submission 167*, p. 6.

41 TGA, *Scheduling delegate's final decisions, March 2017*, 23 March 2017, https://www.tga.gov.au/book-page/21-nicotine-0 (accessed 2 December 2020).

reasons for choosing not to exempt nicotine from Schedule 7 of the Poisons Standard included that:

- the possibility of e-cigarettes leading to nicotine dependence and a greater uptake of smoking among young people;
- the lack of evidence regarding the safety of long term nicotine use;
- the risk of nicotine poisoning, especially for children, and the increased rate of nicotine poisoning seen overseas following the growth in usage of e-cigarettes;
- uncertainties around the effectiveness of e-cigarettes as an aid for quitting smoking;
- risks of inappropriate marketing of e-cigarettes and inadequate protections against the sale of e-cigarettes to people under 18 years of age; and
- under existing regulation it is already possible for an e-cigarette product to be approved by the TGA if it is proven to be effective as a smoking cessation aid.[42]

Interim decision for scheduling of nicotine

2.37 On 23 September 2020, the TGA announced an interim decision that, if finalised, would clarify the scheduling of nicotine in the Poisons Standard. The proposed changes would mean that certain nicotine-containing products for human use could only be supplied with a doctor's prescription.[43]

2.38 As noted above, decisions related to the classification of medicines and poisons under the Poisons Standard are made by a senior medical officer (the delegate) in the Department of Health.[44]

2.39 During the course of its review of the proposed scheduling amendment, the Advisory Committee on Medicines and Chemicals Scheduling stated that the proposed scheduling amendment:

> …would remove a perceived inconsistency between Commonwealth and State and Territory laws regulating nicotine-containing e-cigarettes and help clarify the circumstances under which Australian Border Force may seize e-cigarettes containing nicotine, which are imported into Australia. In effect, it will remove the present uncertainty for some stakeholders over the regulatory treatment of nicotine.[45]

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[42] TGA, *Scheduling delegate's final decisions, March 2017*, 23 March 2017, https://www.tga.gov.au/book-page/21-nicotine-0 (accessed 2 December 2020).

[43] TGA, *Interim decision of entry of nicotine in the Poisons Standard: Information for consumers*, 23 September 2020, https://www.tga.gov.au/interim-decision-entry-nicotine-poisons-standard-information-consumers (accessed 30 November 2020).

[44] Department of Health, *Submission 167*, p. 9.

[45] TGA, *Interim decision of entry of nicotine in the Poisons Standard: Information for consumers*, 23 September 2020, https://www.tga.gov.au/interim-decision-entry-nicotine-poisons-standard-information-consumers (accessed 29 September 2020) p. 8.

2.40 The TGA clarified that the Personal Importation Scheme would remain available to individuals to order their e-cigarettes containing nicotine online with a prescription under the *Therapeutic Goods Act 1989* (Cth).[46]

2.41 A final decision is expected in mid-December 2020. However, the committee notes that the Australian Government's proposal to prohibit the importation of e-cigarettes containing nicotine (discussed below) would further restrict access to e-cigarette products. The interim decision on nicotine scheduling is a separate process from the Australian Government's proposed prohibition on the importation of e-cigarettes containing vaporiser nicotine.[47]

Proposal to prohibit the importation of e-cigarettes containing nicotine

2.42 In June 2020, the Australian Government announced its intention to amend the Customs (Prohibited Import) Regulations 1956 (Cth) to prohibit the importation of e-cigarettes containing vaporiser nicotine (nicotine in solution or in salt or base form) and nicotine-containing refills unless on prescription from a doctor.[48]

2.43 In an announcement on 26 June 2020, the Minister for Health, the Hon Greg Hunt MP, stated:

> In particular, around the world we have seen strong evidence of non-smokers being introduced to nicotine through vaping for the first time.
>
> Therefore the Government is responding to the advice by ensuring that nicotine based e-cigarettes can only be imported on the basis of a prescription from a doctor.
>
> This will help prevent the introduction of non-smokers to nicotine via vaping.
>
> However there is a second group of people who have been using these e-cigarettes with nicotine as a means to ending their cigarette smoking.
>
> In order to assist this group in continuing to end that addiction we will therefore provide further time for implementation of the change by establishing a streamlined process for patients obtaining prescriptions through their GP.

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[46] TGA, *Interim decision of entry of nicotine in the Poisons Standard: Information for consumers*, 23 September 2020, https://www.tga.gov.au/interim-decision-entry-nicotine-poisons-standard-information-consumers (accessed 30 November 2020).

[47] TGA, *Interim decision of entry of nicotine in the Poisons Standard: Information for consumers*, 23 September 2020, https://www.tga.gov.au/interim-decision-entry-nicotine-poisons-standard-information-consumers (accessed 30 November 2020).

[48] The Customs (Prohibited Imports) Amendment (Vaporiser Nicotine) Regulations 2020 (Cth) came into force on 25 June 2020. Prior to commencement, the amendment was repealed to allow time for the scheduling delegate to reach a final decision for the scheduling of nicotine in the Poisons Standard.

> For this reason, the implementation timeframe will be extended by six months to 1 January 2021.[49]

2.44 The TGA advised that the effect of the importation ban would be that individuals would no longer be permitted to import nicotine for use in e-cigarettes directly from an overseas supplier without a valid import permit.[50] The TGA clarified that:

> You will need a prescription from your doctor for an e-cigarette containing vaporiser nicotine, and it will need to be obtained on your behalf by a medical supplier or from a pharmacist who dispenses it for your use as the named patient. The company or the pharmacist will need to be given a copy of your prescription.[51]

2.45 In its submission, the Department of Health advised that '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'.[52]

2.46 The committee received evidence about the possible options for the regulation of nicotine e-cigarette products in Australia and the outcomes of consumer goods regulation rather than a prescription-based model. This is discussed further in Chapter 6.

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[49] The Hon Greg Hunt MP, Minister for Health, 'Prescription Nicotine Based Vaping', *Media Release*, 26 June 2020.

[50] TGA, *Prohibition in importing e-cigarettes containing vaporiser nicotine*, 29 June 2020, https://www.tga.gov.au/behind-news/prohibition-importing-e-cigarettes-containing-vaporiser-nicotine (3 November 2020).

[51] TGA, *Prohibition in importing e-cigarettes containing vaporiser nicotine*, 29 June 2020, https://www.tga.gov.au/behind-news/prohibition-importing-e-cigarettes-containing-vaporiser-nicotine (3 November 2020).

[52] Department of Health, *Submission 167*, p. 9.

Chapter 3 - Jurisdictional comparison

Overview

3.1 Globally, there are significant differences in how countries regulate e-cigarettes and related products. Common approaches include regulating e-cigarettes as tobacco products, a unique product type, a consumer good, a therapeutic product or a combination of these approaches.

3.2 This chapter explores the approaches other jurisdictions have taken towards e-cigarette regulation. In particular, it sets out guidance provided by the World Health Organisation (WHO) and examines regulatory frameworks in New Zealand, the United States, the European Union (EU) and the United Kingdom (UK).

World Health Organization

3.3 The *World Health Organisation Framework Convention on Tobacco Control* (WHO FCTC), to which Australia is a party, has as its objective to:

> Protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke by providing a framework for tobacco control measures to be implemented by the Parties at the national, regional and international levels in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke.[1]

3.4 In 2014, the WHO reported that in countries with very low rates of tobacco smoking, the use of e-cigarettes did not result in reductions in the rates of disease and mortality caused by smoking.[2]

3.5 In 2016, the WHO reported on *Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS)*.[3] This report emphasised that the potential role for e-cigarettes in tobacco control was still subject to debate. The magnitude of health risks associated with e-cigarettes was assessed as likely to be lower than combustible cigarettes, but there was a dearth of evidence to quantify the relative risk between e-cigarettes and combustible cigarettes. In this report, the WHO advocated for measures to safeguard public

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1 WHO FCTC, Geneva, 21 May 2003, entry into force on 27 February 2005, [2005] ATS 7, Article 3.

2 WHO, *Electronic Nicotine Delivery Systems*, July 2014, p. 11.

3 WHO, *Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS)*, August 2016.

health, prevent the proliferation of tobacco addiction problems and protect tobacco control efforts.[4]

3.6 In 2019, the *WHO Report on the Global Tobacco Epidemic* observed that:

> The scientific evidence on e-cigarettes as cessation aids is inconclusive and there is a lack of clarity as to whether these products have any role to play in smoking cessation. There are also real concerns about the risk they pose to non-smokers who start to use them, especially young people. Unlike the tried and tested nicotine and non-nicotine pharmacotherapies that are known to help people quit tobacco use, WHO does not endorse e-cigarettes as cessation aids.[5]

Regulatory responses to e-cigarettes in other jurisdictions

3.7 Currently, there is no international consensus on the most appropriate regulatory framework for e-cigarettes. The regulatory arrangements applicable to e-cigarettes vary considerably within and across countries, ranging from prohibition to minimal or no regulation.

3.8 Broadly, e-cigarettes may be regulated under regulatory frameworks that apply to tobacco products, poisons, medicines (including medical devices) and consumer products.[6] In some countries, such as the UK, e-cigarettes containing nicotine are regulated either as consumer products or as medicines depending whether smoking cessation claims are made for the particular product.[7]

3.9 Professor Wayne Hall and Associate Professor Carol Gartner advised the committee that e-cigarettes may be regulated in a number of ways, including as:

- consumer goods to ensure consumer safety and minimise misleading advertising;
- tobacco products in much the same ways as combustible cigarettes (for example with age restrictions on sales, bans on advertising and no use permitted in enclosed public areas);
- therapeutic aids for smoking cessation; or
- dangerous poisons or drugs prohibited for use by adults.[8]

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4 WHO, *Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS)*, August 2016.

5 WHO, *WHO Report on the Global Tobacco Epidemic, 2019: Offer to help quit tobacco use*, July 2019, p. 47.

6 Department of Health, *Submission 167*, p. 14.

7 Department of Health, *Submission 297*, Standing Committee on Health, Aged Care and Sport, *Inquiry into the use and marketing of electronic cigarettes and personal vaporisers in Australia*, p. 6.

8 Professor Wayne Hall and Associate Professor Coral Gartner, *Submission 159*, p. 5.

3.10 While most countries do not have laws that specifically relate to e-cigarettes, a number of countries have introduced restrictions or bans, including:

- bans on commercial sale;
- bans on sale to minors;
- bans on use in public places;
- product safety;
- taxation; and
- advertising and promotion.[9]

3.11 The following section examines the regulatory frameworks of New Zealand, the United States, the EU and the UK.

New Zealand

3.12 In New Zealand, e-cigarettes are regulated under the *Smokefree Environments and Regulated Products Act 1990* (NZ). The New Zealand Government recently passed the *Smokefree Environments and Regulated Products (Vaping) Amendment Act 2020* (the Amendment Act) which extended the existing restrictions on the advertising, promotion, sale, and distribution of tobacco products to all regulated products (including e-cigarettes).

3.13 According to the Ministry of Health, the Amendment Act 'strikes a balance between ensuring vaping products are available for smokers who want to switch to a less harmful alternative and ensuring these products are not marketed or sold to young people'.[10] E-cigarette products that make therapeutic claims must be approved by Medsafe.

3.14 Under the Amendment Act a range of restrictions apply to e-cigarettes including:

- prohibition of vaping inside workplaces, schools, early childhood education and care centres, and legislated smokefree areas;
- prohibition of advertising and sponsorship relating to vaping products;
- prohibition on the sale of vaping products and toy vaping products to persons under 18 years of age;
- prohibition on the importation and sale of nicotine products for chewing or similar oral use;
- a requirement for manufacturers and importers to report any adverse reactions to vaping products;

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[9] Elizabeth Greenhalgh, Randolph Grace and Michelle Scollo, 'Section 18B.9 International regulatory overview' in Michelle Scollo and Margaret Winstanley (eds), *Tobacco in Australia: Facts and issues*, Cancer Council Victoria, 2019.

[10] New Zealand Ministry of Health, *Regulation of vaping and smokeless tobacco products*, 11 November 2020, https://www.health.govt.nz/our-work/regulation-health-and-disability-system/regulation-vaping-and-smokeless-tobacco-products (accessed 2 December 2020).

- prohibition of vaping and smokeless tobacco products to contain colouring substances;
- prohibition of vaping in motor vehicles carrying children; and
- a requirement for regulated products (including e-cigarettes) to be notified to ensure product safety requirements are met.[11]

3.15 Regulations setting out requirements in relation to packaging and labelling are expected in 2021.

3.16 The Vaping Regulatory Authority is responsible for the regulation of e-cigarettes. As such, it manages applications from retailers to become specialist vape retailers (and to apply for approved vaping premises and approved internet sites) and receives annual reporting information from manufacturers, importers and specialist vape retailers.[12]

3.17 Local councils and individual businesses can make their own policies around vaping as long as they meet the minimum requirements of the law. For example, an employer may decide that a specific outdoor space can be used for vaping, or alternatively no vaping should be allowed in any outdoor areas controlled by the employer.[13]

The United States

3.18 In the United States, the Food and Drug Administration (FDA) classifies e-cigarettes as tobacco products. The FDA regulates the manufacturing, distribution, retail sale and marketing of tobacco products under the *Family Smoking Prevention and Tobacco Control Act 2009* (US) (Tobacco Control Act). Products marketed for therapeutic purposes are regulated by the FDA Center for Drug Evaluation and Research.[14]

3.19 In the United States, a number of restrictions apply in relation to e-cigarettes. These include:

- a minimum age for purchase of tobacco products (including e-cigarettes);[15]

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[11] New Zealand Ministry of Health, *About the Smokefree Environments and Regulated Products (Vaping) Amendment Act*, 20 October 2020, https://www.health.govt.nz/our-work/regulation-health-and-disability-system/regulation-vaping-and-smokeless-tobacco-products/about-smokefree-environments-and-regulated-products-vaping-amendment-act (accessed 9 November 2020).

[12] New Zealand Ministry of Health, *About the Vaping Regulatory Authority*, 9 October 2020, https://www.health.govt.nz/our-work/regulation-health-and-disability-system/regulation-vaping-and-smokeless-tobacco-products/about-vaping-regulatory-authority (accessed 30 November 2020).

[13] New Zealand Ministry of Health and the Health Promotion Agency, *Vaping Law and Policy*, https://vapingfacts.health.nz/the-facts-of-vaping/vaping-law-and-policy/ (accessed 9 November 2020).

[14] FDA, *Development & Approval Process | Drugs*, content current as at 28 October 2019, https://www.fda.gov/drugs/development-approval-process-drugs (accessed 2 December 2020).

[15] On 20 December 2019, legislation that increased the federal minimum age for sale of tobacco products from 18 years to 21 years came into force. The new federal minimum age of sale applies

- restrictions on promotion and advertising;[16]
- requirements for packaging and product information (including child-resistant packaging for nicotine-containing e-liquid containers);[17]
- product quality and safety;[18]
- restrictions on the use of flavours and ingredients;[19] and
- restrictions on where e-cigarettes are used.[20]

3.20 The United States also regulates novel tobacco products using a system of marketing and modified risk orders for novel tobacco products. A Premarket Tobacco Product Application must:

> …provide scientific data that demonstrates a product is appropriate for the protection of public health. In order to reach such a decision and to authorize marketing, FDA considers, among other things:
>
> - Risks and benefits to the population as a whole, including people who would use the proposed new tobacco product as well as nonusers;
> - Whether people who currently use any tobacco product would be more or less likely to stop using such products if the proposed new tobacco product were available;

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to all retail establishments and persons with no exceptions. See FDA, *Tobacco 21*, content current as of 12 February 2020, https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/tobacco-21 (accessed 9 November 2020).

[16] The Tobacco Control Act requires that smokeless tobacco packages and advertisements have larger and more visible warnings. For further information see FDA, *"Covered" Tobacco Products and Roll-Your-Own/ Cigarette Tobacco Labeling and Warning Statement Requirements*, 6 October 2020, https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/covered-tobacco-products-and-roll-your-own-cigarette-tobacco-labeling-and-warning-statement (accessed 30 November 2020).

[17] Any person involved in making, modifying, mixing, manufacturing, fabricating, assembling, processing, labelling, repacking, relabelling or importing any tobacco product including e-cigarettes for sale or distribution in the US is considered a tobacco product manufacturer and must comply with a range of FDA tobacco regulations including submitting tobacco product marketing applications, reporting, registration, ingredient listing, and including required warnings on packaging and advertisements. Packaging and advertisements of e-cigarettes must bear the following warning statement: 'WARNING: This product contains nicotine. Nicotine is an addictive chemical.' For e-cigarettes that are made or derived from tobacco but do not contain nicotine, the alternative statement, 'This product is made from tobacco' should be placed on packaging and advertisements. For further information see FDA, *Vaporizers, E-Cigarettes, and other Electronic Nicotine Delivery Systems (ENDS)*, content current as of 17 September 2020, https://www.fda.gov/tobacco-products/products-ingredients-components/vaporizers-e-cigarettes-and-other-electronic-nicotine-delivery-systems-ends (accessed 9 November 2020).

[18] See 15 USC § 1472a.

[19] In January 2020, the FDA released a policy prioritising enforcement against certain unauthorised flavoured e-cigarette products that appeal to youth, including fruit and mint flavours. For further information see FDA, *Enforcement Priorities for Electronic Nicotine Delivery System (ENDS) and Other Deemed Products on the Market Without Premarket Authorization: Guidance for Industry*, April 2020.

[20] Smoke-free laws are the responsibility of individual states.

- Whether people who currently do not use any tobacco products would be more or less likely to begin using tobacco products if the new product were available; and
- The methods, facilities, and controls used to manufacture, process, and pack the new tobacco product.[21]

3.21 A further regulatory pathway is available for modified risk tobacco products which 'demonstrate that the product will or is expected to benefit the health of the population as a whole.'[22]

The European Union

3.22 In the EU, e-cigarettes are regulated as consumer products under the Tobacco Products Directive (TPD).[23] The TPD does not cover nicotine-containing products that are authorised as medicines.

3.23 The TPD sets out requirements for maximum nicotine concentration, packaging and labelling. The TPD requires EU Member States to:

- meet minimum product standards for the safety and quality of all e-cigarettes refill containers (otherwise known as e-liquids);[24]
- provide information to consumers so that they can make informed choices;
- restrict e-cigarette tanks to a capacity of no more than 2ml;
- restrict the maximum volume of nicotine-containing e-liquid for sale in one refill container to 10ml;
- restrict e-liquids to a nicotine strength of no more than 20mg/ml;
- require nicotine-containing products or their packaging to be child-resistant and tamper evident;
- ban certain ingredients including colourings, caffeine and taurine;
- include new labelling requirements and warnings;
- provide notification requirements prior to the placement of products on the market; and
- ban advertising of e-cigarettes.[25]

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[21] FDA, *Premarket Tobacco Product Applications*, content current as of 11 September 2020, https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications (accessed 7 December 2020).

[22] FDA, *Modified Risk Tobacco Products*, content current as of 1 December 2020, https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-tobacco-products (accessed 7 December 2020).

[23] *Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC, [1994] OJ C 29 April 2014* [2014] OJ L 127/1, article 32.

[24] These include standards for ingredients and emissions.

3.24 EU Member States implement domestic legislation to give effect to these requirements (as discussed below in relation to the UK).

The United Kingdom

3.25 In the UK, e-cigarettes containing nicotine are regulated as consumer goods under the TPD. The TPD is given legal effect through domestic legislation,[26] specifically in relation to safety,[27] sales to minors,[28] advertising,[29] and use of e-cigarettes in public places and workplaces.[30] Non-nicotine containing e-cigarettes in the UK are regulated through the General Product Safety Regulations 2005 (UK) and are enforced by local trading standards.[31]

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[25] Medicines and Healthcare products Regulatory Agency, *E-cigarettes: regulation for consumer products*, 25 November 2020, https://www.gov.uk/guidance/e-cigarettes-regulations-for-consumer-products (accessed 30 November 2020).

[26] The Tobacco and Related Products Regulations 2016 (UK) implements the TPD in the UK and came fully into force on 20 May 2017.

[27] Manufacturers, importers and distributors of e-cigarettes also need to comply with the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 (UK). These regulations limit the amount of certain hazardous substances in specific electrical equipment, of which e-cigarettes are included. They place obligations onto manufacturers, importers and distributors of e-cigarette models. E-cigarette producers must inform Medicines and Healthcare products Regulatory Agency if they have reason to believe that a notifiable product is unsafe, not of good quality or not compliant with the TPD and provide details of the risk to human health and safety and any corrective action taken.

[28] The Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015 (UK) prohibits the sale of nicotine inhaling products, also known as e-cigarettes and certain related parts of such devices to people under the age of 18 years and extends the offence of proxy purchasing of tobacco products to nicotine inhaling products.

[29] Article 20(5) of the TPD requires EU Member States to introduce restrictions on the advertising of electronic cigarettes. In the UK, these rules have been implemented in the *Communications Act 2003* (UK), changes by Ofcom (the communications regulator in the UK) to the UK Code of Broadcast Advertising and in the Tobacco and Related Products Regulations 2016 (UK).

[30] The *Health Act 2006* (UK) prohibits smoking in enclosed public places and workplaces, on public transport and in vehicles used for work. However, e-cigarette use is not covered by this smoke-free legislation as e-cigarettes do not burn tobacco and do not create smoke. Public Health England has issued guidance on the use of e-cigarettes in public places and workplaces which allows businesses and employers to create their own policies on the use of e-cigarettes. For further information see Public Health England, *Guidance: E-cigarettes in public places and workplaces: a 5-point guide to policy making*, 6 July 2016, https://www.gov.uk/government/publications/use-of-e-cigarettes-in-public-places-and-workplaces/e-cigarettes-in-public-places-and-workplaces-a-5-point-guide-to-policy-making (accessed 9 November 2020).

[31] Department of Health, *Submission 167*, p. 27.

3.26 The Medicines and Healthcare products Regulatory Agency is the authority responsible for implementing the majority of provisions under Article 20 of the TPD.[32]

3.27 There are separate requirements to license e-cigarettes as medicines or medical devices in the UK.[33] The Medicines and Healthcare products Regulatory Agency is also responsible for regulating nicotine-containing products that are medicinal products, including e-cigarettes which make therapeutic claims.

3.28 With the UK departure from the EU and the transition period ending on 31 December 2020, the UK made the Tobacco Products and Nicotine Inhaling Products (Amendment etc.) (EU Exit) Regulations 2019 (UK) which will 'ensure that, in the unlikely scenario that the UK leaves the EU with no deal, there will continue to be a functioning statute book on exit day which maintains continuity in relation to tobacco control policy and legislation'.[34]

[32] Medicines and Healthcare products Regulatory Agency, *E-cigarettes: regulations for consumer products*, 29 February 2016, https://www.gov.uk/guidance/e-cigarettes-regulations-for-consumer-products (accessed 9 November 2020).

[33] Medicines and Healthcare products Regulatory Agency, *Guidance: Licensing procedure for electronic cigarettes as medicines*, 14 December 2017, https://www.gov.uk/guidance/licensing-procedure-for-electronic-cigarettes-as-medicines (accessed 2 December 2020).

[34] Explanatory Memorandum, Tobacco Products and Nicotine Inhaling Products (Amendment etc.) (EU Exit) Regulations 2019 (UK), p. 1.

Chapter 4 - Personal accounts

Introduction

4.1 This chapter considers the personal testimonies that were provided to the committee. The committee received over 700 submissions from individuals which outlined their experiences with e-cigarettes. The committee also received 8 324 form letters in support of e-cigarette usage, including a large number from e-cigarette users, which detailed their personal experiences using e-cigarettes. The majority of these personal accounts outlined how individuals have successfully reduced their consumption of combustible cigarettes by using e-cigarettes.

4.2 For additional context, when a submitter is quoted, their age and the length of time that they have previously smoked combustible cigarettes is noted—when known—in the footnote.[1] Submitters have been quoted to the greatest extent possible to accurately convey their lived experiences.

Reasons and motivations for using e-cigarettes

4.3 The following considers why individuals use e-cigarettes. Some submitters reported using e-cigarettes in order to quit or otherwise minimise their usage of combustible cigarettes. A number of submitters also reported improvements to their health, finances and overall lifestyle. We note that the motivations described in the form letters received recounted similar improvements to health, finances and quality of life.

Improved health

4.4 The vast majority of personal accounts received were from current and former smokers who reported significant health improvements as a result of transitioning from combustible cigarettes to e-cigarettes or a reduction in smoking.[2] The committee did not receive any submissions that indicated that

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[1] This report replicates the language used by submitters where possible. Submitters commonly use the terms 'smoker' (i.e. a user of combustible cigarettes) and 'vaper' (i.e. a user of e-cigarettes and related products).

[2] See, for example, Mr Tom Morawetz, *Submission 2*, [p. 1]; Name withheld, *Submission 3*, [p. 1]; Mr James Reid, *Submission 4*, [p. 1]; Mr Alan Beard, *Submission 6*, [p. 1]; Name withheld, *Submission 7*, [p. 1]; Mr Shane Kerrigan, *Submission 8*, [p.1]; Mrs Yvette Hopkins, *Submission 9*, [p. 1]; Ms Maureen Steele, *Submission 10*, [p. 2]; Mr Anthony Barron, *Submission 11*, [p. 1]; Name withheld, *Submission 12*, [p. 1]; Name withheld, *Submission 13*, [p. 1]; Name withheld, *Submission 14*, [p. 1]; Mr Grant Clark, *Submission 15*, [pp. 1-2]; Name withheld, *Submission 17*, [p. 1]; Name withheld, *Submission 18*, [p. 1]; Name withheld, *Submission 19*, [p. 1]; Name withheld,

Submission 20 [p. 1]; Name withheld, *Submission 21* [p. 1]; Name withheld, *Submission 22* [p. 2]; Name withheld, *Submission 24* [p. 2]; Mr Joshua Waters, *Submission 28*, [p. 3]; Mr Michael Sandic, *Submission 29*, [p. 1]; Dr Richard Watkins, *Submission 31*, [p. 1]; Name withheld, *Submission 32* [p. 1]; Mr Colin Mannings, *Submission 33* [p. 1]; Ms Sheryl Mulvey, *Submission 35*, [p. 1]; Mr Lewis Johnson, *Submission 36*, [p. 1]; Mr Graeme Angrave, *Submission 37*, [p. 1]; Name withheld, *Submission 39*, [p. 1]; Mr Troy Jeppesen, *Submission 42*, [p. 1]; Mr Chris Hansen, *Submission 46*, [p. 1]; Mr Chris Hansen, *Submission 46*, [p. 1]; Name withheld, *Submission 47*, [p. 1]; Mr Adrian Sheehan, *Submission 49*, [pp. 1-2]; Mr Adam Metelmann, *Submission 51*, [p. 2]; Name withheld *Submission 53*, [p. 1]; Mr Matthew Landau, *Submission 54*, p. 4; Mr Stuart Bowermann, *Submission 55*, [p. 1]; Shayne O'Neill, *Submission 56*, [p. 1]; Mr Gerrad Geard, *Submission 57*, [p. 1]; Name withheld *Submission 59*, [p. 1]; Name withheld *Submission 60*, [p. 1]; Name withheld, *Submission 64*, [p. 1]; Mr Michael Gorman, *Submission 68*, [p. 1]; Ms Donella Houghton, *Submission 69*, [p. 1]; Name withheld, *Submission 71*, [p. 1]; Name withheld, *Submission 72*, [p. 1]; Name withheld, *Submission 73*, [p. 1]; Mr Steve Rehberger, *Submission 74*, [pp. 1-2]; Mr Samuel Cahir, *Submission 75*, [p. 1]; Mr Bill Stewart, *Submission 76*, [p. 1]; Name withheld, *Submission 78*, [p. 1]; Name withheld, *Submission 79*, [p. 1]; Name withheld, *Submission 81*, [p. 2]; Mr Keith Pengilly, *Submission 82*, [p. 1]; Mr Mark Watson, *Submission 84*, p. 1; Ms Bonnie Schultz, *Submission 86*, p. 1; Name withheld, *Submission 87*, p. 1; Name withheld, *Submission 88*, p. 1; Mr Logan Evans, *Submission 90*, p.1; Name withheld, *Submission 91*, p. 1; Name withheld, *Submission 93*, p. 1; Name withheld, *Submission 96*, p. 1; Name withheld, *Submission 98*, [p. 1];]; Ms Dianne Gorman, *Submission 100*, [p. 1]; Name withheld, *Submission 101*, [p. 1]; Ms Samantha Barratt, *Submission 102*, [p. 1]; Mr John Walker, *Submission 106*, [p. 1]; Mr Paul Montague, *Submission 108*, p. 1; Mr John Richardson, *Submission 109*, [p. 1]; Name withheld, *Submission 111*, [p. 1]; Name withheld, *Submission 112*, [p. 1]; Ms Penelope Turner, *Submission 113*, [p.1]; Name withheld, *Submission 116*, [p. 1]; Mr Damien Noonan, *Submission 117*, [p. 1]; Name withheld, *Submission 118*, [p. 1]; Mr John Littlewood, *Submission 119*, [p. 1]; Mr Ken McNaughton, *Submission 121*, [p. 1]; Name withheld, *Submission 122*, [p. 1]; Mr Michael Stewart, *Submission 124*, [p. 1]; Ms Alison Paul, *Submission 125*, [p. 1]; Mr Shail Akhil, *Submission 126*, [p. 1]; Name withheld, *Submission 127*, [p. 1]; Name withheld, *Submission 128*, [p. 1]; Name withheld, *Submission 131*, [pp. 1-2]; Mr Andrew Thompson, *Submission 133*, [p. 1]; Mr Tim Palmer, *Submission 134*, [p. 1]; Miss Leesa Austin, *Submission 141*, [pp. 1-2]; Mr Luke Oliver, *Submission 142*, [p. 1]; Dr David Mutch, *Submission 143*, [p. 1]; Ms Deborah Smith, *Submission 144*, [p. 1]; Name withheld, *Submission 145*, [p. 1]; Name withheld, *Submission 146*, [p. 1]; Ms Cat Wright, *Submission 147*, [p. 1]; Name withheld, *Submission 149*, [pp. 1-2]; Mr Foo Bar, *Submission 150*, [p. 1]; Ms Licia Pappas, *Submission 152*, [p. 1]; Name withheld, *Submission 154*, [p. 1]; Name withheld, *Submission 168*, [p. 1]; Name withheld, *Submission 175*, [p. 5]; Mr Robert Pestell, *Submission 179*, [p. 1]; Ms Hayley Dekker Lennon, *Submission 181*, [p. 1]; Dr Nicholas Cope, *Submission 185*, [p. 2]; Mr Adam Hazebroek, *Submission 187*, [p. 1]; Name withheld, *Submission 189*, p. 1; *Name withheld, Submission 191*, [p. 1]; Name withheld, *Submission 192*, [p. 1]; Name withheld, *Submission 193*, [p. 1]; Mr Rodney Bambridge, *Submission 196*, [p. 1]; Mr Damien Hackett, *Submission 198*, p. 1; Name withheld, *Submission 201*, [p. 1]; Mr Justin Fowler, *Submission 203*, [p. 2]; Name withheld, *Submission 205*, [p. 1]; Name withheld, *Submission 206*, [p. 1]; Mr Arthur Wielgosz, *Submission 207*, [p. 1]; Mr Charles McCracken, *Submission 211*, [p. 2]; Mr Iain Carson, *Submission 212*, [p. 1]; Name withheld, *Submission 218*, p. 1; Mr Adam Hickmott, *Submission 219*, [p. 1]; Mrs Judith Wolters, *Submission 221*, [p. 1]; Ms Rachael James, *Submission 224*, [p. 1]; Ms Angela Gordon, *Submission 225*, [pp. 1-2]; Mr Brave Front, *Submission 229*, [p. 1]; Name withheld, *Submission 231*, [p. 2]; Mr Norbert Zillatron Schmidt, *Submission 249*, [p. 1]; Mr Robert Richter, *Submission 252*, [p. 1]; Name withheld, *Submission 256*, [p. 1]; Ms Annette Huppatz, *Submission 265*, [p. 1]; Mr Patrick Cameron, *Submission 277*, [p. 1]; Name withheld, *Submission 281*, [p. 1]; Name withheld, *Submission 284*, [p. 1]; Name withheld, *Submission 285*, [p. 1]; Name withheld, *Submission 286*, p. 6; Mr Robert Rogers, *Submission 291*, [p. 1]; Mr Paul Clarence, *Submission 293*, [p. 1]; Mr Wayne Betts, *Submission 295*,

[p. 1]; Mr Christopher Boreham-Carna, *Submission 296*, [p. 1]; Mr Travis Hinds, *Submission 297*, [p. 1]; Mr Duncan McLaren, *Submission 298*, [p. 1]; Ms Lyn Bennetts, *Submission 299*, [p. 1]; Mr Dan Tarasenko, *Submission 300*, [p. 1]; Ms Pam Mulholland, *Submission 301*, [p. 1]; Mr Troy Luff, *Submission 302*, [p. 1]; Mr Damien Noonan, *Submission 303*, [p. 1]; Mr Angelo Ferlauto, *Submission 304*, [pp. 1-2]; Kaye Matthews, *Submission 305*, [p. 1]; Mr Vince McDevitt, *Submission 306*, [p. 1]; Ms Sheryl Mulvey, *Submission 307*, [p. 1]; Mr Alpha Centauri, *Submission 308*, [p. 1]; Mr Paul Briton, *Submission 309*, [p. 1]; Mr Sam Whitehead, *Submission 310*, [p. 1]; Mr Paul Webster, *Submission 311*, [p. 1]; Ms Naomi Groenendyk, *Submission 312*, [p. 1]; Mr Chris Blanch, *Submission 313*, [p. 1]; Mr Keith Lewis, *Submission 314*, [p. 1]; Ms Donna Garrett, *Submission 315*, [p. 1]; Mr Jacent Hipworth, *Submission 316*, [p. 1]; Mr Dan Lucas, *Submission 318*, [p. 1]; Mr Craig Brown, *Submission 320*, [p. 1]; Mr Robert Finlay, *Submission 321*, [p. 1]; Ms Angie Billenstein, *Submission 323*, [p. 1]; Mr Max Gorvel, *Submission 324*, [p. 1]; Mr Troy Smith, *Submission 325*, [p. 1]; Ms Cheryl Rafferty, *Submission 327*, [p. 1]; Ms Kerrie Baker, *Submission 328*, [p. 1]; Ms Paula Foley, *Submission 332*, [p. 1]; Mr Brian Moss, *Submission 334*, [p. 2]; Mr Alistair McQuilkan, *Submission 335*, [p. 1]; Mr D Hart, *Submission 336*, [p. 1]; Mr Nick Hrysanidis, *Submission 339*, [p. 1]; Mr Jason Traynor, *Submission 341*, [p. 1]; Mr Dan Holmes, *Submission 342*, [p. 1]; Mr John Moore, *Submission 343*, [p. 1]; Ms Angela Hauke, *Submission 344*, [p. 1]; Miss Peta Longstaff, *Submission 345*, [p. 1]; Mr Peter Saunders, *Submission 347*, [p. 1]; Ms Tammie Opie, *Submission 348*, [p. 1]; Ms Kathleen Jordan, *Submission 349*, [p. 1]; Ms Maree McClung, *Submission 350*, [p. 1]; Mr George Teepa, *Submission 350*, [p. 1]; Mr Clay Bell, *Submission 351*, [p. 1]; Ms Scarlett Niven, *Submission 352*, [p. 1]; Ms Sandy Hill, *Submission 355* [p. 1]; Mr Bunny Lim, *Submission 356* [p. 1]; Mr Edwin Seward, *Submission 357* [p. 1]; Mr John Brown, *Submission 358* [p. 1]; Ms Lauren Chalmers, *Submission 360*, [pp. 1-2]; Mr Michael Byrne, *Submission 361*, [p. 2]; Mr Shaun Drew, *Submission 362*, [p. 1]; Ms Sheila Marsh, *Submission 363*, [pp. 1-2]; Mr Mark Temple, *Submission 364*, [p. 1]; Mr David Ormsby, *Submission 366*, [p. 1]; Mr Michael Oltmanns, *Submission 367*, [p. 1]; Mr Gerard McLinden, *Submission 368*, [p.21]; Mr Christopher Merry, *Submission 369*, [p. 1]; Mr Chris Cassidy, *Submission 371*, [p. 1]; Mr Gary Russell, *Submission 372*, [p. 1]; Ms Tracey Fawdry, *Submission 373*, [p. 1]; Mr Howard Randell, *Submission 374*, [p. 1]; Ms Tara Orr, *Submission 375*, [p. 1]; Mr Will Weatherly, *Submission 377*, [p. 1]; Mr Jon Starink, *Submission 378*, [p. 1]; Mrs Denise Russell, *Submission 379*, [p. 1]; Mr Shane Robison, *Submission 380*, [p. 1]; Mr Peter Sharman, *Submission 381*, [p. 1]; Mr Cliff Chandler, *Submission 383*, [p. 1]; Mr Bryan Willis, *Submission 385*, [p. 1]; Ms Tara Holyoake, *Submission 386*, [p. 1]; Mr Daniel Stewart, *Submission 387*, [p. 1]; Mr Russ Wilson, *Submission 388*, [p. 1]; Mr Christian O'Brien, *Submission 389*, [p. 1]; Ms Jasmine Pene, *Submission 390*, [p. 1]; Mr Malcolm Bodie, *Submission 391*, [p. 1]; Mr Ben McBeth, *Submission 393*, [p. 1]; Mr Craig Farquharson, *Submission 396*, [p. 1]; Mr Francis M, *Submission 398*, [p. 1]; Mr Simon Wells, *Submission 399*, [p. 1]; Mr Christiaan van Schalkwyk, *Submission 400*, [p. 1]; Mr Jock Mac, *Submission 401*, [p. 1]; Mr Brad Hendry, *Submission 402*, [p. 1]; Name withheld, *Submission 405*, [p. 1]; Name withheld, *Submission 406*, [p. 1]; Name withheld, *Submission 407*, [p. 1 and p. 3]; Name withheld, *Submission 408*, [p. 1]; Name withheld, *Submission 409*, [p. 1]; Name withheld, *Submission 410*, [p. 1]; Name withheld, *Submission 412*, [p. 1]; Name withheld, *Submission 413*, [p. 1]; Name withheld, *Submission 414*, [p. 1]; Name withheld, *Submission 415*, [p. 1]; Name withheld, *Submission 416*, [p. 1]; Name withheld, *Submission 417*, [p. 1]; Name withheld, *Submission 418*, [p. 1]; Name withheld, *Submission 419*, [p. 1]; Name withheld, *Submission 420*, [p. 1]; Name withheld, *Submission 421*, [p. 1]; Name withheld, *Submission 424*, [p. 1]; Name withheld, *Submission 426*, [p. 1]; Name withheld, *Submission 427*, [p. 2]; Name withheld, *Submission 428*, [p. 1]; Name withheld, *Submission 429*, [p. 1]; Name withheld, *Submission 430*, [p. 1]; Name withheld, *Submission 432*, [p. 1]; Name withheld, *Submission 433*, [p. 1]; Name withheld, *Submission 434*, pp. 1-2; Name withheld, *Submission 435*, [p. 1]; Name withheld, *Submission 436*, [p. 1]; Name withheld, *Submission 438*, [p. 1]; Name withheld, *Submission 439*, [p. 1]; Name withheld, *Submission 440*, [p. 1]; Name

health outcomes had worsened due to e-cigarette usage. Improvements to health—particularly in relation to breathing, congestion and a general sense of wellbeing—were consistent throughout the personal accounts submitted to the committee.

4.5 Submitters who previously smoked combustible cigarettes were aware of the health impacts of smoking tobacco. Evidence was provided to the committee that many long-term smokers felt the health impacts of smoking on a daily basis, but were unable to quit smoking, despite multiple attempts to do so. After beginning to use e-cigarettes, submitters reported improvements to their health that ranged from relatively minor to potentially lifesaving.

4.6 One submitter reported what such improvements looked like:

> 2 weeks into vaping and quitting tobacco cigarettes, I no longer felt my breathing was shallow or laboured, my continual coughing stopped, I no longer had phlegm/mucus build-up from my smoking and most definitely now my sense of smell was back (which meant I had to basically throw out the majority of my clothes because I could properly sense how bad they smelled of stale cigarette smoke).[3]

4.7 Another submitter reported improvements to their lung health in particular:

> My partner is asthmatic and he used to have bad coughing attacks which made him vomit and have to use his inhaler a lot and now he does not have these attacks of coughing and only uses his inhaler when needed which is not much, vaping has saved his life and health. I was having bad chest pains to the point of crumpling over in pain and since I have given up smoking I do not suffer these much at all I cant even remember the last time this has happened and I also had a chest xray to see if there was any damage to my lungs from smoking and the results were amazing they are clear but if I kept smoking the outcome could have been a lot worse.[4]

4.8 Similarly, Mrs Judith Wolters observed that the health benefits since switching to vaping included:

- Improvement in my mental health. I often slipped into deep depression when smoking and didn't really care if I lived or died but I don't become depressed now since I switched.
- No more regular chest infections.

withheld, *Submission 441*, [p. 1]; Name withheld, *Submission 442*, [p. 1]; Name withheld, *Submission 443*, [p. 1]; Name withheld, *Submission 444*, [p. 1]; Name withheld, *Submission 445*, [p. 1]; Name withheld, *Submission 447*, [p. 1]; Name withheld, *Submission 448*, [p. 1]; Name withheld, *Submission 450*, [p. 1]; Name withheld, *Submission 452*, [p. 1]; Name withheld, *Submission 455*, [p. 1]; Name withheld, *Submission 456*, [p. 2]; Name withheld, *Submission 457*, [p. 1]; Name withheld, *Submission 458*, [p. 1]; and Name withheld, *Submission 459*, [p. 1].

3 Mr Adam Metelmann, *Submission 51*, [p. 2] (45 years of age, previously a smoker for 23 years).

4 Name withheld, *Submission 13*, [p. 1] (age unknown, previously a smoker for over 29 years).

- I stopped coughing constantly, especially in the mornings when I coughed violently and feared I could break a rib. Now I have to force myself to cough to clear my lungs.
- I could suddenly breathe through my nose and my sleep apnoea stopped. In fact my son was so alarmed when he couldn't hear me snoring he used to check I was still breathing.
- I could walk up my steep 20 metre driveway without wheezing and becoming breathless a few months after I stopped smoking. I needed to drive up to collect my mail before that.
- I did not put on weight.
- My gum disease disappeared and I am hanging onto my last teeth despite my dentist saying they would have to be removed soon years ago because of the gum disease caused by smoking.
- I don't smell like an incinerator.
- I don't fear falling asleep with a lit cigarette in my hand and starting a house fire.[5]

4.9 Another submitter reported that e-cigarettes had allowed him to take control of his health:

> I started [smoking] when was 15 and smoked until 35. In that time, I wasted so much money on cigarettes. I also watched my health decline. I was diagnosed a TYPE 1 diabetic at 22yrs old. I have felt this disease change my life and blamed the diabetes for many of my problems. I had a rude awakening when was given a vape by a friend and started vaping dessert flavours with nicotine. I transitioned for about 2 weeks then gave up the smokes completely. IT ACTUALLY WORKED. The awakening was that after about 2 months on the vape only I started to see improvements in all areas of my life but most importantly in my diabetes. Diabetes will probably kill me before my time if I kept going the way that I was heading. BUT! Since the switch, my sugar levels are controlled like they have never been before, I am more active than ever before, I have no cough and my mental health is better. And let us keep in mind u vape a lot. Thanks to vaping I do not feel scared of dying any more, I feel free from the chains of tobacco and ready to live the rest of my life. I feel the years that I have saved.[6] [emphasis in original]

4.10 Mr Luke Oliver also described the net benefits to his health:

> I am vastly healthier, and there is no way anyone who has not undertaken this transformation could understand it, or how grateful I am to have this second chance.[7]

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5 Mrs Judith Wolters, *Submission 221*, [p. 1] (70 years of age, previously a smoker for over 50 years).

6 Name withheld *Submission 60*, [p. 1] (38 years of age, previously a smoker of 20 years).

7 Mr Luke Oliver, *Submission 142*, [p. 1] (43 years of age, previously a smoker for an estimated 21 years).

Financial matters

4.11 Submitters noted that using e-cigarettes had a significant positive financial impact, due to the substantially lower cost in comparison to combustible cigarettes.[8] Submitters often reported that spending on combustible cigarettes

[8] See, for example, Mr Tom Morawetz, *Submission 2*, [p. 1]; Name withheld, *Submission 3*, [p. 1]; Name withheld, *Submission 7*, [p. 1]; Mr Shane Kerrigan, *Submission 8*, [p.1]; Mrs Yvette Hopkins, *Submission 9*, [p. 2]; Ms Maureen Steele, *Submission 10*, [p. 1]; Name withheld, *Submission 13*, [p. 1]; Name withheld, *Submission 17*, [p. 1]; Name withheld, *Submission 18*, [p. 1]; Name withheld, *Submission 19*, [p. 1]; Name withheld, *Submission 20* [p. 1]; Name withheld, *Submission 21* [p. 1]; Name withheld, *Submission 24* [p. 1]; Mr Michael Sandic, *Submission 29*, [p. 1]; Mr Matthew Barton, *Submission 30*, [p. 1]; Dr Richard Watkins, *Submission 31*, [p. 1]; Mr Lewis Johnson, *Submission 36*, [p. 1]; Mr Adam Metelmann, *Submission 51*, [p. 1]; Name withheld *Submission 53*, [p. 1]; Mr Matthew Landau, *Submission 54*, p. 4; Name withheld, *Submission 64*, [p. 1]; Mr Robert Adams, *Submission 65*, [pp. 1-2]; Name withheld, *Submission 72*, [p. 1]; Name withheld, *Submission 73*, [p. 1]; Mr Steve Rehberger, *Submission 74*, [p. 1]; Mrs Georgia Adams, *Submission 85*, p. 1; Ms Bonnie Schultz, *Submission 86*, p. 1; Name withheld, *Submission 98*, [p. 1]; Ms Samantha Barratt, *Submission 102*, [p. 1]; Name withheld, *Submission 105*, [p. 1]; Mr John Walker, *Submission 106*, [p. 1]; Mr John Richardson, *Submission 109*, [p. 1]; Name withheld, *Submission 116*, [p. 1]; Name withheld, *Submission 118*, [p. 1]; Name withheld, *Submission 122*, [p. 1]; Name withheld, *Submission 131*, [p. 1]; Mr Andrew Thompson, *Submission 133*, [p. 1]; Miss Leesa Austin, *Submission 141*, [p. 1]; Mr Luke Oliver, *Submission 142*, [p. 1]; Dr David Mutch, *Submission 143*, [p. 1]; Ms Deborah Smith, *Submission 144*, [p. 1]; Mr Foo Bar, *Submission 150*, [p. 1]; Name withheld, *Submission 168*, [p. 1]; Name withheld, *Submission 175*, [p. 5]; Name withheld, *Submission 189*, p. 1; Name withheld, *Submission 190*, [p. 1]; Name withheld, *Submission 192*, [p. 1]; Mr Rodney Bambridge, *Submission 196*, [p. 1]; Name withheld, *Submission 201*, [p. 1]; Name withheld, *Submission 205*, [p. 1]; Mr Charles McCracken, *Submission 211*, [p. 2]; Mr Iain Carson, *Submission 212*, [p. 1]; Name withheld, *Submission 213*, [p. 1]; Name withheld, *Submission 218*, p. 1; Ms Rachael James, *Submission 224*, [p. 1]; Mr Patrick Cameron, *Submission 277*, [p. 1]; Name withheld, *Submission 286*, p. 6; Mr Paul Clarence, *Submission 293*, [p. 1]; Mr Wayne Betts, *Submission 295*, [p. 1]; Mr Travis Hinds, *Submission 297*, [p. 1]; Ms Lyn Bennetts, *Submission 299*, [p. 2]; Mr Dan Tarasenko, *Submission 300*, [p. 1]; Mr Troy Luff, *Submission 302*, [p. 1]; Mr Damien Noonan, *Submission 303*, [p. 1]; Mr Angelo Ferlauto, *Submission 304*, [p. 1]; Mr Paul Webster, *Submission 311*, [p. 1]; Ms Naomi Groenendyk, *Submission 312*, [p. 1]; Mr Chris Blanch, *Submission 313*, [p. 1]; Ms Donna Garrett, *Submission 315*, [p. 1]; Mr Jacent Hipworth, *Submission 316*, [p. 1]; Mr Robert Finlay, *Submission 321*, [p. 1]; Mr Max Gorvel, *Submission 324*, [p. 1]; Mr Troy Smith, *Submission 325*, [p. 1]; Ms Cheryl Rafferty, *Submission 327*, [p. 1]; Mr Gana Somayanda, *Submission 331*, [p. 1]; Ms Paula Foley, *Submission 332*, [p. 1]; Mr Brian Moss, *Submission 334*, [p. 1]; Mr Owen Lenegan, *Submission 337*, [p. 1]; Mr Nick Hrysanidis, *Submission 339*, [p. 1]; Mr Daniel Mason, *Submission 340*, [p. 1]; Mr Jason Traynor, *Submission 341*, [p. 1]; Miss Peta Longstaff, *Submission 345*, [p. 1]; Mr Peter Saunders, *Submission 347*, [p. 1]; Ms Tammie Opie, *Submission 348*, [p. 1]; Mr George Teepa, *Submission 350*, [p. 1]; Ms Scarlett Niven, *Submission 352*, [p. 1]; Mr John Brown, *Submission 358* [p. 1]; Ms Lauren Chalmers, *Submission 360*, [p. 1]; Mr Michael Byrne, *Submission 361*, [p. 1]; Mr Shaun Drew, *Submission 362*, [p. 1]; Ms Sheila Marsh, *Submission 363*, [p. 2]; Mr Michael Oltmanns, *Submission 367*, [p. 1]; Mr Christopher Merry, *Submission 369*, [p. 1]; Mr Gary Russell, *Submission 372*, [p. 1]; Mr Howard Randell, *Submission 374*, [p. 1]; Ms Tara Orr, *Submission 375*, [p. 1]; Mr Will Weatherly, *Submission 377*, [p. 1]; Mrs Denise Russell, *Submission 379*, [p. 1]; Mr Shane Robison, *Submission 380*, [p. 1]; Mr Peter Sharman, *Submission 381*, [p. 1]; Mr Cliff Chandler, *Submission 383*, [p. 1]; Ms Tara Holyoake, *Submission 386*, [p. 1]; Mr Malcolm Bodie, *Submission 391*, [p. 1]; Mr Ben McBeth, *Submission 393*, [p. 1];

had resulted in financial hardship. For example, this submitter described his situation:

> I grew to smoking a pack a day (20) cigarettes that would cost anywhere from $50 to $150 a week, depending on what I smoked. So much money, just thrown away! If it was a choice between smokes and food, the smokes won every time.[9]

4.12 Another submitter calculated the financial impact that smoking combustible cigarettes has had on his life:

> From about the age of 16 I smoked a pack day. Conservatively, that is approximately 124,100 cigarettes in about 17 years. Put another way, if a cigarette weighs about 1.0 grams, I smoked my own body weight in tobacco in that time and spent AUD$186,150.00 or more.[10]

4.13 Many submitters compared the cost of smoking combustible cigarettes with smoking e-cigarettes. Mr Michael Byrne submitted:

> I calculated when I started vaping that for the cost of two cartons of cigarettes the raw materials and vaping device purchased would, and did, last 4 years.[11]

4.14 Similarly, a submitter reported an improvement to his financial position since moving from smoking combustible cigarettes to e-cigarettes:

> As a former pack a day smoker, I saved between $12,500 and $15,000 per year by switching to vaping. My wife quit as well, so the combined savings in our household are approximately $25,000 per year or more.[12]

4.15 The impact of such monetary savings extended beyond individuals to entire family units. For example, a submitter reported:

Mr Stafford Lumsden, *Submission 394*, [p. 1]; Mr Simon Wells, *Submission 399*, [p. 1]; Mr Christiaan van Schalkwyk, *Submission 400*, [p. 2]; Mr Brad Hendry, *Submission 402*, [p. 1]; Name withheld, *Submission 407*, [p. 1]; Name withheld, *Submission 413*, [p. 1]; Name withheld, *Submission 414*, [p. 1]; Name withheld, *Submission 416*, [p. 1]; Name withheld, *Submission 417*, [pp. 1-2]; Name withheld, *Submission 418*, [p. 1]; Name withheld, *Submission 420*, [p. 1]; Name withheld, *Submission 422*, [p. 1]; Name withheld, *Submission 426*, [p. 1]; Name withheld, *Submission 427*, [p. 2]; Name withheld, *Submission 428*, [p. 1]; Name withheld, *Submission 430*, [p. 1]; Name withheld, *Submission 434*, p. 1; Name withheld, *Submission 440*, [p. 1]; Name withheld, *Submission 441*, [p. 1]; Name withheld, *Submission 445*, [p. 1]; Name withheld, *Submission 446*, [p. 1]; Name withheld, *Submission 452*, [pp. 1-2]; Name withheld, *Submission 453*, [p. 1]; Name withheld, *Submission 454*, [p. 1]; Name withheld, *Submission 455*, [p. 1]; Name withheld, *Submission 456*, [p. 2]; Name withheld, *Submission 457*, [pp. 1-2]; Name withheld, *Submission 458*, [p. 1]; and Name withheld, *Submission 459*, [p. 1].

9 Name withheld, *Submission 19*, [p. 1] (53 years of age, previously a smoker for 41 years).

10 Mr Stafford Lumsden, *Submission 394*, [p. 1] (age unknown, previously a smoker for 17 years).

11 Mr Michael Byrne, *Submission 361*, [p. 1] (67 years of age, previously a smoker for approximately 44 years).

12 Name withheld, *Submission 131*, [p. 1] (44 years of age, previously a smoker for approximately 25 years).

> We can do more stuff with the kids as we have money to be able to get them the things they missed out on due to our expensive smoking habit, recently we had to get a new 2nd hand car for work and we were able to pay $9000 of the total price of the car which prior to quitting we would never have been able to do this as we could not save due to having to keep buying cigarettes for our hard to quit habit.[13]

4.16 Another submitter reported how using e-cigarettes had allowed him to improve his financial situation:

> Vaping now only costs me $5 to $10 per week, to at most $20 every couple of months if I need to resupply e-liquid, nicotine or other vaping apparatus. I can now afford much healthier food and can even enjoy a few small luxuries like internet & foxtel. I have actually started saving a few dollars for the first time in many years.[14]

4.17 Similarly, Mr Max Gorvel reported that:

> On the wealth level, my weekly budget was $175 for cigarettes ($25 x 7 days) (as much as my rent!) now this same $175, it keeps me going with a full 2 month supply of vape juice. I've been saving so much than I'm now applying for my first home loan.[15]

Improved quality of life

4.18 As well as increased health outcomes and financial stability, submitters reported that using e-cigarettes in lieu of smoking had resulted in an overall better quality of life.[16] For example, Mr Tom Morawetz recounted the overall improvements that he had experienced:

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[13] Name withheld, *Submission 13*, [p. 1] (age unknown, previously a smoker for over 29 years).

[14] Name withheld, *Submission 7*, [p. 1] (56 years of age, previously a smoker for 40 years).

[15] Mr Max Gorvel, *Submission 324*, [p. 1] (32 years old, previously a smoker of 14 years)

[16] See, for example, Mr Tom Morawetz, *Submission 2*, [p. 1]; Name withheld, *Submission 3*, [p. 1]; Mr James Reid, *Submission 4*, [p. 1]; Mr Alan Beard, *Submission 6*, [p. 1]; Name withheld, *Submission 7*, [p. 1]; Mr Shane Kerrigan, *Submission 8*, [p.1]; Mrs Yvette Hopkins, *Submission 9*, [p. 1]; Ms Maureen Steele, *Submission 10*, [p. 2]; Mr Anthony Barron, *Submission 11*, [p. 1]; Name withheld, *Submission 12*, [p. 1]; Name withheld, *Submission 13*, [p. 1]; Name withheld, *Submission 14*, [p. 1]; Mr Grant Clark, *Submission 15*, [pp. 1-2]; Name withheld, *Submission 17*, [p. 1]; Name withheld, *Submission 18*, [p. 1]; Name withheld, *Submission 19*, [p. 1]; Name withheld, *Submission 20* [p. 1]; Name withheld, *Submission 21* [p. 1]; Name withheld, *Submission 22* [p. 2]; Name withheld, *Submission 25* [p. 1]; Name withheld, *Submission 32* [p. 1]; Ms Sheryl Mulvey, *Submission 35*, [p. 1]; Mr Lewis Johnson, *Submission 36*, [p. 1]; Mr Graeme Angrave, *Submission 37*, [p. 1]; Mr Troy Jeppesen, *Submission 42*, [p. 1]; Mr Chris Hansen, *Submission 46*, [p. 1]; Name withheld, *Submission 47*, [p. 1]; Mr Adrian Sheehan, *Submission 49*, [p. 2]; Name withheld *Submission 53*, [p. 1]; Mr Matthew Landau, *Submission 54*, p. 4; Name withheld *Submission 59*, [p. 1]; Name withheld, *Submission 64*, [p. 1]; Mr Robert Adams, *Submission 65*, [p. 1]; Ms Donella Houghton, *Submission 69*, [p. 1]; Name withheld, *Submission 72*, [p. 1]; Name withheld, *Submission 73*, [p. 1]; Mr Bill Stewart, *Submission 76*, [p. 1]; Name withheld, *Submission 79*, [p. 2]; Name withheld, *Submission 81*, [p. 2]; Mr Keith Pengilly, *Submission 82*, [p. 1]; Name withheld, *Submission 87*, p. 1; Name withheld, *Submission 93*, p. 1; Mr Shail Akhil, *Submission 126*, [p. 1]; Name withheld,

> No yellow fingers, no stink breath, fresh clothes, sweet smelling flat and vehicle. No colds or coughs of note, good BP results, eating better now I can taste food and have even lost weight and apart from my non related other ailments actually feel almost spritely!! Well very almost. My dog Minty and I can now walk 3kms a day, his 12 and my 63 need the exercise, and we enjoy this in the morning together.[17]

4.19 A number of people noted that the ability to live a higher-quality, more enjoyable lifestyle had positive benefits for entire families. Mr Logan Evans, for example, summarised the impact that e-cigarettes have had on his and his family's quality of life:

> While playing with my kids outside on a sunny day in July, 2017, I found myself short of breathe and in need of a break. Immediately I lit up a cigarette. Sitting there smoking and watching my kids run around, I had a "vision." I saw myself being wheeled down the isle of their weddings, hooked up to oxygen. I saw myself as the father they would have to care for and bury early, all because I couldn't quit smoking.
>
> That day I made the choice to give vaping a try.
>
> Six days later I was cigarette free and have not had once since. My lung function has significantly improved to the point where I no longer use any medications, even my rescue inhaler, for my asthma. I am able to run, work and play without having to take breaks to catch my breathe. E-cigarettes have given me my life back and have given m[e] a hopeful future. Not only for myself, but for my two daughters.[18]

4.20 Another submitter also outlined the benefits to his family:

> …I have 2 young children and while I understand that vaping is not completely risk free, I do feel that it has given me a better opportunity to live longer and see them grow up. I seriously doubted my ability to be able to quit after so many failed attempts and it makes me very happy to know

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Submission 128, [p. 1]; Miss Leesa Austin, *Submission 141*, [p. 1]; Mr Luke Oliver, *Submission 142*, [p. 1]; Dr David Mutch, *Submission 143*, [p. 1]; Mr Foo Bar, *Submission 150*, [p. 1]; Name withheld, *Submission 193*, [p. 1]; Mr Justin Fowler, *Submission 203*, [pp. 1-2]; Name withheld, *Submission 213*, [p. 1]; Name withheld, *Submission 231*, [p. 2]; Mr Robert Richter, *Submission 252*, [p. 1]; Mr Patrick Cameron, *Submission 277*, [p. 1]; Name withheld, *Submission 286*, p. 6; Mr Travis Hinds, *Submission 297*, [p. 1]; Mr Keith Lewis, *Submission 314*, [p. 1]; Mr Brian Moss, *Submission 334*, [p. 2]; Mr Jason Traynor, *Submission 341*, [p. 1]; Miss Peta Longstaff, *Submission 345*, [p. 1]; Mr Peter Saunders, *Submission 347*, [p. 1]; Mr George Teepa, *Submission 350*, [p. 1]; Mr Shaun Drew, *Submission 362*, [p. 1]; Ms Sheila Marsh, *Submission 363*, [p. 1]; Mr Mark Temple, *Submission 364*, [p. 1]; Mr Christopher Merry, *Submission 369*, [p. 1]; Mr Will Weatherly, *Submission 377*, [p. 1]; Mrs Denise Russell, *Submission 379*, [p. 1]; Mr Christian O'Brien, *Submission 389*, [p. 1]; Mr Malcolm Bodie, *Submission 391*, [p. 1]; Mr Brad Hendry, *Submission 402*, [p. 1]; Name withheld, *Submission 407*, [p. 1]; Name withheld, *Submission 414*, [p. 1]; Name withheld, *Submission 418*, [p. 1]; Name withheld, *Submission 420*, [p. 1]; Name withheld, *Submission 432*, [p. 1]; Name withheld, *Submission 435*, [pp. 1-2]; and Name withheld, *Submission 447*, [p. 1].

[17] Mr Tom Morawetz, *Submission 2*, [p. 1] (63 years of age, previously a smoker for 45 years).

[18] Mr Logan Evans, *Submission 90*, [p. 1] (29 years of age, previously a smoker for 12 years).

> that my family won't be impacted by the serious negative impacts that smoking brings.[19]

4.21 The committee received evidence regarding notable improvements to the quality of life for long-term smokers and those who were already experiencing ill health as a result of smoking combustible cigarettes. One submitter explained that e-cigarettes had led to an overall improvement in their quality of life:

> I have been smoking most of my life and because the price went up so much I was getting desperate to give up as I could no longer afford to smoke and eat at the same time so I tried vaping and was able to stop smoking, As a result I can walk a lot further without getting out of breath and I have stopped coughing and wheezing when I'm sitting down or going to sleep, I don't smell of stale tobacco and my children and grandchildren don't have to put up with second hand smoke when they come near me anymore, I feel so much better as a result of changing over to vaping…
>
> If I started smoking again due to it becoming harder to get the liquid my quality of life would go right down to the pointing where it would be a waste of time getting out of bed anymore, I would be right back where I started, Taking medication for hypertension and high cholesterol just starring out the window.[20]

4.22 Another submitter described the relief he felt in transitioning to e-cigarettes and how his health, and life, had improved:

> Then came my first smoke-free day in several decades, and then a week and then a month. At this point, I went out into the back yard one night and had a cry; I can count on one hand the number of times I have done that as an adult.
>
> The hoped for but long abandoned future where I didn't have to spend a lot of money on killing myself early was here! Forget winning the lottery, forget coming top of the class—the only comparable joy is the birth of your own children. What had started as an experiment to save the furniture by cutting back had yielded a pain free method of quitting.[21]

Methods used to quit smoking

4.23 The following summarises the personal accounts received from submitters regarding their experiences of moving from smoking combustible cigarettes to e-cigarettes. We note that the majority of personal accounts indicated that using e-cigarettes was motivated by a desire to cease using combustible cigarettes.

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[19] Name withheld, *Submission 93*, p. 1 (31 years of age, previously a smoker for an estimated 17 years).

[20] Name withheld, *Submission 72*, [p. 1] (age unknown, previously a smoker for 48 years).

[21] Mr Foo Bar, *Submission 150*, [p. 1] (age unknown, previously a smoker of 30 years).

Attempts to quit smoking via traditional methods

4.24 Submitters reported in detail multiple attempts to stop smoking via traditional means, such as nicotine patches, gum, medical interventions, counselling, and alternative medicine. Some submitters had also sought assistance from their general practitioner. For example, Mr James Reid described his experience of attempting to cease smoking:

> I sought help from numerous GP's on numerous occasions and have tried most approved consumer products from nicotine patches, gum and inhalers to nasal spray, lozenges and even natural remedies such as Lobelia etc. I was signed up to "QUIT" Organisations on multiple occasions and I even paid out considerable sums of money, based on Medical Practitioner's advice, on therapies such as Hypnosis and acupuncture. I've been prescribed drugs such as Champix and Zyban, which actually did more harm than good. None of them worked. It was a no win situation.[22]

4.25 The committee received evidence that submitters were highly motivated to stop smoking combustible cigarettes. Submitters were aware of the consequences of smoking combustible cigarettes, and many submitters were distressed by their addiction. Submitters reported trying medications to cease smoking combustible cigarettes, which had various side effects. For example:

> I tried many times to quit smoking. I tried going cold turkey, prescription medication (Zyban), patches, lozenges, inhalers, nothing worked. The patches gave me painful welts and the Zyban made me super aggressive which was quite scary. It wasn't long before I started to feel the benefits of switching to vaping.[23]

4.26 One submitter described how, after tolerating the side effects of such a medication, he abruptly relapsed:

> I started smoking when I was about 13 and when I quit I was smoking 25 cigarettes a day. I had tried patches at least 7 times (I tried every year), mouth spray, gum and I tried Champix once but it felt like it made me lose my mind. The most horrible side effects from anything I've ever had before. It's no wonder there are so many suicides attributed to that terrible drug. It did help me to get off cigarettes for 8 months though. All it took was one cigarette though and I was back to smoking a pack a day within a few days. Nothing worked. I always went back to smoking eventually.[24]

4.27 A number of submitters reported a sense of resignation and outright despair around remaining addicted to combustible cigarettes. Mr Mark Watson described his attempts to stop smoking, which had previously been unsuccessful:

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[22] Mr James Reid, *Submission 4*, [p. 1] (57 years of age, previously a smoker for over 40 years).

[23] Name withheld, *Submission 205*, [p. 1] (46 years of age, previously a smoker for 30 years).

[24] Mr Peter Saunders, *Submission 347*, [p. 1] (age unknown, previously a smoker since the age of 13).

> I had attempted several times to cease smoking by cold turkey, and using medical practitioner recommended methods which included nicotine patches, gum, and mouth spray, without any success. No matter what nicotine patch I tried, my skin would blister and develop a rash. Using nicotine gum caused the inside of my mouth to blister, along with severe nausea, which was the same result from using nicotine mouth spray. My GP and lung specialist would not let me try Champix, advising that it would cause a dangerous reaction with other medications that I was taking. Due to mental health issues, I found myself unable to build up the will power to cut down or try and go cold turkey again. Therefore, I was resigned that I would be a smoker until the end.[25]

4.28 Noting that he had witnessed the impact of long-term smoking within his family, Mr Malcolm Bodie told the committee that:

> As the eldest son in my family, it fell upon me to give the eulogy for my Mother following her death from lung cancer due to a lifetime of smoking tobacco. She was 57 when first diagnosed with cancer and 3 years later she was dead. I swore that I would quit smoking in the eulogy, I had been smoking for 27 years and I had 3 children who constantly asked me to stop. It took years of trying to quit. I used every product that was available through the doctor or chemist. Nothing worked and 13 years after my Mother died, I was sure that I would die the same way she did. I resigned myself to dying the slow and horrible death as she did.
>
> Then one day someone handed me an e-cigarette to try. I was astounded with its familiarity to smoking and that day was my last day of smoking tobacco. I was 53 years old and grateful that I could stop killing myself with cigarettes. My wheezing eased, my cough eased, my Asthma eased, and I finally could see a life beyond 60. I could taste food again and I could play with my kids without tiring in 10 minutes. The future looked promising again.[26]

Using e-cigarettes to reduce or quit smoking

4.29 The personal accounts of submitters described using e-cigarettes in order to reduce and/or entirely cease smoking combustible cigarettes. Submitters reported that using e-cigarettes had resulted in a reduction in their intake of combustible cigarettes, with some entirely ceasing to smoke combustible cigarettes.[27]

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[25] Mr Mark Watson, *Submission 84*, p. 1 (62 years of age, previously a smoker for approximately 44 years).

[26] Mr Malcolm Bodie, Submission 391, [p. 1] (60 years of age, previously a smoker for 40 years).

[27] See, for example, Name withheld, *Submission 1*, [p. 1]; Mr Tom Morawetz, *Submission 2*, [p. 1]; Name withheld, *Submission 3*, [p. 1]; Mr James Reid, *Submission 4*, [p. 1]; Mr Richard Pruen, *Submission 5*, [p. 1]; Mr Alan Beard, *Submission 6*, [p. 1]; Name withheld, *Submission 7*, [p. 1]; Mr Shane Kerrigan, *Submission 8*, [p.1]; Mrs Yvette Hopkins, *Submission 9*, [p. 1]; Ms Maureen Steele, *Submission 10*, [p. 1]; Mr Anthony Barron, *Submission 11*, [p. 1]; Name withheld, *Submission 12*, [p. 1]; Name withheld, *Submission 13*, [p. 1]; Name withheld, *Submission 14*, [p. 1]; Mr Grant Clark, *Submission 15*, [p. 1]; Name withheld, *Submission 16*, [p. 1]; Name

withheld, *Submission 17*, [p. 1]; Name withheld, *Submission 18*, [p. 1]; Name withheld, *Submission 19*, [p. 1]; Name withheld, *Submission 20* [p. 1]; Name withheld, *Submission 21* [p. 1]; Name withheld, *Submission 22* [p. 2]; Miss Kerri Shannon, *Submission 23*, [p. 1]; Name withheld, *Submission 24* [p. 1]; Name withheld, *Submission 25* [p. 1]; Name withheld, *Submission 26* [p. 1]; Mr Don Brooke, *Submission 27*, [p. 2]; Mr Joshua Waters, *Submission 28*, [pp. 1-2]; Mr Michael Sandic, *Submission 29*, [p. 1]; Mr Matthew Barton, *Submission 30*, [p. 1]; Dr Richard Watkins, *Submission 31*, [p. 1]; Name withheld, *Submission 32* [p. 1]; Mr Colin Mannings, *Submission 33* [p. 1]; Mr Deven Sporn, *Submission 34*, [p. 1]; Ms Sheryl Mulvey, *Submission 35*, [p. 1]; Mr Lewis Johnson, *Submission 36*, [p. 1]; Mr Graeme Angrave, *Submission 37*, [p. 1]; Name withheld, *Submission 39*, [p. 1]; Name withheld, *Submission 40* [p. 1]; Name withheld, *Submission 41* [p. 1]; Mr Troy Jeppesen, *Submission 42*, [p. 1]; Name withheld, *Submission 43* [p. 1]; Mr Martin Kewish, *Submission 44*, [p. 1]; Mr Chris Hansen, *Submission 46*, [p. 1]; Name withheld, *Submission 47*, [p. 1]; Name withheld, *Submission 48*, [p. 2]; Mr Adrian Sheehan, *Submission 49*, [p. 1]; Name withheld, *Submission 50*, [p. 1]; Mr Adam Metelmann, *Submission 51*, [p. 1]; Name withheld *Submission 52*, [p. 1]; Name withheld *Submission 53*, [p. 1]; Mr Matthew Landau, *Submission 54*, p. 4; Mr Stuart Bowermann, *Submission 55*, [p. 1]; Shayne O'Neill, *Submission 56*, [p. 1]; Mr Gerrad Geard, *Submission 57*, [p. 1]; Name withheld *Submission 58*, [p. 1]; Name withheld *Submission 59*, [p. 1]; Name withheld *Submission 60*, [p. 1]; Mr Dan Jackson, *Submission 61*, [p. 1]; Mr Brian Saint, *Submission 62*, [p. 1]; Mrs Tiffany Kereopa, *Submission 63*, [p. 1]; Name withheld, *Submission 64*, [p. 1]; Mr Robert Adams, *Submission 65*, [p. 1]; Name withheld, *Submission 67*, [pp. 1-2]; Mr Michael Gorman, *Submission 68*, [p. 1]; Ms Donella Houghton, *Submission 69*, [p. 1]; Name withheld, *Submission 70*, [p. 1]; Name withheld, *Submission 71*, [p. 1]; Name withheld, *Submission 72*, [p. 1]; Name withheld, *Submission 73*, [p. 1]; Mr Steve Rehberger, *Submission 74*, [p. 1]; Mr Samuel Cahir, *Submission 75*, [p. 1]; Mr Bill Stewart, *Submission 76*, [p. 1]; Mr Michael Ewart, *Submission 77*, [p. 1]; Name withheld, *Submission 78*, [p. 1]; Mr Aaron Fisher, *Submission 80*, [p. 1]; Name withheld, *Submission 81*, [p. 2]; Mr Keith Pengilly, *Submission 82*, [p. 1]; Ms Trina Macleod, *Submission 83*, p. 2; Mr Mark Watson, *Submission 84*, p. 1; Mrs Georgia Adams, *Submission 85*, p. 1; Ms Bonnie Schultz, *Submission 86*, p. 1; Name withheld, *Submission 87*, p. 1; Name withheld, *Submission 88*, p. 1; Ms Ria Hopkins, *Submission 89*, p. 1; Mr Logan Evans, *Submission 90*, p.1; Name withheld, *Submission 91*, p. 1; Name withheld, *Submission 93*, p. 1; Name withheld, *Submission 95*, p. 1; Name withheld, *Submission 96*, p. 1; Name withheld, *Submission 97*, [p. 1]; Name withheld, *Submission 98*, [p. 1]; Ms Dianne Gorman, *Submission 100*, [p. 1]; Name withheld, *Submission 101*, [p. 1]; Ms Samantha Barratt, *Submission 102*, [p. 1]; Mr Paul Marshall, *Submission 103*, [p. 1]; Name withheld, *Submission 105*, [p. 1]; Mr John Walker, *Submission 106*, [p. 1.]; Mr Aaron Fornarino, *Submission 107*, [p. 2]; Mr Paul Montague, *Submission 108*, p. 1; Mr John Richardson, *Submission 109*, [p. 1]; Ms Amy Trezise, *Submission 110*, [p. 1]; Name withheld, *Submission 111*, [p. 1]; Name withheld, *Submission 112*, [p. 1]; Ms Penelope Turner, *Submission 113*, [p.1]; Mr Daniel Perfect, *Submission 114*, [p. 1]; Name withheld, *Submission 115*, [p. 1]; Name withheld, *Submission 116*, [p. 1]; Mr Damien Noonan, *Submission 117*, [p. 1]; Name withheld, *Submission 118*, [p. 1]; Mr John Littlewood, *Submission 119*, [p. 1]; Mr Ken McNaughton, *Submission 121*, [p. 1]; Name withheld, *Submission 122*, [p. 1]; Mr Michael Stewart, *Submission 124*, [p. 1]; Ms Alison Paul, *Submission 125*, [p. 1]; Mr Shail Akhil, *Submission 126*, [p. 1]; Name withheld, *Submission 127*, [p. 1]; Name withheld, *Submission 128*, [p. 1]; Name withheld, *Submission 131*, [p. 1]; Mr Andrew Thompson, *Submission 133*, [p. 1]; Mr Tim Palmer, *Submission 134*, [p. 1]; Name withheld, *Submission 136*, [p. 1]; Name withheld, *Submission 137*, [p. 1]; Mr John Walker, *Submission 138*, [p. 1]; Miss Leesa Austin, *Submission 141*, [p. 1]; Mr Luke Oliver, *Submission 142*, [p. 1]; Dr David Mutch, *Submission 143*, [p. 1]; Ms Deborah Smith, *Submission 144*, [p. 1]; Name withheld, *Submission 145*, [p. 1]; Name withheld, *Submission 146*, [p. 1]; Ms Cat Wright, *Submission 147*, [p. 1]; Name withheld, *Submission 148*, [p. 1]; Name withheld, *Submission 149*, [p. 1]; Mr Foo Bar, *Submission 150*, [p. 1]; Name withheld, *Submission 151*, [p. 1]; Ms Licia Pappas, *Submission 152*, [p. 1]; Name withheld, *Submission 154*, [p. 1]; Name withheld, *Submission 168*, [p. 1];

Miss Alice Pierce, Submission 172, p. 1; Name withheld, *Submission 175*, [p. 1] and [p. 5]; Mr Robert Pestell, *Submission 179*, [p. 1]; Ms Hayley Dekker Lennon, *Submission 181*, [p. 1]; Dr Nicholas Cope, *Submission 185*, [p. 1]; Mr Adam Hazebroek, *Submission 187*, [p. 1]; Name withheld, *Submission 189*, pp. 1-2; Name withheld, *Submission 190*, [p. 1]; Name withheld, *Submission 191*, [p. 1]; Name withheld, *Submission 192*, [p. 1]; Name withheld, *Submission 193*, [p. 1]; Mr Rodney Bambridge, *Submission 196*, [p. 1]; Mr Damien Hackett, *Submission 198*, p. 1; Name withheld, *Submission 200*, [p. 1]; Name withheld, *Submission 201*, [p. 1]; Mr Justin Fowler, *Submission 203*, [p. 1]; Mr Ben Johnson, *Submission 204*, [p. 1]; Name withheld, *Submission 205*, [p. 1]; Name withheld, *Submission 206*, [p. 1]; Mr Arthur Wielgosz, *Submission 207*, [p. 1]; Mr Charles McCracken, *Submission 211*, [p. 2]; Mr Iain Carson, *Submission 212*, [p. 1]; Name withheld, *Submission 213*, [p. 1]; Name withheld, *Submission 216*, [p. 1]; Name withheld, *Submission 218*, p. 1; Mr Adam Hickmott, *Submission 219*, [p. 1]; Mrs Judith Wolters, *Submission 221*, [p. 1]; Ms Rachael James, *Submission 224*, [p. 1]; Ms Angela Gordon , *Submission 225*, [p. 1]; Mr Brave Front, *Submission 229*, [p. 1]; Miss Paige Johnston, *Submission 230*, [p. 1]; *Submission 231*, [p. 1]; Mr Damien Hackett, *Submission 198*, p. 1; Name withheld, *Submission 200*, [p. 1]; Name withheld, *Submission 201*, [p. 1]; Mr Justin Fowler, *Submission 203*, [p. 1]; Mr Ben Johnson, *Submission 204*, [p. 1]; Name withheld, *Submission 205*, [p. 1]; Name withheld, *Submission 206*, [p. 1]; Mr Arthur Wielgosz, *Submission 207*, [p. 1]; Mr Charles McCracken, *Submission 211*, [p. 2]; Mr Iain Carson, *Submission 212*, [p. 1]; Name withheld, *Submission 213*, [p. 1]; Name withheld, *Submission 216*, [p. 1]; Name withheld, *Submission 218*, p. 1; Mr Adam Hickmott, *Submission 219*, [p. 1]; Mrs Judith Wolters, *Submission 221*, [p. 1]; Ms Rachael James, *Submission 224*, [p. 1]; Ms Angela Gordon , *Submission 225*, [p. 1]; Mr Brave Front, *Submission 229*, [p. 1]; Miss Paige Johnston, *Submission 230*, [p. 1]; Name withheld, *Submission 231*, [p. 1]; Mr Norbert Zillatron Schmidt, *Submission 249*, [p. 1]; Mr Robert Richter, *Submission 252*, [p. 1]; Name withheld, *Submission 256*, [p. 1]; Ms Annette Huppatz, *Submission 265*, [p. 1]; Mr Patrick Cameron, *Submission 277*, [p. 1]; Name withheld, *Submission 281*, [p. 1]; Mrs Linda Foster, *Submission 282*, [p. 1]; Name withheld, *Submission 284*, [p. 1]; Name withheld, *Submission 285*, [p. 1]; Name withheld, *Submission 286*, p. 5; Mr Robert Rogers, *Submission 291*, [p. 1]; Mr Paul Clarence, *Submission 293*, [p. 1]; Mr Wayne Betts, *Submission 295*, [p. 1]; Mr Christopher Boreham-Carna, *Submission 296*, [p. 1]; Mr Travis Hinds, *Submission 297*, [p. 1]; Mr Duncan McLaren, *Submission 298*, [p. 1]; Ms Lyn Bennetts, *Submission 299*, [p. 1 and p. 3]; Mr Dan Tarasenko, *Submission 300*, [p. 1]; Ms Pam Mulholland, *Submission 301*, [p. 1]; Mr Troy Luff, *Submission 302*, [p. 1]; Mr Damien Noonan, *Submission 303*, [p. 1]; Mr Angelo Ferlauto, *Submission 304*, [p. 1]; Ms Kaye Matthews, *Submission 305*, [p. 1]; Mr Vince McDevitt, *Submission 306*, [p. 1]; Ms Sheryl Mulvey, *Submission 307*, [p. 1]; Mr Alpha Centauri, *Submission 308*, [p. 1]; Mr Paul Briton, *Submission 309*, [p. 1]; Mr Sam Whitehead, *Submission 310*, [p. 1]; Mr Paul Webster, *Submission 311*, [p. 1]; Ms Naomi Groenendyk, *Submission 312*, [p. 1]; Mr Chris Blanch, *Submission 313*, [p. 1]; Mr Keith Lewis, *Submission 314*, [p. 1]; Ms Donna Garrett, *Submission 315*, [p. 1]; Mr Jacent Hipworth, *Submission 316*, [p. 1]; Mr Caleb Maher, *Submission 317*, [p. 1]; Mr Dan Lucas, *Submission 318*, [p. 1]; Mr Stuart Vanderplank, *Submission 319*, [p. 1]; Mr Craig Brown, *Submission 320*, [p. 1]; Mr Robert Finlay, *Submission 321*, [p. 1]; Mr Graeme Fritz, *Submission 322*, [p. 1]; Ms Angie Billenstein, *Submission 323*, [p. 1]; Mr Max Gorvel, *Submission 324*, [p. 1]; Mr Troy Smith, *Submission 325*, [p. 1]; Ms Cheryl Rafferty, *Submission 327*, [p. 1]; Ms Kerrie Baker, *Submission 328*, [p. 1]; Mr Mick Trajkovski, *Submission 329*, [p. 1]; Mr Gana Somayanda, *Submission 331*, [p. 1]; Ms Paula Foley, *Submission 332*, [p. 1]; Mr Simon Wilson, *Submission 333*, [p. 1]; Mr Brian Moss, *Submission 334*, [p. 1]; Mr Alistair McQuilkan, *Submission 335*, [p. 1]; Mr D Hart, *Submission 336*, [p. 1]; Mr Owen Lenegan, *Submission 337*, [p. 1]; Mr Nick Hrysanidis, *Submission 339*, [p. 1]; Mr Daniel Mason, *Submission 340,* [p. 1]; Mr Jason Traynor, *Submission 341*, [p. 1]; Mr Dan Holmes, *Submission 342*, [p. 1]; Mr John Moore, *Submission 343*, [p. 1]; Ms Angela Hauke, *Submission 344*, [p. 1]; Miss Peta Longstaff, *Submission 345*, [p. 1]; Mr Lee Summers, *Submission 346*, [p. 1]; Mr Peter Saunders, *Submission 347*, [p. 1]; Ms Tammie Opie, *Submission 348*, [p. 1];

4.30 Mr Savvas Dimitriou, the managing director of Vapoureyes Australia—which designs, manufactures, and distributes vaping products—discussed the smoking cessation trends he had observed in his customer base:

Ms Kathleen Jordan, *Submission 349*, [p. 1]; Ms Maree McClung, *Submission 350*, [p. 1]; Mr George Teepa, *Submission 350*, [p. 1]; Mr Clay Bell, *Submission 351*, [p. 1]; Ms Scarlett Niven, *Submission 352*, [p. 1]; Ms Sandy Hill, *Submission 355* [p. 1]; Mr Bunny Lim, *Submission 356* [p. 1]; Mr Edwin Seward, *Submission 357* [p. 1]; Mr John Brown, *Submission 358* [p. 1]; Mr Chris O'Connor, *Submission 359* [p. 1]; Ms Lauren Chalmers, *Submission 360*, [p. 1]; Mr Michael Byrne, *Submission 361*, [p. 1]; Mr Shaun Drew, *Submission 362*, [p. 1]; Ms Sheila Marsh, *Submission 363*, [p. 1]; Mr Mark Temple, *Submission 364*, [p. 1]; Mr Marvin Petilla, *Submission 365*, [p. 1]; Mr David Ormsby, *Submission 366*, [p. 1]; Mr Michael Oltmanns, *Submission 367*, [p. 1]; Mr Gerard McLinden, *Submission 368*, [p. 1]; Mr Christopher Merry, *Submission 369*, [p. 1]; Mr Adam Grace, *Submission 370*, [p. 1]; Mr Chris Cassidy, *Submission 371*, [p. 1]; Mr Gary Russell, *Submission 372*, [p. 1]; Ms Tracey Fawdry, *Submission 373*, [p. 1]; Mr Howard Randell, *Submission 374*, [p. 1]; Ms Tara Orr, *Submission 375*, [p. 1]; Mr Brad Martens, *Submission 376*, [p. 1]; Mr Will Weatherly, *Submission 377*, [p. 1]; Mr Jon Starink, *Submission 378*, [p. 1]; Mrs Denise Russell, *Submission 379*, [p. 1]; Mr Shane Robison, *Submission 380*, [p. 1]; Mr Peter Sharman, *Submission 381*, [p. 1]; Mr Gary McGrath, *Submission 382*, [p. 1]; Mr Cliff Chandler, *Submission 383*, [p. 1]; Mr Bryan Willis, *Submission 385*, [p. 1]; Ms Tara Holyoake, *Submission 386*, [p. 1]; Mr Daniel Stewart, *Submission 387*, [p. 1]; Mr Russ Wilson, *Submission 388*, [p. 1]; Mr Christian O'Brien, *Submission 389*, [p. 1]; Ms Jasmine Pene, *Submission 390*, [p. 1]; Mr Malcolm Bodie, *Submission 391*, [p. 1]; Mr Anthony Wright, *Submission 392*, [p. 1]; Mr Ben McBeth, *Submission 393*, [p. 1]; Mr Stafford Lumsden, *Submission 394*, [p. 1]; Ms Michele Bailey, *Submission 395*, [p. 1]; Mr Craig Farquharson, *Submission 396*, [p. 1]; Ms Cheryl Bennett, *Submission 397*, [p. 1]; Mr Francis M, *Submission 398*, [p. 1]; Mr Simon Wells, *Submission 399*, [p. 1]; Mr Christiaan van Schalkwyk, *Submission 400*, [p. 1]; Mr Jock Mac, *Submission 401*, [p. 1]; Mr Brad Hendry, *Submission 402*, [p. 1]; Name withheld, *Submission 405*, [pp. 1-2]; Name withheld, *Submission 406*, [p. 1]; Name withheld, *Submission 407*, [p. 1]; Name withheld, *Submission 408*, [p. 1]; Name withheld, *Submission 409*, [p. 1]; Name withheld, *Submission 410*, [p. 1]; Name withheld, *Submission 411*, [p. 1]; Name withheld, *Submission 412*, [p. 1]; Name withheld, *Submission 413*, [p. 1]; Name withheld, *Submission 414*, [p. 1]; Name withheld, *Submission 415*, [p. 1]; Name withheld, *Submission 416*, [p. 1]; Name withheld, *Submission 417*, [p. 1]; Name withheld, *Submission 418*, [p. 1]; Name withheld, *Submission 419*, [p. 1]; Name withheld, *Submission 420*, [p. 1]; Name withheld, *Submission 421*, [p. 1]; Name withheld, *Submission 422*, [p. 1]; Name withheld, *Submission 423*, [p. 1]; Name withheld, *Submission 424*, [p. 1]; Name withheld, *Submission 425*, [p. 1]; Name withheld, *Submission 426*, [p. 1]; Name withheld, *Submission 427*, [p. 1]; Name withheld, *Submission 428*, [p. 1]; Name withheld, *Submission 429*, [p. 1]; Name withheld, *Submission 430*, [p. 1]; Name withheld, *Submission 432*, [p. 1]; Name withheld, *Submission 433*, [p. 1]; Name withheld, *Submission 434*, p. 1; Name withheld, *Submission 435*, [p. 1]; Name withheld, *Submission 436*, [p. 1]; Name withheld, *Submission 437*, [p. 1]; Name withheld, *Submission 438*, [p. 1]; Name withheld, *Submission 439*, [p. 1]; Name withheld, *Submission 440*, [p. 1]; Name withheld, *Submission 441*, [p. 1]; Name withheld, *Submission 442*, [p. 1]; Name withheld, *Submission 443*, [p. 1]; Name withheld, *Submission 444*, [p. 1]; Name withheld, *Submission 445*, [p. 1]; Name withheld, *Submission 446*, [p. 1]; Name withheld, *Submission 447*, [p. 1]; Name withheld, *Submission 448*, [p. 1]; Name withheld, *Submission 449*, [p. 1]; Name withheld, *Submission 450*, [p. 1]; Name withheld, *Submission 451*, [p. 1]; Name withheld, *Submission 452*, [p. 1]; Name withheld, *Submission 453*, [p. 1]; Name withheld, *Submission 454*, [p. 1]; Name withheld, *Submission 455*, [p. 1]; Name withheld, *Submission 456*, [p. 1]; Name withheld, *Submission 457*, [p. 1]; Name withheld, *Submission 458*, [p. 1]; Name withheld, *Submission 459*, [p. 1]; and Name withheld, *Submission 460*, [p. 1].

> They'll transition to vaping over a period of a week to a month or thereabouts. There'll be a period of dual use and then they'll eventually transition completely to vaping. After that six months they typically drop off and either quit vaping completely or, in some rare cases, end up going back to smoking because they can't find the right device for their needs or whatever it might be. But the vast majority end up on that kind of six-month slide I suppose.[28]

4.31 Submitters also described the experience of moving from smoking combustible cigarettes to e-cigarettes. Ms Sheila Marsh told the committee that:

> On our return [from a cruise] I sent off for the vaping material needed to have a good effect and was willing to try but I kept spare cigarettes just in case it did not work?
>
> The first day, I was surprised, but thought surely it won't stop my smoking? So continued and decided I would not smoke a normal cigarette till I reached that dreadful stage of feeling anxious and desperate for a smoke, even to the point of crying as I was so addicted. It never happened! In fact I was so sure the next day, I would be reaching for my smokes, and was completely gobsmacked that I felt happy and relieved at not needing a smoke! I immediately sent off for more liquid.
>
> That was 7 years ago, and I have not looked back. Granted I still have the odd vape, but it has changed our life.[29]

4.32 Mr James Reid provided his observation of smokers moving to e-cigarettes and related products:

> I am, however, involved with a number of online vapers' forums and groups made up of thousands of everyday Australians who have one thing in common: we've all struggled over many years to give up smoking tobacco tobacco or cigarettes and we have finally found a way out, thanks to vaping. We discuss giving up smoking tobacco tobacco and we discuss vaping. We discuss emerging scientific evidence and discussion papers and we share our own personal stories. Most of us have tried all of the approved nicotine replacement therapies and prescribed medication, hypnosis, acupuncture, natural remedies, quit lines and simple willpower. Many of us have tried these techniques multiple times under the guidance of our GPs and failed. Along came vaping and everything changed. A lot of us were able to give up overnight. A few found it took a short period of dual use before switching completely.[30]

4.33 The committee heard a number of accounts from individuals who engaged initially in dual usage of both combustible cigarettes and e-cigarettes. It was noted that those who undertook dual usage often did so with the long-term

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[28] Mr Savvas Dimitriou, Managing Director, Vapoureyes Australia, *Committee Hansard*, 19 November 2020, p. 18.

[29] Ms Sheila Marsh, *Submission 363*, [p. 1] (age unknown, previously a smoker for 43 years).

[30] Mr James Reid, Private capacity, *Committee Hansard*, Canberra, 13 November 2020, p. 57 (57 years of age, previously a smoker for over 40 years).

goal of ceasing smoking combustible cigarettes entirely. Heavy smokers reported gradually reducing their consumption of combustible cigarettes with the goal of being 'smoke free'—that is, only utilising e-cigarette products. Most submitters reported going through a period of dual use—from a handful of weeks to over a year—before shifting to exclusively using e-cigarettes.

4.34 One submitter described the experience of shifting from a high level of combustible cigarette smoking to e-cigarette use:

> I started vaping in earnest in 2012. Soon, I had cut my cigarettes down from 40-60 per day to around 20-30 per day, by vaping as well (dual using). This was a HUGE win for me and I was proud of myself. I continued like this, dual using, vaping more and cutting down the smokes for about 14 months. Then one day soon after, a miracle happened, I became smoke free for the first time in over 50 years. I was over the moon (and still am!). Since that day, 6 ½ years ago, I can truthfully say that I have not once had a tobacco cigarette.[31]

4.35 A number of submitters reported being able to shift from dual usage to using only e-cigarettes, including a 50-year-old Victorian who indicated that they had transitioned to e-cigarettes five years ago:

> This literally saved my life! I never thought I could stop smoking and nobody loved it more than I did. Then one day it happened (my 50g pouches of rolling tobacco were around $55 at the time). I had been cutting down cigarettes by alternating with vaping until 6 months later, I completely stopped smoking—with comparative (to NRT) ease. I had zero success with other recommended quit aids, and caused myself a lot of unnecessary anxiety in the process(es) of trying to quit smoking.[32]

4.36 Similarly, Mrs Judith Wolters explained that she had:

> …smoked for 50 years and tried to stop smoking for 45 or more of those years, although in reality my life with tobacco began when I was 5 years old because I was taught to light my father's cigarettes while he was driving. Before I began vaping I was smoking 50 cigarettes a day. I began vaping in March or April 2014 and duel used before I could stop smoking in September 2014. I still craved tobacco for possibly a year after that but continued to vape. Nicotine is not the only element contributing to the addictive nature of tobacco.[33]

4.37 Some submitters also noted that, not only had they ceased dual usage, but also that combustible cigarettes—even including the flavour of tobacco—had become highly unappealing:

> These [quitting] approaches worked for a limited time, sometimes an hour, sometimes a month, however I always returned to smoking tobacco cigarettes. My NVP journey began with a month of dual use, after which

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31 Name withheld, *Submission 191*, [p. 1] (73 years of age, previously a smoker for over 50 years).

32 Name withheld Submission 53, [p. 1] (50 years of age, previously a smoker for 32 years).

33 Mrs Judith Wolters, *Submission 221*, [pp. 1-3] (70 years of age, previously a smoker for 50 years)

> time I exclusively vaped nicotine e-liquids as cigarettes lost their appeal. I am happy to report I have remained smokefree for over four years. I continue to use NVPs daily, with fruity or confectionary flavoured e-liquids with alternating nicotine levels between 12-24mg, I detest all tobacco flavoured e-liquids.[34]

4.38 One submitter reported that after a time spent using e-cigarettes they attempted to smoke a combustible cigarette:

> A few months ago, out of curiosity, I had a cigarette to see if it was as good as I remembered. It was gross and unsatisfying. I can honestly say that if I have a choice between vaping and smoking, I would like [to] stay vaping.[35]

4.39 Another submitter described how being around combustible cigarettes would previously cause a relapse, and how he now felt a lack of desire towards smoking combustible cigarettes:

> If there is experience to share in this, before vaping, I would always love a cigarette, even having not smoked for a couple of years. But every time I walked past someone, it smelt sweet, I wanted one, and eventually a circumstance would arise, a mate offering me one, when I would succumb and have a smoke again. What vaping has done for me, it has broken that desire for a cigarette, I never ever want another cigarette, they are disgusting to me now. Vaping means I will never smoke cigarettes again, it has successfully reduced the possibility of my premature demise, it has reduced harm.[36]

Reduction in nicotine consumption

4.40 For those submitters who used e-cigarette 'juices' that contain nicotine, some sought to gradually reduce their consumption of nicotine, while others sought to completely cease their consumption of nicotine.

4.41 A number of submitters reported that the experience of completely stopping smoking combustible cigarettes was not always easy. Some people who were attempting to move from smoking combustible cigarettes to e-cigarettes solutions that did not contain nicotine faced particular difficulties. One submitter described their experience:

> After getting used to vaping, I dropped my cigarette intake from around 50 a day to 20 a day. For 12 months, I vaped and smoked.
>
> In August last year, I set myself a quit day, and successfully stopped smoking. The quitting smoking was still hard, I craved that instant nicotine hit you get from a cigarette. After a couple of days of not smoking, my

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[34] Name withheld, *Submission 286*, p. 5 (age and length of smoking duration unknown).

[35] Name withheld, *Submission 201*, [p. 1] (38 years of age, previously a smoker since the age of 19).

[36] Name withheld, *Submission 405*, [p. 2] (age unknown, previously a smoker for 25 years).

> morning routine of coughing so much I vomited stopped. Then the coughing all night stopped.[37]

4.42 After reporting that he had transitioned from smoking combustible cigarettes to e-cigarettes in only 72 hours, another submitter noted the dramatic reduction in nicotine consumption he had undertaken while using e-cigarettes:

> Over the past four years I have reduced my nicotine strength [from] 20 mg to just 1 mg and often will vape with no nicotine. This strength reduction can not be done with cigarettes. I have gone from being exhausted just walking up my driveway to walking 5 km every day and 36 holes of golf each week. My lungs are clear and no longer wheeze, my circulation has returned to my feet and I no longer smell like an ashtray.[38]

4.43 While some submitters elected to continue using e-cigarettes indefinitely, or with reduced amounts of nicotine, others reported using e-cigarettes with the goal of ceasing all forms of nicotine delivery. One submitter reported that she only used e-cigarettes very intermittently, while seeking to avoid a relapse into smoking combustible cigarettes:

> I don't vape very often now. Using nicotine liquid and vaping, did not nearly feel as addictive as cigarettes. Now, I will only use it occasionally when I get an intense craving out of no where. It keeps me away from the temptation of smoking.[39]

4.44 Mr Luke Oliver explained his method of ceasing smoking combustible cigarettes and using e-cigarettes entirely, according to a long-term plan:

> In my four years of vaping I have cut down from 12 mg vape juice to 9mg, 6mg and 3mg at yearly intervals. Next April I intend to cut down to 1.5 mg, and 12 months later stop. This is my plan and I have stuck to it every step of the way.[40]

4.45 In a similar example, Mrs Linda Foster described how she overcame her addiction to combustible cigarettes by using e-cigarettes, and noted that now she neither smokes nor vapes:

> A friend introduced me to vaping 6 yrs ago, using PG and VG with flavouring and nicotine. I used this for around 2 years. One day I ran out of nicotine and just kept on using the vap with just the PG, VG and flavour. After another 1 year I put my vaper down one evening and never picked it

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[37] Name withheld, *Submission 201*, [p. 1] (38 years of age, previously a smoker for approximately 19 years).

[38] Mr Paul Webster, *Submission 311*, [p. 1] (54 years of age, previously a smoker for 30 years).

[39] Ms Tara Orr, *Submission 375*, [p. 1] (age unknown; submitter had previously been a smoker since 13 years of age).

[40] Mr Luke Oliver, *Submission 142*, [p. 1] (43 years of age, previously a smoker for approximately 21 years).

> up again. That was 3 years ago. To this date I've never wanted to smoke or vape again.[41]

Access to nicotine products

4.46 The following section describes submitters' accounts of how nicotine solutions and other products were acquired. The vast majority of submitters reported acquiring nicotine products online (see below), while others described experiences with the Therapeutic Goods Administration's (TGA) Personal Importation Scheme and seeking a prescription for nicotine products from their general practitioners.

Importation of nicotine

4.47 The committee heard that many individuals ordered nicotine online from overseas suppliers. Submitters noted that the most common method of accessing nicotine was to 'purchase and import e-liquid containing nicotine from international websites, most notably New Zealand and the United States of America'.[42] Other submitters told the committee about importing nicotine from China, Canada and the United Kingdom.[43]

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41 Mrs Linda Foster, *Submission 282*, [p. 1] (previously had smoked from the age of 10 to 64).

42 Name withheld, *Submission 22* [p. 1]. See also Mr James Reid, *Submission 4*, [p. 1]; Mr Shane Kerrigan, *Submission 8*, [p.1]; Mr Anthony Barron, *Submission 11*, [p. 1]; Name withheld, *Submission 13*, [p. 1]; Name withheld, *Submission 22* [p. 1]; Mr Joshua Waters, *Submission 28*, [p. 1]; Mr Deven Sporn, *Submission 34*, [p. 1]; Mr Graeme Angrave, *Submission 37*, [p. 1]; Mr Chris Hansen, *Submission 46*, [p. 1]; Name withheld, *Submission 48*, [p. 2]; Name withheld, *Submission 50*, [p. 1]; Mr Robert Adams, *Submission 65*, [p. 1]; Name withheld, *Submission 67*, [p. 2]; Name withheld, *Submission 73*, [p. 1]; Mr Bill Stewart, *Submission 76*, [p. 1]; Mr Aaron Fisher, *Submission 80*, [p. 1]; Name withheld, *Submission 81*, [p. 2]; Mr Mark Watson, *Submission 84*, p. 1; Name withheld, *Submission 88*, p. 1; Ms Ria Hopkins, *Submission 89*, p. 2; Name withheld, *Submission 95*, p. 1; Mr Paul Marshall, *Submission 103*, [p. 2]; Name withheld, *Submission 105*, [p. 2]; Name withheld, *Submission 111*, [p. 1]; Name withheld, *Submission 112*, [p. 1]; Name withheld, *Submission 127*, [p. 1]; Name withheld, *Submission 131*, [p. 2]; Mr Tim Palmer, *Submission 134*, [p. 1]; Dr David Mutch, *Submission 143*, [p. 1]; Name withheld, *Submission 145*, [p. 1]; Name withheld, *Submission 146*, [p. 1]; Ms Cat Wright, *Submission 147*, [p. 2]; Name withheld, *Submission 148*, [p. 1]; Name withheld, *Submission 149*, [p. 2]; Name withheld, *Submission 168*, [p. 1]; Mr Robert Pestell, *Submission 179*, [p. 1]; Dr Nicholas Cope, *Submission 185*, [p. 2]; Name withheld, *Submission 191*, [p. 1]; Mr Damien Hackett, *Submission 198*, p. 1; Ms Angela Gordon, *Submission 225*, [p. 10]; Mr Dan Tarasenko, *Submission 300*, [p. 1]; Mr Craig Brown, *Submission 320*, [p. 1]; Mr Gana Somayanda, *Submission 331*, [p. 1]; Mr Dan Holmes, *Submission 342*, [p. 1]; Ms Tammie Opie, *Submission 348*, [p. 1]; Mr Bunny Lim, *Submission 356* [p. 1]; Mr Chris O'Connor, *Submission 359* [p. 1]; Ms Sheila Marsh, *Submission 363*, [p. 1]; Mr Gerard McLinden, *Submission 368*, [p. 1]; Name withheld, *Submission 407*, [p. 1]; Name withheld, *Submission 430*, [pp. 2-3]; Name withheld, *Submission 440*, [p. 1]; and Name withheld, *Submission 452*, [p. 1].

43 See, for example, Mr Tom Morawetz, *Submission 2*, [p. 1]; Name withheld, *Submission 71*, [p. 1]; Ms Alison Paul, *Submission 125*, [p. 1]; Name withheld, *Submission 137*, [p. 1]; Mr Iain Carson, *Submission 212*, [p. 1]; *Submission 216*, [p. 1]; Mr Sam Whitehead, *Submission 310*, [p. 1]; *Submission 331*, [p. 1]; and Ms Angela Hauke, *Submission 344*, [p. 1].

4.48 Individuals also told the committee about purchasing non-nicotine flavoured e-liquids in Australia and ordering nicotine online. Mr Deven Sporn, for example, described his experience:

> …I have been vaping for approximately 7 years now with nicotine, starting from a pre dosed vape juice of 12mg from the USA and the importing my own nicotine to add to Australian made juices to which I only use 3mg today and haven't had a cigarette since.[44]

4.49 Submitters highlighted the issues associated with ordering nicotine online and noted that mixing it with e-liquids themselves can be problematic, as 'there are issues with storing and decanting of this liquid, and if not done correctly, with appropriate Personal Protective Equipment, could result in harm to the individual'.[45] Another individual submitted:

> I bought my hardware and flavoured non nicotine e juice (wild berries) from a local vendor and placed an order online for the nicotine from overseas. I practiced vaping with my non nicotine e juice whilst waiting for the nicotine, but continued smoking also. After the nicotine arrived I had to learn how to mix it myself (something I should never have to do) and find the right amount of nicotine I needed and the right flavouring for me before I quit cigarettes altogether.[46]

4.50 Many individuals who purchased nicotine online reported that 'there was a lot of trial and error involved'[47] and that it often took 'several attempts at finding the correct device and flavor to finally throw away the cigarettes'.[48]

4.51 Ms Bonnie Schultz told the committee:

> I must admit that I did spend a few hundred dollars on different devices and many many flavours. But no more than what I had spent over the years of trying to quit and far far less than I would have spent on cigarettes. Then I found the one I like the most.[49]

Obtaining a prescription

4.52 As outlined in Chapter 2, the Personal Importation Scheme currently requires a prescription from a general practitioner which outlines the patient's medical need for products containing nicotine. However, submitters told the committee of the difficulties they had faced trying to obtain a prescription

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[44] Mr Deven Sporn, *Submission 34*, [p. 1] (age unknown, previously a smoker since the age of 15).

[45] Name withheld, *Submission 22*, [p. 1] (40 years of age, previously a long-term smoker).

[46] Name withheld, *Submission 67*, [p. 2] (66 years of age, previously a smoker for 50 years).

[47] Mrs Tiffany Kereopa, *Submission 63*, [p. 1] (age unknown, previously a smoker for 20 years, after commencing at the age of 13).

[48] Ms Amy Trezise, *Submission 110*, [p. 1] (38 years of age, previously a smoker for 23 years).

[49] Ms Bonnie Schultz, *Submission 86*, [p. 1] (age unknown, previously a smoker for 45 years).

from doctors (to import nicotine legally into Australia).[50] Mr Tim Palmer stated that he 'obtained a prescription to cover my importation, but that was complex and difficult with less than ten prescribing doctors in all of Australia'.[51]

4.53 In evidence, Mr Reid told the committee that although he was 'able to import liquid nicotine, on prescription, under the TGA's Personal Importation Scheme', as he had a supportive general practitioner, that was not the case for many people:

> I'm so surprised that the vast majority—there's one or two others I know of that have had my experience—have spoken to their GP only to be told either, "I won't do it," or, "I don't know how to do it," or, "I don't think I can do it." The message hasn't gotten through to the knowledge base of a lot of GPs (1) that they can or (2) how they go about writing a prescription for someone to legally import their nicotine.[52]

4.54 The committee also heard that another common problem when trying to get a prescription for nicotine was that their general practitioner was unable to find the option through the prescription software. One individual stated 'I asked my doctor to write me a prescription for nicotine liquid, and he showed me how it wasn't an available option through his prescription system'.[53]

Proposal to prohibit personal importation

4.55 In June 2020, the Australian Government announced that it intended to amend the *Customs (Prohibited Import) Regulations 1956* to prohibit the importation of e-cigarettes containing nicotine solutions, as well as refills of nicotine solutions (unless the individual seeking to import such substances had obtained a prescription from a doctor). Many submitters opposed the prohibition on importation, and argued, amongst other things, that it would curtail the emerging e-cigarette industry in Australia, and increase the burden on doctors' surgeries and pharmacies.[54]

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[50] See, for example, Mr James Reid, *Submission 4*, [p. 1]; Mrs Yvette Hopkins, *Submission 9*, [p. 2]; Mr Matthew Landau, *Submission 54*, p. 4; Name withheld, *Submission 70*, [p. 1]; Name withheld, *Submission 79*, [p. 1]; Mr Tim Palmer, *Submission 134*, [p. 1]; Mr Foo Bar, *Submission 150*, [p. 2]; Name withheld, *Submission 151*, [p. 1]; Name withheld, *Submission 201*, [p. 2]; Name withheld, *Submission 216*, [p. 1]; Name withheld, *Submission 218*, pp. 1-3.

[51] Mr Tim Palmer, *Submission 134*, [p. 1] (55 years of age, previously an occasional smoker for approximately 15 years and a more regular smoker for around a decade).

[52] Mr Reid, *Committee Hansard*, 13 November 2020, p. 60. (57 years of age, previously a smoker for over 40 years).

[53] Name withheld, *Submission 201*, [p. 2] (38 years of age, previously a smoker since the age of 19).

[54] See, for example, Mrs Yvette Hopkins, *Submission 9*, [p. 2]; Mr Deven Sporn, *Submission 34*, [p. 1]; Stuart Bowermann, *Submission 55*, [p. 1]; and Mr Robert Adams, Submission 65, [p. 2].

Comments on the prescription-based model

4.56 The personal accounts of individual submitters often addressed the prescription-based model. These submitters generally opposed the prescription-based model.[55]

[55] See, for example, Name withheld, *Submission 1*, [p. 1]; Name withheld, *Submission 3*, [p. 1]; Mr Shane Kerrigan, *Submission 8*, [p.1]; Mrs Yvette Hopkins, *Submission 9*, [p. 2]; Mr Anthony Barron, *Submission 11*, [p. 1]; Name withheld, *Submission 12*, [p. 1]; Name withheld, *Submission 14*, [p. 2]; Name withheld, *Submission 19*, [p. 1]; Name withheld, *Submission 21* [p. 2]; Name withheld, *Submission 22* [p. 1]; Miss Kerri Shannon, *Submission 23*, [p. 2]; Name withheld, *Submission 24* [p. 2]; Mr Joshua Waters, *Submission 28*, [p. 4]; Mr Colin Mannings, *Submission 33* [p. 2]; Mr Deven Sporn, *Submission 34*, [p. 1]; Name withheld, *Submission 40* [p. 1]; Name withheld, *Submission 43* [p. 1]; Name withheld, *Submission 47*, [p. 2]; Name withheld, *Submission 48*, [p. 2]; Name withheld, *Submission 50*, [p. 1]; Mr Adam Metelmann, *Submission 51*, [p. 2]; Name withheld *Submission 53*, [p. 1]; Shayne O'Neill, *Submission 56*, [p. 3]; Mr Gerrad Geard, *Submission 57*, [p. 1]; Name withheld *Submission 58*, [p. 1]; Mr Brian Saint, *Submission 62*, [p. 1]; Mrs Tiffany Kereopa, *Submission 63*, [p. 1]; Mr Robert Adams, *Submission 65*, [p. 1]; Mr Robert Adams, *Submission 65*, [p. 2]; Name withheld, *Submission 67*, [p. 2]; Name withheld, *Submission 70*, [p. 1]; Name withheld, *Submission 72*, [p. 1]; Name withheld, *Submission 73*, [p. 1 and pp. 4-5]; Mr Samuel Cahir, *Submission 75*, [p. 1]; Mr Michael Ewart, *Submission 77*, [p. 1]; Mr Aaron Fisher, *Submission 80*, [pp. 1-2]; Name withheld, *Submission 81*, [p. 2]; Name withheld, *Submission 122*, [p. 1]; Mr Mark Watson, *Submission 84*, p. 1; Name withheld, *Submission 87*, p. 1; Ms Ria Hopkins, *Submission 89*, p. 2; Name withheld, *Submission 91*, p. 1; Name withheld, *Submission 95*, p. 2; Name withheld, *Submission 97*, [p. 1]; Name withheld, *Submission 98*, [p. 1]; Ms Samantha Barratt, *Submission 102*, [p. 1]; Mr Paul Marshall, *Submission 103*, [p. 2]; Name withheld, *Submission 105*, [p. 1]; Mr John Richardson, *Submission 109*, [p. 2]; Ms Amy Trezise, *Submission 110*, [p. 1]; Name withheld, *Submission 112*, [p. 1]; Name withheld, *Submission 115*, [p. 1]; Name withheld, *Submission 118*, [p. 1]; Mr Ken McNaughton, *Submission 121*, [p. 1]; Name withheld, *Submission 122*, [p. 1]; Name withheld, *Submission 127*, [p. 2]; Name withheld, *Submission 131*, [p. 1]; Mr John Walker, *Submission 138*, [p. 1]; Mr Luke Oliver, *Submission 142*, [p. 1]; Ms Deborah Smith, *Submission 144*, [p. 2]; Ms Cat Wright, *Submission 147*, [p. 1]; Mr Foo Bar, *Submission 150*, [p. 2]; Name withheld, *Submission 151*, [p. 1]; Name withheld, *Submission 175*, [pp. 3-4]; Mr Robert Pestell, *Submission 179*, [pp. 1-2]; Mr Adam Hazebroek, *Submission 187*, [p. 1]; Name withheld, *Submission 190*, [p. 1]; Name withheld, *Submission 191*, [p. 1]; Name withheld, *Submission 193*, [p. 1]; Name withheld, *Submission 201*, [p. 2]; Mr Justin Fowler, *Submission 203*, [p. 1]; Mr Ben Johnson, *Submission 204*, [p. 1]; Name withheld, *Submission 205*, [p. 1]; Name withheld, *Submission 206*, [p. 1]; Mr Charles McCracken, *Submission 211*, [p. 2 and pp. 4-5]; Name withheld, *Submission 213*, [p. 1]; Name withheld, *Submission 216*, [p. 2]; Mr Adam Hickmott, *Submission 219*, [p. 1]; Ms Rachael James, *Submission 224*, [p. 2]; Ms Angela Gordon , *Submission 225*, [p. 3]; Mr Robert Richter, *Submission 252*, [p. 1]; Ms Annette Huppatz, *Submission 265*, [p. 1]; Mr Patrick Cameron, *Submission 277*, [pp. 1-2]; Name withheld, *Submission 281*, [p. 1]; Name withheld, *Submission 284*, [p. 1]; Name withheld, *Submission 286*, p. 6; Mr Robert Rogers, *Submission 291*, [pp. 2-3]; Mr Duncan McLaren, *Submission 298*, [p. 1]; Ms Lyn Bennetts, *Submission 299*, [pp. 1-2]; Mr Angelo Ferlauto, *Submission 304*, [p. 1]; Ms Sheryl Mulvey, *Submission 307*, [p. 1]; Mr Jacent Hipworth, *Submission 316*, [p. 2, p. 4 and p. 6]; Mr Caleb Maher, *Submission 317*, [p. 1]; Mr Stuart Vanderplank, *Submission 319*, [p. 1]; Mr Craig Brown, *Submission 320*, [p. 1]; Mr Robert Finlay, *Submission 321*, [p. 1]; Mr Troy Smith, *Submission 325*, [p. 1]; Mr Gana Somayanda, *Submission 331*, [p. 1]; Ms Paula Foley, *Submission 332*, [p. 1]; Mr Simon Wilson, *Submission 333*, [p. 2]; Mr Brian Moss, *Submission 334*, [p. 1]; Mr D Hart, *Submission 336*, [p. 1]; Mr Owen Lenegan, *Submission 337*, [p. 1]; Mr Daniel Mason, *Submission 340*, [p. 1]; Mr John Moore, *Submission 343*, [p. 1]; Ms Tammie Opie, *Submission 348*, [p. 1];

4.57 Concerns were also raised about general practitioners who would be unwilling or unable to write a prescription to import nicotine solutions (and other e-cigarette products) for personal use.[56] It was noted that:

> Doctors and pharmacies we have so far approached with the upcoming ban, have already stated that they will not be participating in the new prescription and importation model and for us, that would leave us with little choice and force us elsewhere.[57]

4.58 It was also argued that the proposed regime would limit competition in the market:

> Up until now, it has been almost impossible to get a doctor's prescription for e-cigarette nicotine. While the Royal Australian College of General Practitioners generally supports their use, in my personal experience, most doctors will not prescribe. By their own admission, this is due to the existing regulations/standards/recommendations put in place by organisations like the government, the TGA etc. For them, prescribing is risky and complex, so they don't do it, even when they know the patient is already using these products, will continue to do so, and that these products are far superior to the alternatives. New restrictions only make it more difficult for doctors to prescribe. Even if one can secure a prescription, the new restrictions make it extremely difficult to acquire the products, and the products that will be available will be less diverse, and not as effective, as those currently available on the import market. I know, again from experience, that the products available through the Australian market, from doctors who both prescribe and sell retail merchandise, are unsatisfactory. They have a monopoly on the legal market, and have no incentive to innovate or compete on product choice or price.[58]

Mr Edwin Seward, *Submission 357* [p. 1]; Mr Gerard McLinden, *Submission 368*, [p.21]; Mr Christopher Merry, *Submission 369*, [p. 1]; Ms Tracey Fawdry, *Submission 373*, [p. 1]; Mr Bryan Willis, *Submission 385*, [p. 1]; Mr Daniel Stewart, *Submission 387*, [p. 1]; Mr Christian O'Brien, *Submission 389*, [p. 1]; Ms Jasmine Pene, *Submission 390*, [p. 1]; Mr Malcolm Bodie, *Submission 391*, [p. 1]; Mr Ben McBeth, *Submission 393*, [p. 1]; Mr Simon Wells, *Submission 399*, [p. 1]; Name withheld, *Submission 408*, [p. 1]; Name withheld, *Submission 412*, [p. 1]; Name withheld, *Submission 414*, [p. 1]; Name withheld, *Submission 419*, [p. 1]; Name withheld, *Submission 420*, [p. 1]; Name withheld, *Submission 421*, [p. 1]; Name withheld, *Submission 422*, [p. 1]; Name withheld, *Submission 423*, [p. 1]; Name withheld, *Submission 424*, [p. 1]; Name withheld, *Submission 425*, [p. 1]; Name withheld, *Submission 426*, [p. 1]; Name withheld, *Submission 427*, [p. 1]; Name withheld, *Submission 433*, [p. 1]; Name withheld, *Submission 436*, [p. 1]; Name withheld, *Submission 437*, [p. 1]; Name withheld, *Submission 440*, [p. 1]; Name withheld, *Submission 441*, [p. 1]; Name withheld, *Submission 442*, [p. 1]; Name withheld, *Submission 445*, [p. 1]; Name withheld, *Submission 448*, [p. 1]; Name withheld, *Submission 449*, [p. 1]; Name withheld, *Submission 451*, [p. 1]; Name withheld, *Submission 452*, [p. 2]; Name withheld, *Submission 455*, [p. 1]; and Name withheld, *Submission 460*, [p. 1].

[56] For particularly detailed discussions of the matter, see, for example, Mr Adam Hickmott, *Submission 219*, [p. 1]; Mr Chris Blanch, *Submission 313*, [p. 4]; Mr Christopher Merry, *Submission 369*, [p. 1]; and Mr Daniel Stewart, *Submission 387*, [p. 1].

[57] Name withheld, *Submission 12*, [p. 1] (39 years of age, previously a smoker for 24 years).

[58] Name withheld, *Submission 193*, [p. 1] (38 years of age, smoking duration unknown).

4.59 Submitters were also concerned that the introduction of a prescription-based regime would place an undue burden on general practitioners and the pharmacy system. For example, Mr Deven Sporn stated that:

> …having access via prescription will put a huge load on not only GP services that are at times stretched but the cost to taxpayers for these GP visits will be enormous and I fear that it would create a large, expensive and very dangerous black market for nicotine and run the risk of people not knowing what they are getting and the potential for fatal consequences.[59]

4.60 Similarly, Mr Reid argued that '[d]octors and pharmacists don't have the time or resources to become pseudo vaping outlets. They are doctors and pharmacists, and their core business and time are already at a premium'.[60]

4.61 Other submitters were concerned that a prescription-based model would increase the cost of e-cigarettes and related products, and create the same financial hardship that the increase in the tobacco excise had caused. For example, Ms Ria Hopkins submitted:

> This will result in reduced access and increased prices for these products and result in people, including myself, returning to traditional tobacco products in the form of combustible cigarettes.[61]

4.62 Submitters who were based in rural and regional areas were particularly concerned that accessing a prescription via a general practitioner would be onerous or even completely inaccessible. A submitter stated:

> I am concerned that should changes be made to any law that further restricts my ability to legally purchase vaping products, particularly proposed changes by the TGA regarding e-liquid, I will return to smoking. Even if that does not occur I feel that should the purchase of nicotine require me to obtain a prescription it may not be possible where I live. I live in a regional area of New South Wales where there is no guarantee that a doctor will issue such a prescription nor that such a product will be available in a local pharmacy. Given that a visit to the doctor currently costs me: over $50 in taxi fares; plus doctors fees (variable but increasing); plus additional expense should I be required to travel to a pharmacy; plus the unknown cost of such a purchase at the pharmacy (I suspect considerably more than I currently spend on e-liquid), I think it may be cheaper (certainly a lot easier) to purchase cigarettes.[62]

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[59] Mr Deven Sporn, *Submission 34*, [p. 1] (age unknown, previously a smoker from 15 years of age).

[60] Mr Reid, *Committee Hansard*, 13 November 2020, p. 58 (57 years of age, previously a smoker for over 40 years).

[61] Ms Ria Hopkins, *Submission 89*, p. 2 (29 years of age, previously a smoker for over 10 years).

[62] Name withheld, *Submission 50*, [p. 1] (age unknown, previously a smoker for over 30 years).

Potential impact on small businesses

4.63 It was also suggested that a prescription-based model would have a negative impact on small, Australian-based businesses specialising in e-cigarettes and related products.[63] A number of submitters were concerned that an emerging Australian industry—and associated jobs—would be curtailed. It was argued that:

> Australia is a world leader in the food and beverage industry with many iconic products and sensible vaping regulations would be all we need to create e-liquid development, lab analysis, manufacturing (bottles and labels), marketing and retail employment. Sensible nicotine regulation would allow our juice industry to grow and sell either free of nicotine or in various strengths and stop the money and jobs from flowing out of Australia into other economies.[64]

4.64 Mr Robert Adams, the owner of an e-cigarette store in Townsville, expressed his concerns regarding the future of his business and the ramifications for his customers:

> We currently employ 7 people between our two stores and have ideas to expand to create more employment to our local area, if the laws change and take the accessibility of nicotine away from our customers then that will mean the closure of our businesses, the loss of income to the 7 families that we employ and worse at least 5,000 people just in Townsville that will most likely start smoking again.[65]

Potential creation of a black market

4.65 A number of submitters stated that should a prescription-based model be enforced, they would either return to smoking or access nicotine e-cigarette products illegally.[66] The creation of a black market was regarded as highly

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[63] See, for example, Name withheld, *Submission 1*, [p. 1]; Mr Tom Morawetz, *Submission 2*, [p. 1]; Mr Joshua Waters, *Submission 28*, [p. 2]; Mr Michael Sandic, *Submission 29*, [p. 3]; Name withheld, *Submission 50*, [p. 1]; Mr Adam Metelmann, *Submission 51*, [p. 2]; Mr Stuart Bowermann, *Submission 55*, [p. 1]; Mr Robert Adams, *Submission 65*, [pp. 1-2]; Name withheld, *Submission 78*, [p. 1];

Mr Aaron Fisher, *Submission 80*, [p. 1]; Ms Alison Paul, *Submission 125*, [p. 2]; Name withheld, *Submission 127*, [p. 2]; Mrs Amanda Whitney, *Submission 153*, [p. 1]; Name withheld, *Submission 168*, [p. 2]; Name withheld, *Submission 175*, [p. 3]; Mr Damien Hackett, *Submission 198*, p. 2; Mr Charles McCracken, *Submission 211*, [pp. 4-5]; Ms Rachael James, *Submission 224*, [p. 2]; Name withheld, *Submission 231*, [p. 2]; Ms Lyn Bennetts, *Submission 299*, [p. 2]; Ms Angie Billenstein, *Submission 323*, [p. 1]; Mr George Teepa, *Submission 350*, [p. 1]; Mr Cliff Chandler, *Submission 383*, [p. 1]; Name withheld, *Submission 412*, [p. 1]; Name withheld, *Submission 440*, [p. 1]; and Name withheld, *Submission 452*, [p. 2].

[64] Name withheld, *Submission 231*, [p. 2] (58 years of age, previously a smoker since the age of 13).

[65] Mr Robert Adams, *Submission 65*, [p. 2] (age unknown, previously a long-term smoker).

[66] These submitters have not been directly referenced for their own protection.

undesirable by submitters, who expressed a clear preference for e-cigarettes and related products to be available in a legal and regulated manner.[67]

4.66 It was also argued that, should such a black market occur, it would result in products being consumed that were neither safe nor regulated:

> Limiting our access to these products through bans, prescription models, pharmacy only sales and extreme taxation will only lead to 2 possible outcomes; vapers going back to smoking or illegal imports and black market purchases which will never be safe nor regulated.[68]

4.67 Noting that, historically, prohibition had been largely unsuccessful, Mr Robert Rogers raised several questions:

> There are about 500,000 vapers in Australia, are we actually going to cut them off at the end of the year, have some of them go back to tobacco smoking. I doubt that the government will have the prescription system in place. Are we just going to prosecute them and make them criminals, are we going to enable a black market? Prohibition has never really worked, we should regulate it, tax it. If not, we will end up with unregulated goods and have the situation as in the USA where black market THC products included vitamin E acetate.[69]

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[67] See, for example, Name withheld, *Submission 14*, [p. 1]; Mr Don Brooke, *Submission 27*, [pp. 2-3]; Name withheld, *Submission 70*, [p. 1]; Name withheld, *Submission 88*, p. 2; Name withheld, *Submission 93*, p. 1; Mr Sam Macartney, *Submission 94*, [p.1]; Name withheld, *Submission 95*, p. 2; Name withheld, *Submission 97*, [p. 2]; Ms Dianne Gorman, *Submission 100*, [p. 2]; Ms Samantha Barratt, *Submission 102*, [p. 1]; Mr Paul Marshall, *Submission 103*, [p. 2]; Ms Amy Trezise, *Submission 110*, [p. 1]; Ms Penelope Turner, *Submission 113*, [p.1]; Mr Daniel Perfect, *Submission 114*, [p. 2]; Name withheld, *Submission 116*, [p. 1]; Name withheld, *Submission 175*, [p. 3]; Dr Nicholas Cope, *Submission 185*, [p. 2]; Mr Damien Hackett, *Submission 198*, p. 2; Name withheld, *Submission 218*, p. 1; Mr Robert Richter, *Submission 252*, [p. 2];Name withheld, *Submission 284*, [p. 1]; Name withheld, *Submission 286*, p. 6; Mr Wayne Betts, *Submission 295*, [p. 1]; Mr Duncan McLaren, *Submission 298*, [p. 1]; Mr Bunny Lim, *Submission 356* [p. 1]; Ms Lauren Chalmers, *Submission 360*, [p. 1]; Mr David Ormsby, *Submission 366*, [p. 1]; Mr Michael Oltmanns, *Submission 367*, [p. 1]; Mr Christopher Merry, *Submission 369*, [p. 1]; Mr Adam Grace, *Submission 370*, [p. 1]; Mr Brad Martens, *Submission 376*, [p. 1]; Mr Will Weatherly, *Submission 377*, [p. 1]; Mrs Denise Russell, *Submission 379*, [p. 1]; Mr Peter Sharman, *Submission 381*, [p. 1]; Mr Gary McGrath, *Submission 382*, [p. 1]; Mr Bryan Willis, *Submission 385*, [p. 1]; Mr Daniel Stewart, *Submission 387*, [p. 1]; Mr Russ Wilson, *Submission 388*, [p. 1]; Mr Ben McBeth, *Submission 393*, [p. 1]; Mr Stafford Lumsden, *Submission 394*, [p. 2]; Ms Michele Bailey, *Submission 395*, [p. 1]; Mr Craig Farquharson, *Submission 396*, [p. 1]; Cheryl Bennett, *Submission 397*, [p. 1]; Mr Jock Mac, *Submission 401*, [p. 1]; Name withheld, *Submission 407*, [p. 2]; Name withheld, *Submission 411*, [p. 1]; Name withheld, *Submission 430*, [p. 4]; Name withheld, *Submission 434*, p. 1; Name withheld, *Submission 437*, [p. 1]; Name withheld, *Submission 439*, [p. 1]; Name withheld, *Submission 445*, [p. 1]; Name withheld, *Submission 448*, [p. 1]; and Name withheld, *Submission 456*, [p. 1].

[68] Name withheld, *Submission 218*, p. 4 (45 years of age, previously a smoker for 20 years).

[69] Mr Robert Rogers, *Submission 291*, [p. 3] (a non-smoker who is concerned for his nephews, two of whom smoke combustible cigarettes).

Concerns over returning to combustible cigarettes

4.68 Submitters expressed concerns over returning to smoking combustible cigarettes if e-cigarettes and their associated liquids (including nicotine solutions) became overly cumbersome to access.[70] A small number were also concerned about the inability to continue using e-cigarettes and noted they had begun to accumulate supplies.[71] Others described emotional distress at potentially being unable to access products relied on, to reduce, or cease their consumption of combustible cigarettes.

4.69 Mr Justin Fowler explained that submitters were concerned about returning to smoking combustible cigarettes, should acquiring e-cigarettes and related products become too cumbersome or expensive:

> I am also deeply concerned that if vaping was further restricted that I would be definitely [sic] forced back to smoking poisonous tobacco products again as I have done in the past time and time again. I have finally beaten the grasp of tobacco products and rid them from my life for the benefit of myself, my family and all the others around me and this thought genuinely terrifies me.[72]

4.70 Another submitter described the mix of anxiety and trepidation that characterised the wait to see what regime would be instituted:

> Although I have been off cigarettes for 5 years (by using vaping), I am almost embarrassed to say that I feel anxious about the possibility of resorting to cigarette use if nicotine vaping was made so difficult and convoluted (and certainly not possible in the way I choose to vape). I'm genuinely scared - it is a delicate, fragile position to be in, and frustrating

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[70] See, for example, Name withheld *Submission 53*, [p. 1]; Name withheld, *Submission 72*, [p. 1]; Mr Mark Watson, *Submission 84*, p. 1; Ms Ria Hopkins, *Submission 89*, Name withheld, *Submission 91*, p. 1; Name withheld, *Submission 93*, p. 1; Name withheld, *Submission 96*, p. 1; Name withheld, *Submission 98*, [p. 1]; Name withheld, *Submission 118*, [p. 1]; Mr John Littlewood, *Submission 119*, [p. 1]; Mr Adam Hazebroek, Mr Shail Akhil, *Submission 126*, [p. 1]; *Submission 187*, [p. 1]; Name withheld, *Submission 191*, [p. 1]; Name withheld, *Submission 193*, [p. 1]; Mr Damien Hackett, *Submission 198*, p. 1; Name withheld, *Submission 200*, [p. 1]; Name withheld, *Submission 201*, [p. 1]; Mr Justin Fowler, *Submission 203*, [p. 2]; Name withheld, *Submission 206*, [p. 1]; Name withheld, *Submission 218*, p. 4; Mr Adam Hickmott, *Submission 219*, [p. 1];Name withheld, *Submission 285*, [pp. 2-3]; Mr Robert Rogers, *Submission 291*, [p. 3]; Mr Christopher Boreham-Carna, *Submission 296*, [p. 1]; Ms Pam Mulholland, *Submission 301*, [p. 1]; Mr Troy Luff, *Submission 302*, [p. 1]; Mr Angelo Ferlauto, *Submission 304*, [pp. 1-2]; Mr Alpha Centauri, *Submission 308*, [p. 1]; Mr Paul Briton, *Submission 309*, [p. 1]; Mr Jacent Hipworth, *Submission 316*, [p. 2 and p. 7]; Mr Dan Lucas, *Submission 318*, [p. 1]; Mr Troy Smith, *Submission 325*, [p. 1]; Mr Brian Moss, *Submission 334*, [p. 1]; Mr Lee Summers, *Submission 346*, [p. 1]; Mr Marvin Petilla, *Submission 365*, [p. 1]; Ms Tara Holyoake, *Submission 386*, [p. 1]; Name withheld, *Submission 429*, [p. 1]; Name withheld, *Submission 433*, [p. 1]; Name withheld, *Submission 436*, [p. 1]; Name withheld, *Submission 437*, [p. 1]; Name withheld, *Submission 437*, [p. 1]; and Name withheld, *Submission 444*, [p. 1].

[71] These submitters have not been referenced, as this practice is illegal in some states.

[72] Mr Justin Fowler, *Submission 203*, [p. 2] (34 years of age, previously a smoker from the age of 12).

> when there are clearly superior ways to manage vaping in Australia other than what is being proposed.[73]

4.71 The ability to use e-cigarette products in an accessible manner was seen as a priority by many:

> For the sake of many of us ex smokers, and many current smokers, who will become future ex smokers because vaping will help them quit, please do not make it any more difficult to access the only thing that ensures we do not use tobacco. Please do not, inadvertently, be the cause of 1000's of ex smokers, going back to smoking again. Please do not inadvertently deny access to the best stop smoking aid there is to the many current smokers, meaning many of them will fail to quit. Please do not be the cause of many 1000's of extra deaths, and smoking related health problems because you denied Australians easy access to the best stop smoking aid there is. Vaping.[74]

4.72 A 77-year-old submitter, who had begun using e-cigarettes after smoking combustible cigarettes at a rate of two packs a day, made the same point more simply, by asking '[p]lease do not hurt me'.[75]

Suggested reforms

4.73 The following considers the regulatory suggestions and other reforms proposed by submitters, who offered their personal perspective of what reforms are viable and most needed for users of e-cigarettes and the public more generally. Overwhelmingly, individual participants called for the regulation of e-cigarettes in Australia.[76] Submitters made the following suggestions:

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[73] Name withheld, *Submission 53*, [p. 1] (50 years of age, previously a smoker for 32 years).

[74] Name withheld, *Submission 200*, [p. 1] (age and smoking duration unknown).

[75] Mr Alpha Centauri, *Submission 308*, [p. 1] (77 years of age, and a long-term smoker).

[76] See, for example, Name withheld, *Submission 7*, [p. 2]; Mr Shane Kerrigan, *Submission 8*, [p. 2]; Name withheld, *Submission 14*, [p. 1]; Mr Don Brooke, *Submission 27*, [pp. 2-3]; Name withheld, *Submission 70*, [p. 1]; Name withheld, *Submission 88*, p. 2; Name withheld, *Submission 93*, p. 1; Mr Sam Macartney, *Submission 94*, [p.1]; Name withheld, *Submission 95*, p. 2; Name withheld, *Submission 97*, [p. 2]; Ms Dianne Gorman, *Submission 100*, [p. 2]; Ms Samantha Barratt, *Submission 102*, [p. 1]; Mr Paul Marshall, *Submission 103*, [p. 2]; Ms Amy Trezise, *Submission 110*, [p. 1]; Ms Penelope Turner, *Submission 113*, [p.1]; Mr Daniel Perfect, *Submission 114*, [p. 2]; Name withheld, *Submission 116*, [p. 1]; Name withheld, *Submission 175*, [p. 3]; Dr Nicholas Cope, *Submission 185*, [p. 2]; Mr Damien Hackett, *Submission 198*, p. 2; Name withheld, *Submission 218*, p. 1; Mr Robert Richter, *Submission 252*, [p. 2]; Name withheld, *Submission 284*, [p. 1]; Name withheld, *Submission 286*, p. 6; Mr Duncan McLaren, *Submission 298*, [p. 1]; Mr Bunny Lim, *Submission 356* [p. 1]; Ms Lauren Chalmers, *Submission 360*, [p. 1]; Mr David Ormsby, *Submission 366*, [p. 1]; Mr Michael Oltmanns, *Submission 367*, [p. 1]; Mr Christopher Merry, *Submission 369*, [p. 1]; Mr Adam Grace, *Submission 370*, [p. 1]; Mr Brad Martens, *Submission 376*, [p. 1]; Mr Will Weatherly, *Submission 377*, [p. 1]; Mrs Denise Russell, *Submission 379*, [p. 1]; Mr Peter Sharman, *Submission 381*, [p. 1]; Mr Gary McGrath, *Submission 382*, [p. 1]; Mr Bryan Willis, *Submission 385*, [p. 1]; Mr Daniel Stewart, *Submission 387*, [p. 1]; Mr Russ Wilson,

- 'What we do need is sensible legislation and regulation. We need effective enforcement of those regulations to ensure it remains an adult-only harm reduction consumer product with strict advertising, packaging and labelling regulations'.[77]
- 'I believe the production, import and sale of nicotine vaping products should be legalized, and regulated. Manufacture and import of nicotine products should be allowed with manufacturing and import licences, and the same sale laws and regulations should be used in Australia to allow for the sale of nicotine-containing vape liquid'.[78]
- 'I believe access to vaping products should, at the very least, be no more difficult than popping to the local shop or service station to buy cigarettes'.[79]

4.74 The argument was also made that nicotine should be available for vaping in Australia as a consumer product, with appropriate protections and controls in place.[80]

4.75 The issue of age restrictions was raised by submitters who believed that there should be minimum age restrictions for the sale of nicotine in Australia. Mr Paul Marshal suggested that '[f]or those under 18 an age restriction should apply and be enforced much like current smoking age restrictions'.[81] Another individual stated '[t]here should be an 18+ rule with ID checks, similar to alcohol'.[82]

4.76 It was also argued that tough penalties should be implemented 'for any vendors or persons caught selling to or supplying minors [with nicotine]'.[83]

Submission 388, [p. 1]; Mr Ben McBeth, *Submission 393*, [p. 1]; Mr Stafford Lumsden, *Submission 394*, [p. 2]; Ms Michele Bailey, *Submission 395*, [p. 1]; Mr Craig Farquharson, *Submission 396*, [p. 1]; Cheryl Bennett, *Submission 397*, [p. 1]; Mr Jock Mac, *Submission 401*, [p. 1]; Name withheld, *Submission 407*, [p. 2]; Name withheld, *Submission 411*, [p. 1]; Name withheld, *Submission 430*, [p. 4]; Name withheld, *Submission 434*, p. 1; Name withheld, *Submission 437*, [p. 1]; Name withheld, *Submission 439*, [p. 1]; Name withheld, *Submission 445*, [p. 1]; Name withheld, *Submission 448*, [p. 1]; and Name withheld, *Submission 456*, [p. 1].

77 Mr Reid, *Committee Hansard*, 13 November 2020, p. 58 (57 years of age, previously a smoker for over 40 years).

78 Name withheld, *Submission 88*, p. 2 (37 years of age, previously a smoker for approximately 15 years).

79 Ms Dianne Gorman, *Submission 100*, [p. 1] (70 years of age, previously a smoker for 45 years).

80 Miss Kerri Shannon, *Submission 23*, [p. 2]. See also Ms Hayley Dekker Lennon, *Submission 181*, [p. 1.]; Ms Rachael James, *Submission 224*, [p. 3]; Name withheld, *Submission 409*, [p. 1]; and Name withheld, *Submission 445*, [p. 1].

81 Mr Paul Marshall, *Submission 103*, [p. 2] (52 years of age, previously a smoker for 25 years).

82 Name withheld, *Submission 97*, [p. 2] (are unknown, previously a smoker for eight years).

83 Name withheld, *Submission 7*, [p. 2] (56 years of age, previously a smoker for over 40 years).

4.77 The need for regulation surrounding product safety was highlighted.[84] Submitters told the committee that currently high-strength nicotine imported into Australia is often provided in non-childproof packaging.[85] Ms Maureen Steele, for example, argued that '[w]e want the product to be safe with the creation of safety standards to ensure high quality of the product, child proof caps, warning labels etc'.[86]

4.78 Similarly, Mr Luke Oliver told the committee that nicotine e-juice:

> …should always have childproof caps. Information on nicotine handling should be mandatory with purchase. I would actually welcome government regulation of nicotine juice, in terms of safety standards and manufacturing information.[87]

4.79 In addition, Ms Cara King proposed that further regulation include a list of all ingredients and information on nicotine content.[88]

4.80 Submitters suggested various approaches to advertising and the promotion of e-cigarettes. Some submitters told the committee that advertising restrictions should be applied to e-cigarettes to ensure that individuals are 'aware of what products are available' and to allow 'retailers to display and demonstrate their

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[84] See, for example, Name withheld, *Submission 1*, [p. 1]; Name withheld, *Submission 3*, [p. 1]; Mr James Reid, *Submission 4*, [p. 1]; Mrs Yvette Hopkins, *Submission 9*, [p. 2]; Ms Maureen Steele, *Submission 10*, [p. 2]; Name withheld, *Submission 17*, [p. 1]; Name withheld, *Submission 21* [p. 2]; Name withheld, *Submission 22* [p. 1]; Miss Kerri Shannon, *Submission 23*, [p. 2]; Name withheld, *Submission 24*, [p. 2]; Mr Joshua Waters, *Submission 28*, [p. 1]; Dr Richard Watkins, *Submission 31*, [p. 2]; Mr Colin Mannings, *Submission 33* [p. 2]; Mr Chris Hansen, *Submission 46*, [p. 1]; Mr Adam Metelmann, S*ubmission 51*, [p. 2]; Name withheld, *Submission 52*, [p. 2]; Name withheld, *Submission 67*, [pp. 2-3]; Mr Bill Stewart, *Submission 76*, [p. 1]; Name withheld, *Submission 78*, [p. 1]; Mr Aaron Fisher, *Submission 80*, [p. 1]; Ms Samantha Barratt, *Submission 102*, [p. 2]; Mr Ken McNaughton, *Submission 121*, [p. 1]; Miss Leesa Austin, *Submission 141*, [p. 1]; Ms Deborah Smith, *Submission 144*, [p. 2]; Name withheld, *Submission 151*, [p. 2]; Name withheld, *Submission 168*, [p. 2]; Name withheld, *Submission 175*, [p. 1]; Mr Damien Hackett, *Submission 198*, p. 1; Mr Ben Johnson, *Submission 204*, [p. 1]; Name withheld, *Submission 218*, p. 1; Name withheld, *Submission 231*, [p. 2]; Ms Annette Huppatz, *Submission 265*, [p. 1]; Mr Patrick Cameron, *Submission 277*, [p. 2]; Name withheld, *Submission 284*, [p. 1]; Name withheld, *Submission 285*, [pp. 2-3]; Name withheld, *Submission 286*, p. 6; Ms Pam Mulholland, *Submission 301*, [p. 1]; Mr Jacent Hipworth, *Submission 316*, [pp. 2-3]; Mr Gana Somayanda, *Submission 331*, [p. 1]; Mr John Moore, *Submission 343*, [p. 1]; Mr George Teepa, *Submission 350*, [p. 1]; Mr Brad Martens, *Submission 376*, [p. 1]; Name withheld, *Submission 412*, [p. 1]; Name withheld, *Submission 437*, [p. 1]; Name withheld, *Submission 450*, [p. 1]; and Name withheld, *Submission 458*, [p. 1].

[85] Mr Reid, *Committee Hansard*, 13 November 2020, p. 58 (57 years of age, previously a smoker for over 40 years).

[86] Ms Maureen Steele, *Submission 10*, [p. 2] (51 years of age, previously a smoker since the age of 18).

[87] Mr Luke Oliver, *Submission 142*, [p. 2] (43 years of age, previously a smoker for approximately 12 years).

[88] See, for example, Ms Cara King, *Submission 254*, [p. 6] (age unknown, previously a smoker for 27 years).

various products'.[89] Others suggested restrictions or a complete ban on marketing and advertising of e-cigarettes.[90]

Sale of nicotine e-cigarette products and the use of specialist stores

4.81 Many submitters stated that they would like to buy nicotine from specialist vaping stores 'run by experienced and knowledgeable people with quality products'.[91] Submitters stated it would be safer for appropriately trained staff 'to mix nicotine prior to being sold to customers rather than risk unqualified people to store and mix nicotine in their homes'.[92] Ms Deborah Smith explained that:

> Vape nicotine should be available over the counter in specialist vape shops where good advice on vape appliances and nicotine liquids and strengths can be given. Pharmacists can't be expected to be familiar enough with different vapers, adjustments and nicotine strengths to help people quit.[93]

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[89] Mr Paul Marshall, *Submission 103*, [p. 2] (52 years of age, previously a smoker for 25 years).

[90] See, for example, Ms Cara King, *Submission 254*, [p. 6] (age unknown, previously a smoker for 27 years) and Name withheld, *Submission 235*, [p. 4] ().

[91] See, for example, Mr John Walker, *Submission 106*, [p. 2]. See also Mr Tom Morawetz, *Submission 2*, [p. 1]; Name withheld, *Submission 3*, [p. 1]; Name withheld, *Submission 7*, [p. 2]; Mr Shane Kerrigan, *Submission 8*, [p.1]; Ms Maureen Steele, *Submission 10*, [p. 2]; Name withheld, *Submission 12*, [p. 1]; Name withheld, *Submission 14*, [p. 1]; Name withheld, Submission 24 [p. 2]; Mr Joshua Waters, *Submission 28*, [p. 1 and p. 4]; Mr Michael Sandic, *Submission 29*, [p. 3]; Mr Colin Mannings, *Submission 33* [p. 2]; Mr Deven Sporn, *Submission 34*, [p. 1]; Ms Sheryl Mulvey, *Submission 35*, [p. 1]; Mr Graeme Angrave, *Submission 37*, [p. 1]; Name withheld, *Submission 39*, [p. 1]; Mr Troy Jeppesen, *Submission 42*, [p. 1]; Mr Martin Kewish, *Submission 44*, [p. 1]; Name withheld, *Submission 48*, [p. 2]; Name withheld *Submission 52*, [pp. 1-2]; Name withheld, *Submission 53*, [p. 1]; Mr Stuart Bowermann, *Submission 55*, [p. 1]; Mr Gerrad Geard, *Submission 57*, [p. 1]; Name withheld, *Submission 59*, [p. 1]; Mrs Tiffany Kereopa, *Submission 63*, [p. 1]; Mr Robert Adams, *Submission 65*, [pp. 1-2]; Name withheld, *Submission 67*, [p. 3]; Mr Aaron Fisher, *Submission 80*, [pp. 1-3]; Mr Mark Watson, *Submission 8*4, p. 1; Mrs Georgia Adams, *Submission 85*, p. 1; Mr John Walker, *Submission 106*, [p. 2]; Name withheld, *Submission 118*, [p. 1]; Ms Alison Paul, *Submission 125*, [p. 2]; Name withheld, *Submission 127*, [p. 2]; Mr Luke Oliver, *Submission 142*, [p. 1]; Dr David Mutch, *Submission 143*, [pp. 1-2]; Ms Deborah Smith, *Submission 144*, [p. 1]; Name withheld, *Submission 151*, [p. 2]; Name withheld, *Submission 168*, [p. 2]; Name withheld, *Submission 206*, [p. 1]; Mr Charles McCracken, *Submission 211*, [pp. 4-5]; Name withheld, *Submission 216*, [p. 2]; Ms Angela Gordon, *Submission 225*, [p. 3]; Ms Annette Huppatz, *Submission 265*, [p. 1]; Mr John Moore, *Submission 343*, [p. 1]; Ms Angela Hauke, *Submission 344*, [p. 1]; Mr George Teepa, *Submission 350*, [p. 1]; Mr Daniel Stewart, *Submission 387*, [p. 1]; Mr Malcolm Bodie, *Submission 391*, [p. 1]; Mr Anthony Wright, *Submission 392*, [p. 1]; Name withheld, *Submission 408*, [p. 1]; Name withheld, *Submission 410*, [p. 1]; Name withheld, *Submission 445*, [p. 1]; and Name withheld, *Submission 452*, [p. 2].

[92] Mr John Walker, *Submission 106*, [p. 2] (41 years of age, previously a smoker from the age of around 14 to 15).

[93] Ms Deborah Smith, *Submission 144*, [p. 1] (age unknown, previously a smoker for over 40 years).

4.82 Submitters also argued that the experience of going into a vaping shop is a different experience to seeing a general practitioner. Ms Dianne Gorman explained:

> If you go to a vape shop, you're talking to someone who has been through the experience. If you go to your GP, they really don't have a clue about what it's like to be that sort of smoker.[94]

4.83 Further, Ms Gorman stated '[m]y local pharmacist knows zip, zero, zilch about vaping. They don't even know about smoking. They certainly don't know anything at all about vaping'.[95]

4.84 In addition to age restrictions for the purchase of nicotine e-juice in vaping shops, the committee received further suggestions on how e-cigarettes could be sold in specialist stores:

- vaping shops to be allowed to display goods and discuss options;[96]
- vaping shops to be allowed to sell juice up to 50mg/ml;[97] and
- online sales of vaping products with third-party age verification, particularly for rural and remote adult smokers and vapers where vape shops may not be readily accessible.[98]

4.85 The importance of having access to a variety of flavours was also highlighted. Ms Gorman told the committee that '[i]f you do choose vaping as a quit method, you also need to be able to choose the devices and flavours that work for you. That's why so many flavours are available'.[99]

4.86 In addition, the taxation of e-cigarettes was discussed during the inquiry. Mr Michael Sandic recommended that 'vaping products should be taxed in Australia the same way NRT's (nicotine fruit flavoured gums, patches, fruit flavoured liquid sprays etc.) currently are'.[100] Mr Gary Russell also suggested '[o]k, put some tax on it, but not the astounding amount of tax that tobacco attracts'.[101] It was also suggested that '[a] moderate tax on the sale of nicotine could be used to assist in any costs that regulations may incur'.[102]

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94 Ms Dianne Gorman, Private capacity, *Committee Hansard*, Canberra, 13 November 2020, p. 62 (70 years of age, previously a smoker for 45 years).

95 Ms Gorman, *Committee Hansard*, 13 November 2020, p. 64.

96 Mr Colin Mannings, *Submission 33*, [p. 2] (52 years of age, previously a smoker since the age of 18).

97 Mr Colin Mannings, *Submission 33*, [p. 2].

98 Mr Charles McCracken, *Submission 211*, [p. 6] (67 years of age, previously a long-term smoker).

99 Ms Gorman, *Committee Hansard*, 13 November 2020, p. 57.

100 Mr Michael Sandic, *Submission 29*, [p. 3] (37 years of age, smoking duration unknown).

101 Mr Gary Russell, *Submission 372*, [p. 1] (age unknown and smoking duration unknown).

102 Name withheld, *Submission 417*, [p. 1] (69 years of age, previously a smoker for 50 years).

Jurisdictional comparison

4.87 Many submitters noted that they had undertaken personal research into e-cigarettes, nicotine solutions and related vaping products. Submitters cited research from the United Kingdom, New Zealand and the United States, with many noting that Australia's arrangements regarding e-cigarettes and related products were out of step with international best practice.[103]

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[103] See, for example, Mr James Reid, *Submission 4*, [p. 1]; Mr Richard Pruen, *Submission 5*, [p. 1]; Mr Alan Beard, *Submission 6*, [p. 1]; Name withheld, *Submission 7*, [p. 2]; Mr Anthony Barron, *Submission 11*, [p. 1]; Name withheld, *Submission 13*, [p. 2]; Name withheld, *Submission 14*, [pp. 1-2]; Name withheld, *Submission 18*, [p. 1]; Name withheld, *Submission 22* [pp. 1-2]; Name withheld, *Submission 24* [p. 2]; Mr Don Brooke, *Submission 27*, [p. 1]; Mr Joshua Waters, *Submission 28*, [p. 1]; Mr Michael Sandic, *Submission 29*, [p. 2]; Mr Colin Mannings, *Submission 33* [p. 2]; Mr Lewis Johnson, *Submission 36*, [p. 1]; Name withheld, *Submission 40* [p. 1]; Mr Martin Kewish, *Submission 44*, [p. 1]; Name withheld, *Submission 47*, [p. 1]; Mr Adrian Sheehan, *Submission 49*, [p. 2]; Mr Adam Metelmann, *Submission 51*, [pp. 1-2]; Name withheld *Submission 52*, [p. 1]; Name withheld *Submission 53*, [p. 1]; Mr Matthew Landau, *Submission 54*, p. 6; Shayne O'Neill, *Submission 56*, [pp. 2-3]; Name withheld *Submission 58*, [p. 1]; Name withheld *Submission 59*, [p. 1]; Mrs Tiffany Kereopa, *Submission 63*, [p. 1]; Mr Steve Rehberger, *Submission 74*, [p. 2]; Mr Samuel Cahir, *Submission 75*, [p. 1]; Name withheld, *Submission 81*, [p. 3]; Ms Trina Macleod, *Submission 83*, p. 2; Name withheld, *Submission 95*, p. 2; Name withheld, *Submission 97*, [p. 2]; Ms Samantha Barratt, *Submission 102*, [p. 2]; Name withheld, *Submission 111*, [p. 2]; Name withheld, *Submission 131*, [p. 1]; Mr Tim Palmer, *Submission 134*, [p. 2]; Name withheld, *Submission 137*, [pp. 2-3]; Dr David Mutch, *Submission 143*, [p. 2]; Ms Deborah Smith, *Submission 144*, [p. 3]; Name withheld, *Submission 146*, [p. 2]; Name withheld, *Submission 148*, [p. 1]; Name withheld, *Submission 168*, [p. 3]; Miss Alice Pierce, Submission 172, p. 2; Name withheld, *Submission 174*, [p. 1]; Name withheld, *Submission 175*, [p. 1] and [p. 3]; Mr Robert Pestell, *Submission 179*, [pp. 1-2]; Ms Hayley Dekker Lennon, *Submission 181*, [p. 1]; Name withheld, *Submission 193*, [pp. 1-3]; Mr Damien Hackett, *Submission 198*, pp. 2-3; Mr Ben Johnson, *Submission 204*, [p. 1]; Mr Arthur Wielgosz, *Submission 207*, [pp. 2-3]; Mr Charles McCracken, *Submission 211*, [pp. 3-4]; Name withheld, *Submission 216*, [p. 2]; Name withheld, *Submission 218*, pp. 2-3; Mrs Judith Wolters, *Submission 221*, [pp. 2-3]; Ms Rachael James, *Submission 224*, [p. 3]; Ms Angela Gordon , *Submission 225*, [p. 3]; Miss Paige Johnston, *Submission 230*, [pp. 2-3]; Mr Robert Richter, *Submission 252*, [p. 2]; Name withheld, *Submission 281*, [p. 1]; Name withheld, *Submission 284*, [p. 1]; Mr Robert Rogers, *Submission 291*, [p. 2]; Ms Pam Mulholland, *Submission 301*, [p. 1]; Mr Troy Luff, *Submission 302*, [p. 1]; Mr Damien Noonan, *Submission 303*, [p. 1]; Mr Chris Blanch, *Submission 313*, [p. 1]; Ms Paula Foley, *Submission 332*, [p. 1]; Mr Simon Wilson, *Submission 333*, [p. 2]; Mr Daniel Mason, *Submission 340,* [p. 1]; Mr John Moore, *Submission 343*, [p. 1]; Mr Edwin Seward, *Submission 357* [p. 1]; Mr Michael Byrne, *Submission 361*, [p. 2]; Mr David Ormsby, *Submission 366*, [p. 1]; Mr Michael Oltmanns, *Submission 367*, [p. 1]; Mr Adam Grace, *Submission 370*, [p. 1]; Mr Chris Cassidy, *Submission 371*, [p. 1]; Mr Gary Russell, *Submission 372*, [p. 1]; Mr Will Weatherly, *Submission 377*, [p. 1]; Mr Jon Starink, *Submission 378*, [pp. 1-3]; Mr Bryan Willis, *Submission 385*, [p. 1]; Mr Anthony Wright, *Submission 392*, [p. 1]; Mr Stafford Lumsden, *Submission 394*, [pp. 1-2]; Mr Simon Wells, *Submission 399*, [p. 1]; Mr Christiaan van Schalkwyk, *Submission 400*, [p. 3]; Name withheld, *Submission 405*, [p. 2]; Name withheld, *Submission 417*, [p. 1]; Name withheld, *Submission 435*, [p. 1]; Name withheld, *Submission 436*, [p. 1]; Name withheld, *Submission 440*, [p. 1]; Name withheld, *Submission 441*, [p. 1]; Name withheld, *Submission 447*, [p. 1]; Name withheld, *Submission 450*, [p. 2]; Name

4.88 Submitters also pointed to the juxtaposition between the approach taken in countries such as the United Kingdom, the United States and New Zealand and Australia's current (and proposed) approach to e-cigarettes. Several submitters proposed that the Australian Government consider using the New Zealand model. Mrs Tiffany Kereopa, for example, submitted that:

> My family in New Zealand often remark on how effortless their attempts and ongoing maintenance of their vaping is. They query why we, over here in Australia, struggle to provide access and support for smokers who simply want to improve their health and in turn, their lives and the lives of their families. New Zealand report steep declines in smoking rates as vaping continues to prove an effective quit method, along with a number of countries around the globe.[104]

4.89 It was also noted that certain overseas jurisdictions have not experienced high rates of youth vaping:

> The technologies of tobacco harm reduction should be encouraged as they have been in the UK, New Zealand and Japan. They are transformative and will, I have no doubt, totally supplant cigarette smoking. Beyond the health benefits these products produce vastly less environmental contamination (both passive smoke, odours and physical non-biodegradable wastes) and, as has been noted by fire brigades in the UK, remove a significant cause of building fires…
>
> The experience with well regulated nicotine vaping in the UK, EU and New Zealand show that the fears regarding young people taking them up on mass are unfounded, there is no evidence in these well regulated jurisdictions of people initiating smoking after vaping and they've shown eliquid vaping is an effective and popular means of quitting smoking. What has been seen in Japan with heat not burn products is very similar in its success; where over 3 million smokers quit using these harm reduction devices there since 2016.[105]

A brief message to all submitters

4.90 We thank all submitters who provided accounts of their lived experience, including those who submitted their experiences via form letters. Accounts of submitters' experiences with e-cigarettes and related products offer the committee insights into their personal lives and histories, as well as practical regulatory suggestions. We very much appreciate these shared experiences.

withheld, *Submission 452*, [p. 2]; Name withheld, *Submission 453*, [pp. 1-2]; Name withheld, *Submission 456*, [p. 2]; and Name withheld, *Submission 457*, [p. 1].

[104] Mrs Tiffany Kereopa, *Submission 63*, [p. 1] (age unknown, previously a smoker for 20 years, after commencing at the age of 13).

[105] Name withheld, *Submission 47*, [p. 1] (44 years of age, smoking duration unknown).

Chapter 5 - Issues

5.1 In Australia, the sale of nicotine e-cigarette products is prohibited unless approved as an aid to quit smoking combustible cigarettes. At the time of writing, no e-cigarette products have been approved for this purpose. E-cigarettes have generated considerable debate across the public health sector and among medical experts, both within Australia and internationally. Much of the evidence presented to the committee highlighted the varying views of stakeholders and the lack of scientific consensus regarding the safety of e-cigarettes and their efficacy as a smoking cessation aid.

5.2 Many submitters argued that e-cigarettes were less harmful than combustible cigarettes and sought their promotion to adult smokers as a less harmful alternative.[1] However, the view that e-cigarettes are effective cessation devices, with considerable health benefits, is contested. A number of submitters argued that e-cigarettes have the potential to be harmful and undermine tobacco control, with potentially damaging effects at the population level.[2] Others indicated that they were undecided due to what they perceived to be insufficient evidence.[3]

5.3 This chapter examines the evidence presented in relation to:

- whether e-cigarettes are less harmful than smoking combustible cigarettes;
- whether e-cigarettes are effective in helping people to quit smoking combustible cigarettes;
- whether the greater availability of e-cigarettes is likely to result in more young people and non-smokers taking up smoking combustible cigarettes; and

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1 See, for example, factasia, *Submission 45*, pp. 1-3; National Retail Association, *Submission 156*, p. 2; Ampol, *Submission 165*, pp. 1-2; Legalise Vaping, *Submission 173*, pp. 4-5; Tasmanian Small Business Council, *Submission 208*, p. 1; TSG Franchise Management, *Submission 215*, pp. 1-2; United Kingdom Vaping Industry Association, Submission 236, p. 1 and p. 3; and Juul Labs, *Submission 242*, pp. 1-4.

2 See, for example, Dr Michelle Jongenelis, *Submission 66*, p. 4; Thoracic Society of Australia and New Zealand, *Submission 162*, pp. 304; Department of Health, *Submission 167*, pp. 10-18; RACP, *Submission 170*, pp. 2-3 and pp. 14-15; New South Wales Health, *Submission 171*, pp. 3-4; Cancer Council, *Submission 194*, p. 4 and pp. 7-9; European Tobacco Harm Reduction Advocates, *Submission 202*, pp. 7-8; Cancer Australia, *Submission 251*, pp. 2-3 and pp. 6-7; Asthma Australia, *Submission 273*, p. 4; and Australian Health Promotion Association, *Submission 274*, p. 1 and p. 4;

3 See, for example, Australian Health Promotion Association, *Submission 274*, p. 1; and Stroke Foundation, *Submission 278*, p. 5.

- the public health impacts of e-cigarettes.

Harm reduction

5.4 A significant proportion of those who provided evidence in support of the legalisation of nicotine e-cigarette products highlighted the harm reducing potential of e-cigarettes.[4] Many submitters put forward the view that e-cigarettes may assist some smokers to move away from using tobacco products towards a cleaner form of nicotine delivery, and may ultimately be able to cease smoking.[5] Some also suggested that the public policy focus should be on reducing harm to combustible cigarette users, rather than eliminating smoking.[6]

5.5 The committee heard that harm reduction is a widely used concept across health, road safety and public policy. Examples of harm reduction include 'car seat belts, airbags, motorcycle helmets, bicycle helmets, frangible roadside poles and encouraging swimmers to swim between the flags'.[7]

5.6 The Australian Tobacco Harm Reduction Association (ATHRA) explained to the committee that:

> The main purpose of tobacco harm reduction (THR) is to reduce (not necessarily eliminate) the harm from smoking. The aim is not to stop nicotine as nicotine causes little harm. Tobacco harm reduction involves encouraging smokers to switch from high-risk combustible (burnable) cigarettes to a lower-risk nicotine alternative such as vaping.[8]

5.7 Harm reduction encompasses a range of pragmatic policies, regulations and actions which either reduce health risks by providing safer forms of products or substances, or encourage less risky behaviours.[9]

5.8 To this end, the *World Health Organization Framework Convention on Tobacco Control* (WHO FCTC) has recognised the importance of harm reduction as a key strategy for reducing the burden of tobacco products.[10]

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4 See, for example, ATHRA, *Submission 166*, pp. 5-6 and pp. 23-24; Legalise Vaping, *Submission 173*, pp. 4-5; New South Wales Users and AIDS Association, *Submission 253*, pp. 2-4 and 6-7; Vaping Trade Association of New Zealand, *Submission 263*, pp. 9-19; and Progressive Public Health Alliance, *Submission 271*, pp. 5-7.

5 See, for example, Juul Labs, *Submission 242*, p. 2; Nurses' Professional Association of Queensland, *Submission 258*, p. 2; and Vaping Trade Association of New Zealand, *Submission 263*, p. 30.

6 See, for example, National Retail Association, *Submission 156*, p. 3.

7 Progressive Public Health Alliance, *Submission 271*, p. 6.

8 ATHRA, *Submission 166*, p. 23.

9 Knowledge Action Change, *Burning Issues: The Global State of Tobacco Harm Reduction 2020*, 2nd edition, November 2020, p. 5.

10 WHO FCTC, Geneva, 21 May 2003, entry into force 27 February 2005, [2005] ATS 7, Article 1(d).

5.9 Similarly, in their submission, Professor Wayne Hall and Associate Professor Coral Gartner noted that:

> For people who are unable to quit smoking, switching to a less harmful way of obtaining nicotine may enable them to quit sooner and reduce the smoking-related harm they would experience if they continued to smoke. It is arguably unethical and unjust to deny people who have great difficulty ending their nicotine addiction from using less harmful alternatives while they continue to have ready access to tobacco cigarettes.[11]

Comparative lower harm of e-cigarettes

5.10 The committee received evidence from submitters who argued that e-cigarettes are less harmful than combustible cigarettes, but did not receive specific evidence from health organisations and government witnesses that e-cigarettes are more harmful than combustible cigarettes. However, the degree to which e-cigarettes are less harmful than combustible cigarettes was a topic of considerable debate, with varying views presented to the committee.

5.11 For example, Dr Michelle Jongenelis informed the committee that '[b]ased on the evidence to date, e-cigarettes are likely to be less harmful than conventional cigarettes, but they are not harmless'.[12] Dr Jongenelis stated:

> They have been found to contain a number of substances known to be harmful to people including formaldehyde, tobacco-specific nitrosamines, nicotine, and heavy metals. The flavourings added to e-liquids have been shown to be unsafe when inhaled directly to the lungs, posing a potential threat to the health of users. This is a particular concern for young adults who have been found to cite the availability of e-liquid flavourings as a major contributor to their initiation and continued use of e-cigarettes. There are significant health risks associated with the use of e-cigarettes, including reduced lung function, stiffness of the arteries, and increased risk of cardiovascular disease.[13]

5.12 Emeritus Professor Simon Chapman and Emeritus Professor Mike Daube also raised product ingredients as an area of concern: specifically, 'industrial grade glycols and glycerine that are unsafe for inhalation and food flavourings or other additives that may be safe for ingestion but not for exposure to the huge surface that our lungs represent'.[14]

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[11] Professor Hall and Associate Professor Gartner, *Submission 159*, p. 5.

[12] Dr Jongenelis, answer to written question on notice QoN 016-01, 20 November 2020 (received 22 November 2020).

[13] Dr Jongenelis, answer to written question on notice QoN 016-01, 20 November 2020 (received 22 November 2020).

[14] Emeritus Professor Simon Chapman and Emeritus Professor Mike Daube, answer to written question on notice QoN 014-09, 20 November 2020 (received 26 November 2020).

5.13 While the committee did not receive evidence from health organisations or government witnesses that e-cigarette use was more harmful than smoking, the Australian Medical Association (AMA) expressed the view that it was not accurate to characterise e-cigarette use as less harmful than smoking, as the health effects of e-cigarettes may include:

- exposure to nicotine, potentially at higher levels than that included in combustible cigarettes, which can harm adolescent brain development, including functions related to attention, learning, mood and impulse control;
- exposure to toxins that have been classified as cancer-forming agents, such as formaldehyde and various solvents;
- exposure to particulate matter, which may worsen existing illnesses or increase the risk of developing cardiovascular or respiratory disease;
- adverse events ranging from mouth and throat irritation, to life-threatening injuries caused by e-cigarettes overheating or exploding; and
- nicotine poisoning resulting from the accidental ingestion of e-liquids, with symptoms ranging from nausea and vomiting to severe life-threatening illness.[15]

5.14 In a joint submission, the Cancer Council, the National Heart Foundation of Australia and the Australian Council on Smoking and Health also suggested that e-cigarettes may negatively impact health. They stated:

> E-cigarettes expose users to chemicals and toxins at levels that have the potential to cause health effects including solvents such as propylene glycol, glycerol or ethylene glycol, which may form toxic or cancer-causing compounds when vaporised.[16]

5.15 The committee also heard evidence that use of e-cigarettes by smokers trying to quit 'is likely to lead to greater long-term exposure to nicotine than use of other smoking cessation measures'.[17] However, Professor Ron Borland noted that:

> Regardless of dependence, if use of low-toxin nicotine is much less harmful, the public health consequences of long-term use are still going to be much less than for smoking.[18]

5.16 A number of submitters argued that e-cigarettes are significantly less harmful than combustible cigarettes.[19] For example, Mr Clive Bates advised the committee that:

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[15] AMA, answers to written question on notice QoN 013-01, 19 November 2020 (received 25 November 2020).

[16] Cancer Council, the National Heart Foundation of Australia and the Australian Council on Smoking and Health, *Submission 194*, p. 7.

[17] Professor Emily Banks, *Submission 157*, p. 4.

[18] Professor Ron Borland, *Submission 160*, p. 6.

> Vaping is, beyond any reasonable doubt, far safer than smoking and may not be harmful at all. We know this from the basic physics and chemistry of the processes involved (combustion versus heated aerosol formation); the toxicology of the vapour (far fewer hazardous agents are detectable and at much lower levels), and much lower concentrations of key toxins found in the blood, urine or saliva of vapers compared to smokers.[20]

5.17 Similarly, Mr Konstantinos Farsalinos submitted that regulation of e-cigarettes should be risk proportionate and that currently 'there is compelling and undisputed evidence on the low risk of electronic cigarettes, especially when compared with the devastating effects of smoking'.[21]

5.18 A number of submitters questioned why the proposed regulations for e-cigarettes should be more stringent than the regulation that exists for combustible cigarettes. For example, the National Retail Association submitted that:

> The NRA and its members argue that it is completely illogical that, while retailers across 20,000 locations in Australia are permitted to sell their customers' cigarettes – universally acknowledged to be the most dangerous way for humans to consume nicotine – they are barred from retailing less harmful smoke-free vaping and heated tobacco products.[22]

5.19 Another submission noted that:

> The ban of e-cigarettes in Australia would remove the option for an alternative to tobacco smoking and is unethical to criminalize a product when a more harmful one is still legally available. While e-cigarettes provide a harm reduced option for consumption of nicotine products, it does not mean that they are harm-free and need to be regulated adequately.[23]

5.20 Professor Hayden McRobbie told the committee that 'based on the current data, the general consensus is that electronic cigarettes are less harmful than combustible tobacco, and therefore represent, in smokers who switch completely to electronic cigarettes, a harm reduction approach'.[24]

5.21 This view has been broadly adopted across a number of other jurisdictions, including the United Kingdom (UK) and New Zealand. Professor John Britton,

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[19] See, for example, factasia, *Submission 45*, pp. 1-3; National Retail Association, *Submission 156*, p. 2; Ampol, *Submission 165*, pp. 1-2; Legalise Vaping, *Submission 173*, pp. 3-5; Tasmanian Small Business Council, *Submission 208*, p. 1; TSG Franchise Management, *Submission 215*, pp. 1-2; United Kingdom Vaping Industry Association, *Submission 236*, p. 1 and p. 3; and Juul Labs, *Submission 242*, pp. 1- 4.

[20] Mr Clive Bates, *Submission 158*, Appendix, p. 2.

[21] Mr Konstantinos Farsalinos, *Submission 250*, [p. 2].

[22] National Retail Association, *Submission 156*, p. 2.

[23] Name withheld, *Submission 230*, [p. 1].

[24] Professor Hayden McRobbie, *Committee Hansard*, 13 November 2020, p. 29.

University of Notttingham, advised the committee that for many years 'UK policy has therefore been to encourage smokers, so far as possible, to try to quit smoking using current best medical therapy but failing that, to switch from tobacco to electronic cigarettes'.[25]

5.22 While debate continues about the level of safety, Public Health England has determined that there is consensus across the UK's public health community that e-cigarettes are significantly safer for users than smoking combustible cigarettes.[26] For example, the UK Royal College of Physicians, in its report *Nicotine without smoke: Tobacco harm reduction* found that:

> Although it is not possible to precisely quantify the long-term health risks associated with e-cigarettes, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products and may well be substantially lower than this figure.[27]

Claim that e-cigarettes are 95 per cent less harmful than combustible cigarettes

5.23 In 2015, Public Health England released its report *E-cigarettes: An evidence update* which stated that 'best estimates show e-cigarettes are 95 per cent less harmful to your health than normal cigarettes, and when supported by a smoking cessation service, help most smokers to quit tobacco altogether'.[28] The claim that e-cigarettes are 95 per cent less harmful than combustible cigarettes was quoted heavily in evidence received by the committee.

5.24 However, the Department of Health questioned the basis for the claim. It submitted that:

> Under typical conditions of use, the number and concentrations of potentially toxic substances emitted from unadulterated e-cigarettes are generally lower than tobacco smoke. 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.[29]

5.25 When questioned in relation to the 95 per cent figure, Dr Bernie Towler, Principal Medical Adviser, Department of Health, commented that despite the absence of definitive studies 'we would suspect that electronic cigarettes are safer'.[30]

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25 Professor John Britton, *Submission 130*, [p. 1].

26 Public Health England, *Use of e-cigarettes in public places and workplaces: Advice to inform evidence-based policy making*, July 2016, p. 4.

27 Royal College of Physicians, *Nicotine without smoke: Tobacco harm reduction*, April 2016, p. 84.

28 Public Health England, *E-cigarettes: an evidence update. A report commissioned by Public Health England*, 2015, p. 5.

29 Department of Health, *Submission 167*, p. 24.

30 Dr Bernie Towler, Principal Medical Adviser, Department of Health, *Committee Hansard*, 13 November 2020, p. 14.

5.26 Similarly, when questioned during Senate Estimates, Professor John Skerritt stated:

> I think the evidence is that vaping is less harmful than tobacco smoking, but I don't think the harm is trivial, and I don't think it's 95 per cent, or any figure like that, less harmful. In fact, there's a significant body of evidence on harm due to vaping containing nicotine. Nicotine is a dangerous poison. It's also highly addictive. But, say, for someone who has a mental illness—and that's a group that is disproportionately high in their smoking rates—certainly many people who work with people with mental illness are transitioning them from combustible tobacco smoking to vaping. But the end point for most doctors is nicotine freedom—not smoking and not vaping.[31]

5.27 Emeritus Professor Simon Chapman, Emeritus Professor Mike Daube and Professor Matthew Peters noted that the claim that e-cigarettes are 95 per cent less harmful than combustible cigarettes was first made in a 2014 report written by 12 individuals, 'some with a history of association with tobacco interests', and provided 'no transparent workings of how this figure was actually calculated'.[32]

5.28 However, since this study, Public Health England has commissioned a series of independent evidence reviews. One such review published in 2018 reinforced the previous finding that:

> Vaping poses only a small fraction of the risks of smoking and switching completely from smoking to vaping conveys substantial health benefits over continued smoking. Based on current knowledge, stating that vaping is at least 95% less harmful than smoking remains a good way to communicate the large difference in relative risk unambiguously so that more smokers are encouraged to make the switch from smoking to vaping. It should be noted that this does not mean e-cigarettes are safe.[33]

5.29 Professor Ron Borland noted that while the 95 per cent estimate was a reasonable estimation of the differential risk, '[it] needs to be kept under constant review if new evidence emerges that suggests some of the assumptions are flawed'.[34]

5.30 Professor Borland also noted that:

> The claim is grounded in good science, which is not the same as direct evidence. Of course there is no direct evidence as to what the effects of vaping will be over a lifetime of use: only the very earliest adopters of this

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[31] Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, *Senate Community Affairs Legislation Committee Hansard*, 27 October 2020, p. 14.

[32] Emeritus Professor Simon Chapman, Emeritus Professor Mike Daube and Professor Matthew Peters, *Submission 195*, p. 20.

[33] Public Health England, *Evidence review of e-cigarettes and heated tobacco products 2018: A report commissioned by Public Health England*, February 2018, p 20.

[34] Professor Ron Borland, *Submission 160*, p. 2.

> technology could have been vaping for as much as 10 years, or of what benefits shifting to NVPs from smoking may provide at different ages, and how this compares with quitting nicotine altogether at the same age. It will take decades of use to establish actual outcomes. That is why we need science, the evidence grounded elaboration of mechanisms to help us predict likely outcomes.[35]

Uncertainty about long-term effects of e-cigarette usage

5.31 Submitters highlighted a lack of long-term evidence on the potential harm, if any, from e-cigarette use.[36] For example, it was the position of the National Drug and Alcohol Research Centre that although it is generally agreed that e-cigarette use is less harmful than smoking combustible cigarettes 'the exact degree of harm reduction is not yet certain'.[37] Furthermore, it is 'likely that long-term use of regular e[-cigarettes] among never smokers will be associated with a degree of health harm, but the degree of such harm is uncertain'.[38]

5.32 The Royal Australasian College of Physicians (RACP) reiterated that the long-term impact on e-cigarette users remains unknown and that the safest option remained to cease all forms of nicotine consumption:

> The current evidence is unable to quantify the degree of harm reduction and to ascertain, in particular, long-term health impacts to vapers, including long-term health outcomes in their organ systems. What is known for certain at this point in time is that vaping is not without adverse health impacts. … Both e-cigarettes and tobacco products pose risks to health. The safest option for the community is not to use either. Thus, the RACP holds that not smoking tobacco or using e-cigarettes remain the safest options for the community; the proven and registered smoking cessation treatments are advised to be used ahead of vaping.[39]

5.33 The AMA likewise submitted that:

> The relative novelty of e-cigarette use compared to tobacco smoking means that there is a lack of robust longitudinal studies to confirm what the long-term health effects of e-cigarette use are, *and* whether these effects can be quantified as less harmful than those associated with tobacco smoking [emphasis in original].[40]

5.34 Some submitters, such as Professor Wilson, highlighted the publication of studies around e-cigarettes use and lung injury in the United States as 'why we

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35 Professor Ron Borland, *Submission 160*, p. 5.

36 See, for example, Emeritus Professor Simon Chapman, Emeritus Professor Mike Daube and Professor Matthew Peters, *Submission 195*, p. 3.

37 National Drug and Alcohol Research Centre, University of Sydney, *Submission 164*, p. 8.

38 National Drug and Alcohol Research Centre, University of Sydney, *Submission 164*, p. 8.

39 RACP, answer to questions on notice, 19 November 2020 (received 25 November 2020), p. 1.

40 AMA, answers to question on notice, 19 November 2020 (received 25 November 2020).

need a risk mitigation strategy'.[41] However, Dr Moller, Dr Kelso and Professor Jones told the committee that:

> E-cigarette or vaping related lung injury (EVALI) which was a lung condition, mostly in young individuals in the US in 2019 which led to 68 deaths and 2,668 hospitalizations, has been linked to contaminated THC (cannabis) vaping cartridges and was not associated with nicotine-containing e-cigarettes or liquids.[42]

5.35 Professor Allan indicated that 'we haven't got the long-term effects of e-cigarettes, but it's likely that those effects are a lot less than those of smoking tobacco'. He emphasised the 'enormous harm done by tobacco' and that regulating tobacco should take priority.[43]

5.36 Furthermore, Mr Paul Montague told the committee that 'although there is insufficient data…to accurately predict the long-term health effects of vaping…[w]hat we do know is the harm caused by tobacco use in the short, medium and long term'.[44]

5.37 The ATHRA submitted that 'the risks of NOT adopting vaping are much greater because cigarettes are substantially more harmful [emphasis in original]'.[45]

5.38 The UK Vaping Industry Association submitted that 'while not risk-free, vaping is a less harmful alternative for adults who would otherwise continue to smoke'.[46]

5.39 The need for more evidence to determine the potential long-term health effects of e-cigarettes was widely acknowledged, including among those advocating for policy change. However, many proponents of e-cigarettes shared the view that that 'we [do] know enough to be reassured about long term risk'.[47] Mr Bates submitted:

> The argument that we do not know the long-term risks is a statement of the obvious for a product that has been in the market for about twelve years. It is often claimed that it took decades for the harms of smoking to emerge and therefore that regulators should adopt a 'precautionary' approach. However, this is not the clinching argument many appear to assume it is. Bioscience and toxicology have advanced a immeasurably

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41 Professor Simon Wilson, President, RACP, *Committee Hansard*, 19 November 2020, p. 43.

42 Dr Moller, Dr Kelso and Professor Jones, *Submission 220*, p. 3.

43 Professor John Allan, President, Royal Australian and New Zealand College of Psychiatrists, *Committee Hansard*, 19 November 2020, p. 43.

44 Mr Paul Montague, *Submission 108*, p. 2.

45 ATHRA, *Submission 166*, p. 27.

46 UK Vaping Industry Association, *Submission 236*, [p. 1].

47 Mr Clive Bates *Submission 158*, p. 3.

> since the 1950s and we do not generally need to wait decades to determine risks associated with toxic exposures – for example, we would know immediately that cigarettes are highly dangerous if they were introduced today. We would not need to wait decades for smoking-related cancers and heart disease to develop.[48]

Potential negative impacts

Uptake by youth and non-smokers

5.40 Some submitters observed that there 'is strong evidence that young people who use e-cigarettes are substantially more likely to take up tobacco smoking than young people who don't use e-cigarettes'.[49] The ATHRA explained that the 'gateway theory postulates that young people who would never have become smokers will try vaping and that as a result a substantial proportion will become nicotine dependent and progress to regular cigarette smoking'.[50]

5.41 Emeritus Professor Mike Daube expressed concern that, should e-cigarette usage be normalised, Australia may risking losing health gains obtained in the area of youth smoking:

> While progress is always too slow, Australia is a leader in reducing smoking. Having 11 per cent of people smoking daily would have been beyond our expectations even a few years ago. Across the country, there are about 79,000 smokers—just that—in the 12-to-17 age range, and having three per cent among 12- to 15-year-olds is sensational. The tobacco industry has described Australia as 'the darkest market in the world'. So anything that renormalises smoking behaviour would be disastrous.[51]

5.42 Adjunct Professor John Skerritt, representing the Department of Health, told the committee that, within Australia and internationally, there was statistical evidence of a rise in youth using e-cigarettes:

> For example, just to quote from some statistics—we've talked about the [Australian Institute of Health and Welfare] statistics before—as recently as 2016, 2.3 per cent of kids and young adults aged 15 to 24 in Australia were regular vapers. That's now 4.5, almost a doubling. Among US high school students, it's gone in two years from 11.7 per cent in 2017 to 27.5 per cent in 2019 characterising themselves as current e-cigarette users. Among Canadians, it's gone from six per cent in 2017 to 15 per cent.[52]

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48 Mr Clive Bates *Submission 158*, p. 3.

49 Professor Emily Banks, Professor of Epidemiology and Population Health, ANU, *Committee Hansard*, 13 November 2020, p. 17.

50 ATHRA, *Submission 166*, p. 17.

51 Emeritus Professor Mike Daube, Private capacity, *Committee Hansard*, 19 November 2020, p. 2.

52 Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, *Committee Hansard*, 13 November 2020, p. 7.

5.43 In contrast, Professor Hall and Associate Professor Gartner raised the following concerns in relation to evidence claiming that the use of e-cigarettes increases smoking among adolescents:

- these studies over-estimate the association, as any young person who smokes a single puff of a cigarette is classified as a 'smoker';
- adolescents who are most likely to experiment with ENDS are those who are already at higher risk of using cigarettes (i.e. more likely to have the traits of sensation seeking and risk-taking);
- these studies were conducted in countries when there were no age restrictions on the purchase of ENDS; and
- epidemiological monitoring studies indicate that ENDS use has not increased regular cigarette smoking among young people, as would be the case if they were a gateway to cigarette smoking.[53]

5.44 The Royal College of Physicians of London in its report *Nicotine without smoke: Tobacco harm reduction*, concluded that while there was concern that e-cigarettes could act as a gateway to smoking for young people there was 'no evidence that [this] is occurring to any significant degree in the UK'.[54]

5.45 Similarly, the New Zealand Ministry of Health stated in September 2020 that:

> Despite some experimentation with vaping products among never smokers, vaping products are attracting very few people who have never smoked into regular vaping, including young people.[55]

5.46 A number of submitters expressed similar views.[56] For example, Professor Borland advised that 'these studies are also completely consistent with other possible relationships, most notably that the kinds of adolescents who try vaping would, in the absence of vaping, have tried smoking anyway and perhaps sooner'.[57]

5.47 Professor Borland continued:

> If there is a systematic causal relationship of vaping leading to smoking, then a rise in vaping levels should be associated with a rise in smoking levels at population level within the comparable time period. As the studies typically have one year follow-up, this would mean year to year increases in smoking as vaping increased. This has not been found in the countries where uptake of smoking is assessed regularly (largely the same

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[53] Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 159,* pp. 9–10.

[54] Royal College of Physicians of London, *Nicotine without smoke: Tobacco harm reduction*, April 2016, p. 190.

[55] New Zealand Ministry of Health, *Position statement on vaping*, September 2020

[56] See, for example, Professor Bullen and Associate Professor Walker, *Submission 138*, p. 5; Professor Kenneth Warner, *Submission 129*, p. 2; and Alcohol and Drug Foundation, Submission 209, p. 6.

[57] Professor Ron Borland, *Submission 160,* p. 6.

> countries, eg USA from which the observational studies come). Indeed, there is evidence that the rate of decline in smoking actually increased over the period when vaping first become popular in the USA.[58]

5.48 Similarly, the ATHRA submitted that a more plausible explanation for the association between youth vaping and smoking is due to shared risk factors:

> This posits that young people who experiment with risky behaviours such as vaping are simply more likely to also later try cigarette smoking because of shared risk factors (confounders) such as peer smoking, a family history of smoking, low socio-economic status and rebelliousness.[59]

5.49 In addition, some submitters referenced the advice of the Surgeon-General of the United States Public Health Service who characterised the increase in e-cigarette use amongst youth in the United States as an 'epidemic'.[60] On this point, Professor Hayden McRobbie informed the committee that:

> Certainly in some states in the US they have seen quite a large increase in the use of vaping products. 'Ever used' may not be a particular problem, because 'ever used' is often described as even just one puff. That doesn't necessarily cause ongoing vaping. However, what they have seen in some states with some electronic cigarette products is more regular or daily use in never-smokers. However, I think the data seems to restrict that mainly to the US. If we turn our heads to the EU or particularly England we don't see that same pattern occurring. That might be due to differences in advertising restrictions.[61]

Nicotine toxicity

5.50 As nicotine for e-cigarettes is not readily available in Australia, many individuals import nicotine and mix it into the e-liquid themselves. Evidence was offered to suggest that nicotine available in liquid form (for use in e-cigarettes) may present a risk of acute nicotine poisoning.[62] Nicotine poisoning can affect users of e-cigarettes directly, but may also occur when children unintentionally access nicotine solutions. The Department of Health submitted that:

> 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. Since 2013, there has been a significant

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58 Professor Ron Borland, *Submission 160*, p. 6.

59 ATHRA, *Submission 166*, p. 17.

60 Centres for Disease Control and Prevention, *Surgeon General's Advisory on E-cigarette Use Among Youth*, 9 April 2019, https://www.cdc.gov/tobacco/basic_information/e-cigarettes/surgeon-general-advisory/index.html (accessed 26 November 2020).

61 Professor Hayden McRobbie, *Committee Hansard*, 13 November 2020, p. 31.

62 See ATHRA, *Submission 166*, p. 22; RACP, *Submission 170*, p. 16; and Dr Jody Moller, *Submission 220*, p. 5.

> increase in the number of calls to Australian Poisons Centres involving cases related to e-cigarette exposures (191 between 2013 and 2016), and in 2018, a young child in Victoria died from poisoning after consuming an e-liquid containing nicotine.[63]

5.51 Such unintentional poisonings can be a result of unsafe products, and the committee heard that a lack of regulation 'puts users at risk of unsafe imported products'.[64] For example, the RACP expressed concern about nicotine ingestion in children and infants, noting that 'the risk of accidental exposure or ingestion of nicotine in e-liquid is a growing problem in that there is currently no regulation on child resistant packaging'.[65]

5.52 Many users of e-cigarettes who wrote to the committee requested regulation to improve product safety, noting that the current practice of importing nicotine solutions was leading to substandard products.[66]

5.53 For adult users of e-cigarettes, avoiding nicotine poisoning can be managed by individuals. E-cigarette users can regulate nicotine dosages by reducing intake based on early symptoms of overdose such as headache, dizziness and nausea.[67]

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[63] Department of Health, *Submission 167*, p. 20.

[64] ATHRA, *Submission 166*, p. 22.

[65] RACP, *Submission 170*, p. 17.

[66] See, for example, Name withheld, *Submission 1*, [p. 1]; Name withheld, *Submission 3*, [p. 1]; Mr James Reid, *Submission 4*, [p. 1]; Mrs Yvette Hopkins, *Submission 9*, [p. 2]; Ms Maureen Steele, *Submission 10*, [p. 2]; Name withheld, *Submission 17*, [p. 1]; Name withheld, *Submission 21* [p. 2]; Name withheld, *Submission 22* [p. 1]; Miss Kerri Shannon, *Submission 23*, [p. 2]; Name withheld, *Submission 24* [p. 2]; Mr Joshua Waters, *Submission 28*, [p. 1]; Dr Richard Watkins, *Submission 31*, [p. 2]; Mr Colin Mannings, *Submission 33* [p. 2]; Mr Chris Hansen, *Submission 46*, [p. 1]; Mr Adam Metelmann, *Submission 51*, [p. 2]; Name withheld *Submission 52*, [p. 2]; Name withheld, *Submission 67*, [pp. 2-3]; Mr Bill Stewart, *Submission 76*, [p. 1]; Name withheld, *Submission 78*, [p. 1]; Mr Aaron Fisher, *Submission 80*, [p. 1]; Ms Samantha Barratt, *Submission 102*, [p. 2]; Mr Ken McNaughton, *Submission 121*, [p. 1]; Miss Leesa Austin, *Submission 141*, [p. 1]; Ms Deborah Smith, *Submission 144*, [p. 2]; Name withheld, *Submission 151*, [p. 2]; Name withheld, *Submission 168*, [p. 2]; Name withheld, *Submission 175*, [p. 1]; Mr Damien Hackett, *Submission 198*, p. 1; Mr Ben Johnson, *Submission 204*, [p. 1]; Name withheld, *Submission 218*, p. 1; Name withheld, *Submission 231*, [p. 2]; Ms Annette Huppatz, *Submission 265*, [p. 1]; Mr Patrick Cameron, *Submission 277*, [p. 2]; Name withheld, *Submission 284*, [p. 1]; Name withheld, *Submission 285*, [pp. 2-3]; Name withheld, *Submission 286*, p. 6; Ms Pam Mulholland, *Submission 301*, [p. 1]; Mr Jacent Hipworth, *Submission 316*, [pp. 2-3]; Mr Gana Somayanda, *Submission 331*, [p. 1]; Mr John Moore, *Submission 343*, [p. 1]; Mr George Teepa, *Submission 350*, [p. 1]; Mr Brad Martens, *Submission 376*, [p. 1]; Name withheld, *Submission 412*, [p. 1]; Name withheld, *Submission 437*, [p. 1]; Name withheld, *Submission 450*, [p. 1]; and Name withheld, *Submission 458*, [p. 1].

[67] See Alcohol and Drug Foundation, *Submission 209*, p. 5; Nurses' Professional Association of Queensland, *Submission 258*, p. 146; and Australian Health Promotion Association, *Submission 274*, p. 4.

5.54 In addition, there are in-built protections with some e-cigarette devices. Professor Borland commented that 'most modern devices use thermistors to prevent overheating, further reducing any risk of acutely high intakes of such compounds'.[68]

5.55 In order to ensure that e-cigarette devices have appropriate protections and e-liquids are appropriately packaged to prevent children from accessing them, the ATHRA argued that 'a legal supply chain of regulated products will guarantee safer products with accurate labelling, health warnings and child-proof caps'.[69]

5.56 Professor Borland advised the committee that:

> Vaping products, very much like cigarettes, don't necessarily deliver a standard dose of nicotine to the user. It depends on how you use them, the power or the strength of the solution and maybe even the make-up of the mix of propylene glycol and vegetable glycerine, which can have an impact on nicotine delivery. So I think there's a nice balance between regulating the product to exclude things that we know are potentially harmful and being flexible over time to be able to adapt and change as we learn more.[70]

Dual use

5.57 Evidence before the committee suggested that e-cigarettes may be used concurrently with combustible cigarettes (referred to as dual use).[71] The Department of Health stated that this 'calls into question whether [e-cigarettes] will reduce harm among most smokers', and noted that current evidence suggests that dual usage and exclusive use of e-cigarettes may result in prolonged exposure to nicotine, which remains harmful.[72]

5.58 In discussing dual usage, Emeritus Professor Simon Chapman and Emeritus Professor Mike Daube directed the committee to a recent paper from the Longitudinal Population Assessment of Tobacco and Health Study,[73] which found that the vast majority of smokers who vape keep using cigarettes: 'one

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68 Professor Ron Borland, *Submission 160,* p. 2.

69 ATHRA, *Submission 166,* p. 22.

70 Professor Ron Borland, *Committee Hansard*, 13 November 2020, p. 35.

71 See, for example, Cancer Council, *Submission 251*, p. 2; Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 159*, pp. 10-11; Thoracic Society of Australia and New Zealand, *Submission 162,* p. 5; Department of Health, *Submission 167,* p. 25; RACP, *Submission 170*, p. 3; and Asthma Australia, *Submission 273*, p. 4.

72 Department of Health, *Submission 167,* p. 25.

73 Andrew F Brouwer, Jihyoun Jeon, Jana L Hirschtick, Evelyn Jimenez-Mendoze, Ritesh Mistry, Irina V Bondarekno, Stephanie R Land, Theodore R Holford, David T Levy, Jeremy M G Taylor, Nancy L Fleischer and Rafael Meza, 'Transitions between cigarette, ENDS and dual use in adults in the PATH study (waves 1–4): multistate transition modelling accounting for complex survey design', *Tobacco Control*, 16 November 2020, http://dx.doi.org/10.1136/tobaccocontrol-2020-055967.

in five exclusive ENDS [electronic nicotine delivery systems] users quit, and three in five (58%) of dual users (about half of all ENDS users in Australia) drop ENDS and go back to cigarettes after two years'.[74]

5.59 Similarly, the Thoracic Society of Australia and New Zealand submitted that 'no harm reduction is achieved through dual use, and the worst of both worlds is achieved'.[75] Professor Matthew Peters also told the committee that 'dual use is a harm accentuation'.[76] The Asthma Society likewise did not view dual use as productive for smoking cessation.[77]

5.60 In contrast, Associate Professor Coral Gartner and Professor Wayne Hall noted that there have been issues with past surveys that consider dual use:

> …the fact that many people who use ENDS [electronic nicotine delivery systems] also smoke cigarettes in cross sectional surveys (i.e. engage in 'dual use') is potentially misleading. These surveys do not distinguish between people who are trialling ENDS, people who are using them to cut down before quitting, and people who are engaging in long term dual use.[78]

5.61 Associate Professor Gartner and Professor Hall also raised the need for further long-term studies in order to determine what percentage of combustible cigarette smokers move to exclusive e-cigarette usage and what number engage in long-term dual use.[79]

5.62 Professor Chris Bullen noted that, regardless of the rates of dual usage by e-cigarette users, there may still be some limited benefits to dual usage:

> The scientific evidence points out the fact that there is a lot of dual use that goes on. Having said that, even cutting down the amount of cigarettes you smoke isn't perfect, but it does reduce your risk of long-term respiratory consequences, though probably not the cardiovascular consequences. There are still probably some risks of various forms of cancer, but there's emerging evidence of the risk of respiratory consequences of smoking. If you go to dual use you're smoking fewer cigarettes, and then that's of benefit. So there is some benefit, but it's not perfect.[80]

5.63 In contrast to the evidence described above, the overwhelming majority of e-cigarette users who wrote to the committee detailed many examples where

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[74] Emeritus Professor Simon Chapman and Emeritus Professor Mike Daube, answer to written question on notice QoN 014-04, 20 November 2020 (received 26 November 2020).

[75] Thoracic Society of Australia and New Zealand, *Submission 162*, p. 5.

[76] Professor Matthew Peters, former President and Co-Chair of Electronic Cigarettes Working Party, Thoracic Society of Australia and New Zealand, *Committee Hansard*, 19 November 2020, p. 28.

[77] Asthma Australia, *Submission 273*, p. 4.

[78] Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 159*, p. 10.

[79] Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 159*, p. 11.

[80] Professor Chris Bullen, *Committee Hansard*, 13 November 2020, p. 46.

smokers of combustible cigarettes had tried e-cigarettes and 'never looked back'.[81] These accounts also indicate that some e-cigarette users may smoke combustible cigarettes for a short period of time while transitioning solely to e-cigarette use.[82] More specific information on views is provided in Chapter 4 of the report.

E-cigarettes and smoking cessation

5.64 E-cigarettes are considered by some health professionals as an option to help people quit smoking combustible cigarettes, although this view is strongly contested and the published evidence is mixed. In the midst of uncertainty about the effectiveness of e-cigarettes as an aid to smoking cessation, health organisations have expressed a broad spectrum of opinions about the access to, and use, of e-cigarettes.

5.65 The Department of Health has expressed concern that there is no clear evidence that e-cigarettes assist smoking cessation. Rather, 'some evidence suggests the opposite effect: that overall they may be depressing smoking cessation'.[83] In addition, the Department of Health has stated that:

> Health claims for e-cigarettes, such as that they are effective smoking cessation aids or safe alternatives to conventional tobacco products, should be rejected by health authorities in the absence of robust supporting scientific evidence to substantiate these claims.[84]

5.66 The National Health and Medical Research Council's position is that, currently, there is insufficient evidence to conclude whether e-cigarettes can assist smokers to quit combustible cigarettes:

> Experts disagree about whether e-cigarettes may help smokers to quit, or whether they will become 'dual users' of both e-cigarettes and tobacco cigarettes. There is currently insufficient evidence to demonstrate that e-cigarettes are effective in assisting people to quit smoking and no brand of

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[81] See Mr James Reid, *Submission 4*, [p. 1]. See also Mr Damien Hackett, *Submission 198*, p. 1; Mr Damien Hackett, *Submission 198*, p. 1; Name withheld, *Submission 200*, [p. 1]; Mr Paul Webster, *Submission 311*, [p. 1]; and Ms Sheila Marsh, *Submission 363*, [p. 1].

[82] See, for example, Name withheld, *Submission 53*, [p. 1]; Mr Luke Oliver, *Submission 142*, [p. 1]; Name withheld, *Submission 191*, [p. 1]; Mr Damien Hackett, *Submission 198*, p. 1; Name withheld, *Submission 201*, [p. 1]; Mr Arthur Wielgosz, *Submission 207*, [p. 2]; Mrs Judith Wolters, *Submission 221*, [pp. 1-3]; Ms Rachael James, *Submission 224*, [p. 1]; Mr Norbert Zillatron Schmidt, *Submission 249*, [p. 1]; Mrs Linda Foster, *Submission 282*, [p. 1]; **N**ame withheld, *Submission 286*, p. 5; Mr Clay Bell, *Submission 351*, [p. 1]; Ms Tara Orr, *Submission 375*, [p. 1]; and Name withheld, *Submission 405*, [p. 2].

[83] Australian Government, Department of Health, *Policy and regulatory approach to electronic cigarettes (e-cigarettes) in Australia*, 28 November 2019, p. 2.

[84] Australian Government, Department of Health, *Policy and regulatory approach to electronic cigarettes (e-cigarettes) in Australia*, 28 November 2019, p. 2.

> e-cigarette has been approved by the Therapeutic Goods Administration for this purpose.[85]

5.67 The Therapeutic Goods Administration, AMA, Cancer Australia, Cancer Council Australia, National Heart Foundation of Australia and the RACP support the National Health and Medical Research Council's position.[86]

5.68 In addition, it was the position of the Thoracic Society of Australia and New Zealand that '[e]-cigarettes, whether containing nicotine or not, are not suitable consumer products'.[87]

5.69 The RACP advised the committee that:

> The current evidence is limited and insufficient in many aspects of e-cigarettes, ranging from its impacts, health risks, to its overall role in public health. In the absence of unequivocal evidence, any recommendation to further relax e-cigarette regulation is associated with potentially grave ramifications, impacting generations to come.[88]

5.70 In 2018, the Commonwealth Scientific and Industrial Research Organisation (CSIRO), after reviewing the available evidence on e-cigarettes, concluded that e-cigarette usage by non-smoking youths did predict future smoking and that e-cigarette usage was not proven as an effective smoking cessation method.[89] The CSIRO submitted that:

> It is a critical research question to determine the effectiveness of e-cigarettes compared to other smoking cessation methods among Australian smokers generally, and also among specific groups with a high smoking rate. The rate at which young people and adults in Australia start smoking as a result of using e-cigarettes should be assessed and monitored to fill a research gap. On present evidence, it is not possible to determine whether less restrictive access to e-cigarettes would reduce rates of smoking in Australia.[90]

5.71 Similarly, Ms Sharon Appleyard, a representative of the Department of Health, explained that 'while e-cigarettes may be helpful to some smokers individually in relation to smoking cessation, there's no evidence at a population level'.[91]

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85 National Health and Medical Research Council, *CEO Statement: Electronic cigarettes*, 3 April 2017.

86 RACP, *Submission 170*, p. 6.

87 Thoracic Society of Australia and New Zealand, *Submission 162*, p. 1.

88 RACP, *Submission 170*, p. 5.

89 CSIRO, *E-cigarettes, smoking and health*, June 2018, p. v.

90 Stephanie Byrne, Emily Brindal, Gemma Williams, Kim Anastasiou, Anne Tonkin, Samantha Battams and Malcolm Riley, CSIRO, *E-cigarettes, smoking and health: A literature review update*, 22 June 2018, pp. vi-viii.

91 Ms Sharon Appleyard, First Assistant Secretary, Department of Health, *Committee Hansard*, 13 November 2020, p. 6.

5.72 In contrast, Professor Kenneth Warner, Professor Emeritus of Health Management and Policy from the University of Michigan's School of Public Health, submitted that the current evidence 'indicates that vaping nearly doubles the odds of quitting smoking compared to governmentally-approved nicotine replacement therapy products.[92]

The evidence on smoking cessation

5.73 There have been a number of high-level studies into the effectiveness of e-cigarettes as smoking cessation aids. The following section considers the substantial reviews undertaken by the Australian National University (ANU) and Cochrane.[93]

The Australian National University summary report

5.74 The Australian Government commissioned the ANU to undertake a summary review of work conducted to date on the health impacts of e-cigarettes. The 2020 summary report found that 'there was insufficient evidence that nicotine e-cigarette products were a more effective smoking cessation aid than no intervention, non-nicotine e-cigarettes, placebo existing nicotine-replacement therapy or other best-practice interventions'.[94] However, the review noted that 'preliminary evidence highlights the potential for nicotine delivering e-cigarettes to support cessation, and more reliable, large-scale evidence is needed'.[95]

5.75 The summary report concluded that:

- Recent declines in smoking were largely driven by very low smoking uptake in younger people with 97 per cent of 14–17 year olds in 2019 having never smoked.
- The large majority of people successfully quitting smoking do so unaided or by going 'cold turkey'.

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92 Professor Kenneth Warner, *Submission 129*, p. 2.

93 Cochrane reviews are internationally acclaimed scientific reviews of evidence which cover a wide range of topics. The Australian Government funds free public access to the Cochrane Library, and the Department of Health notes that '[t]he Cochrane Collaboration is an international, non-profit organisation that produces unbiased analyses of reliable and relevant research studies. Cochrane systematic reviews are widely acknowledged as constituting the highest level of scrutiny of the scientific evidence available.' For further information, see Department of Health, *National Health and Medical Research Council (NHMRC) Program – Cochrane Library*, 12 December 2014, https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-cochrane.htm (accessed 10 December 2020).

94 Emily Banks, Katie Beckwith, Grace Joshy, ANU, *Summary report on use of e-cigarettes and relation to tobacco smoking uptake and cessation, relevant to the Australian context*, 24 September 2020, p. 7.

95 Emily Banks, Katie Beckwith, Grace Joshy, ANU, *Summary report on use of e-cigarettes and relation to tobacco smoking uptake and cessation, relevant to the Australian context*, 24 September 2020, p. 6.

- Current patterns of use in Australia are largely inconsistent with short term use of e-cigarettes for smoking cessation. Patterns are more consistent with people using e-cigarettes in addition to combustible cigarettes, substitution of combustible cigarettes with e-cigarettes and uptake of e-cigarettes by people who have never smoked.
- Among people who have never smoked or are current non-smokers, those who use e-cigarettes are, on average, around three times as likely to take up smoking of combustible cigarettes as those who have not used e-cigarettes.
- Current evidence suggests that nicotine-delivering e-cigarettes can result in prolonged exposure to nicotine through ongoing exclusive e-cigarette use or dual use with combustible cigarettes.[96]

5.76 In evidence, concerns were raised about one of the studies in the ANU's review which included a nicotine delivery amount of only 0.01 milligrams per millilitre, which was suggested to be an inappropriately low amount. In response, Professor Emily Banks explained the rationale in including such a study:

> Because of the remit to consider all types of e-cigarettes, because e-cigarettes are considered to have additional elements that may be supportive of quitting above and beyond nicotine (e.g. hand to mouth movements, taste, simulation of other aspects of the smoking experience) and because the dose of nicotine received by the user depends on the characteristics of the device as well as the nicotine concentration in the e-liquid, the review of e-cigarette efficacy for smoking cessation was inclusive of all doses of nicotine – including the potential to include e-cigarette interventions not delivering nicotine.[97]

The Cochrane reviews

5.77 The committee's attention was drawn to a series of reviews undertaken by Cochrane, which investigate elements of tobacco addiction, including:

- interventions at the population level;
- interventions to help smokers and other tobacco users to quit;
- interventions to prevent tobacco use;
- interventions to reduce harm in people who use tobacco; and
- other reviews on related matters.[98]

5.78 The 2014 Cochrane review of e-cigarettes as a smoking cessation tool found that e-cigarettes helped some people to stop smoking.[99] Based largely on the

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[96] Emily Banks, Katie Beckwith, Grace Joshy, ANU, *Summary report on use of e-cigarettes and relation to tobacco smoking uptake and cessation, relevant to the Australian context*, 24 September 2020, p. 7.

[97] Professor Emily Banks, Professor of Epidemiology and Population Health, ANU, answer to written question on notice, QoN 19-01, 25 November 2020 (received on 30 November 2020).

[98] All of Cochrane's reviews can be found on the organisation's website.

[99] Jamie Hartmann-Boyce, Hayden McRobbie, Chris Bullen, Rachna Begh, Lindsay F Stead and Peter Hajek, 'Electronic cigarettes for smoking cessation', *Cochrane Database of Systematic Reviews*, vol. 12,

combined results of two randomised controlled trials, involving over 600 people, the review found that using e-cigarettes containing nicotine increased the chances of stopping smoking combustible cigarettes long-term, compared to using e-cigarettes without nicotine. However, the review also noted that the quality of the evidence was low, because it was based on a small number of studies.[100]

5.79 These findings were affirmed in the results of an updated Cochrane review, which was published in 2016.[101] This review included an examination of 24 completed studies, three of which were randomised controlled trials and 21 of which were cohort studies. The updated review incorporated 11 new observational studies. However, the review's authors again noted that the quality of the evidence overall was low because it was based on a small number of studies.

5.80 In 2020, the Cochrane review was updated once again, with the results published on 14 October 2020. The latest version of the review included 50 completed studies, representing 12,430 participants, of which 26 studies

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no. CD010216, 2014. This was the first review of e-cigarettes to pool data and to conduct a meta-analysis.

[100] The review included randomised controlled trials, cohort follow-up studies and randomised cross-over trials each of which measured abstinence rates of current smokers (who were motivated or not motivated to quit) at six months or longer.

[101] Jamie Hartmann-Boyce, Hayden McRobbie, Chris Bullen, Rachna Begh, Lindsay F Stead and Peter Hajek, 'Electronic cigarettes for smoking cessation', *Cochrane Database of Systematic Reviews*, vol. 9, no. CD010216, 2016. A subsequent systematic review of the evidence on the harms and benefits of e-cigarettes, conducted by researchers from the Centre for Addictions Research of British Columbia, reached similar conclusions to those of the Cochrane review. The Centre for Addictions Research of British Columbia's review, which incorporated the findings of the Cochrane review, concluded on the basis of 18 research studies of strong to moderate quality, that the limited amount of data from these studies does not allow for a definitive judgement about the efficacy of vapour devices for cessation. Nonetheless, researchers in many of the cessation studies and surveys found that an appreciable number of vapour device users are quitting tobacco. Also, it appears that as many as half or more of tobacco quitters continued to use vapour devices after cessation. The research is mixed as to whether or not vapour device use had any effect on the desire or ability of those who smoke to quit tobacco use, but based on the preponderance of findings, it is clear that claims for a negative impact of vapour devices on cessation are unjustified. In a small number of studies researchers have suggested that newer devices are likely more effective for cessation, so studies performed with earlier models (which are rapidly falling out of favour among consumers) could reasonably be excluded in future evaluations of the effectiveness of vapour devices for cessation. The generalisability of the research findings is constrained by the large number of different devices and liquids used in the studies. See Renée O'Leary, Marjorie MacDonald, Tim Stockwell and Dan Reist, *Clearing the Air: A systematic review on the harms and benefits of e-cigarettes and vapour devices*, University of Victoria, 2017.

were randomised controlled trials.[102] On the basis of their analysis, the review's authors determined that there was:

> Moderate-certainty evidence that [e-cigarettes] with nicotine increase quit rates compared to [e-cigarettes] without nicotine and compared to [nicotine replacement therapy]. Evidence comparing nicotine [e-cigarettes] with usual care/no treatment also suggests benefit, but is less certain.[103]

5.81 The review observed that more studies were needed to confirm the degree to which e-cigarettes assisted with harm reduction. While the review's authors did not detect any clear evidence of harm from nicotine e-cigarettes, they noted that 'the longest follow-up was two years and the overall number of studies was small'.[104]

5.82 The 2020 Cochrane review noted that further randomised controlled trials of the effectiveness of e-cigarettes as cessation aids are underway and that their review will be updated as relevant new evidence becomes available.

Impact of e-cigarettes on smoking prevalence

5.83 Evidence on the impact of e-cigarettes on smoking cessation and tobacco consumption is beginning to accumulate. However, the committee received submissions which called for further research in this area.

5.84 The evidence that is currently available suggests that e-cigarettes can be at least as effective as other nicotine replacement therapies as aids to quitting smoking. The impact of legalising e-cigarettes on rates of smoking, was noted by Professor Ron Borland in the context of declining smoking rates abroad:

> The countries we tend to compare ourselves with most: New Zealand, Canada, the UK, US, and Europe all have much more liberal policies around vaping, indeed in the case of NZ and Canada, both have moved in the last few years from the same historical position Australia began with to explicitly legalize vaping in various forms and have put in place (or are putting in place) regulatory frameworks to minimize the risk. As far as we can tell, from those countries with enough data, smoking rates are

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[102] Jamie Hartmann-Boyce, Hayden McRobbie, Nicola Lindson, Chris Bullen, Rachna Begh, Annika Theodolou, Caitlin Notley, Nancy A Rogott, Tari Turner, Ailsa R Butler and Peter Hajek, Electronic cigarettes for smoking cessation, *Cochrane Database of Systematic Reviews*, vol. 10, no. CD010216, 2016.

[103] Jamie Hartmann-Boyce, Hayden McRobbie, Nicola Lindson, Chris Bullen, Rachna Begh, Annika Theodolou, Caitlin Notley, Nancy A Rogott, Tari Turner, Ailsa R Butler and Peter Hajek, Electronic cigarettes for smoking cessation, *Cochrane Database of Systematic Reviews*, vol. 10, no. CD010216, 2016.

[104] Jamie Hartmann-Boyce, Hayden McRobbie, Nicola Lindson, Chris Bullen, Rachna Begh, Annika Theodolou, Caitlin Notley, Nancy A Rogott, Tari Turner, Ailsa R Butler and Peter Hajek, Electronic cigarettes for smoking cessation, *Cochrane Database of Systematic Reviews*, vol. 10, no. CD010216, 2016.

> declining at least as fast, probably faster in those other countries than in Australia.[105]

5.85 International studies have been undertaken to model and better understand the long term impacts of e-cigarettes on smoking prevalence. For example, in the United States,[106] New Zealand,[107] and Singapore.[108] However, as Dr Elizabeth Greenhalgh and Dr Michelle Scollo observed:

> Such modelling is limited by a lack of understanding of long-term health effects, effects on smoking uptake, and effectiveness for cessation, and conclusions subsequently vary substantially depending on the assumptions and parameters used by researchers.[109]

The role of the tobacco industry

5.86 A key concern for submitters, particularly those in the health community, was that major tobacco companies were increasingly directly involved in the e-cigarette industry. For example, the Cancer Council, the National Heart Foundation of Australia and the Australian Council on Smoking and Health submitted that '[t]he tobacco industry is by far the dominant player in the global e-cigarette and other novel tobacco products market worth USD$11.73 billion in 2019'.[110]

5.87 Dr Michelle Jongenelis submitted that '[e]-cigarettes are part of Big Tobacco's product diversification strategy to deliver new and novel nicotine delivery

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[105] Professor Ron Borland, *Submission 160*, p. 7.

[106] David T Levy, Ron Borland, Eric N Lindblom, Maciej L Goniewicz, Rafael Meza, Theodore R Holford, Zhe Yuan, Yuying Luo, Richard J O'Connor, Raymond Niaura and David B Adams, 'Potential deaths averted in USA by replacing cigarettes with e-cigarettes', *Tobacco Control*, 27(1), 2018, pp. 18-25. See also this study's predecessor: David T Levy, Ron Borland, Andrea C Villanti, Raymond Niaura, Zhe Yuan, Rafael Meza, Theodore R Holford, Geoffrey Fong, Cummings K Michael and David B Adrams, 'The application of a decision-theoretic model to estimate the public health impact of vaporized nicotine product initiation in the United States', *Nicotine and Tobacco Research*, 19(2), 2017, pp. 149-59. For further information see National Academies of Sciences Engineering and Medicine, *Public health consequences of e-cigarettes*, The National Academies Press, Washington, DC, 2018.

[107] Frederieke S Petrovic-van der Deen, Nick Wilson, Anna Crothers, Christine L Cleghorn, Coral Gartner and Tony Blakely, 'Potential country-level health and cost impacts of legalizing domestic sale of vaporized nicotine products', *Epidemiology*, 30(3), 2019, pp. 396-404.

[108] Thi Thanh Tra Doan, Ken Wei Tan, Borame Sue Lee Dickens, Yin Ai Lean, Qianyu Yang and Alex R Cook, 'Evaluating smoking control policies in the e-cigarette era: a modelling study', *Tobacco Control 29.5*, 2019.

[109] Dr Elizabeth Greenhalgh and Dr Michelle Scollo, Chapter 18, Potential for harm reduction in tobacco control in Elizabeth Greenhalgh, Michelle Scollo and Margaret Winstanley (eds), *Tobacco in Australia: facts and issues*, Cancer Council Victoria, Melbourne, 2020.

[110] Cancer Council, the National Heart Foundation of Australia and the Australian Council on Smoking and Health, *Submission 194*, p. 9.

devices'.[111] In particular, Dr Jongenelis suggested that the vaping industry targets adolescents and young adults to drive their profits through the development and promotion of youth-orientated e-juice flavours and the use of appealing packaging and product design.[112]

5.88 The Australian Council on Smoking and Health commented that the involvement of Big Tobacco is motivated by profitability. Mr Maurice Swanson, Chief Executive Officer, stated:

> Their objective…is to provide a range of nicotine delivery devices, from traditional cigarettes to e-cigarettes through to heated tobacco products, and their reason for doing so is that they know that in many Western countries the prevalence of smoking is falling and they need to maintain profitability. If they can dress up their alternative nicotine delivery products as being safer—that's what they're promoting—then they can maintain both their share value and their profitability. That's the bottom line here.[113]

5.89 In contrast, Professor David Sweanor, Chair, Advisory Board for the Centre for Health Law, Policy and Ethics, University of Ottawa, told the committee that '[vaping] completely destroys [Big Tobacco's] business model'.[114] Professor Sweanor submitted that:

> The most important point to make is that vaping is absolutely not a strategy hatched by Big Tobacco to somehow create gains for their shareholders. Vaping is a classic example of disruptive technology that was developed independently of Big Tobacco, has been spurred on by consumers and entrepreneurs, and is an existential threat to the longstanding business model of Big Tobacco.[115]

5.90 Professor Sweanor went on to state that:

> The five-year stock charts of transnational tobacco companies show that they have been devastated since the advent of viable safer alternatives to cigarettes…Overall, these companies have lost over US$300 billion of collective market value.[116]

5.91 This point was also reiterated by Mr Savvas Dimitriou, Managing Director of Vapoureyes Australia, who told the committee that legalising e-cigarette use

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111 Dr Michelle Jongenelis, *Submission 66*, p. 6.

112 Dr Michelle Jongenelis, *Submission 66*, p. 6.

113 Mr Maurice Swanson OAM, Chief Executive Officer, Australian Council on Smoking and Health *Committee Hansard*, 19 November 2020, p. 34.

114 Professor David Sweanor, Chair, Advisory Board for the Centre for Health Law, Policy and Ethics, University of Ottawa, *Committee Hansard*, 19 November 2020, p. 21.

115 Professor David Sweanor, *Submission 161*, p. 2.

116 Professor David Sweanor, Chair, Advisory Board for the Centre for Health Law, Policy and Ethics, University of Ottawa, *Committee Hansard*, 19 November 2020, p. 21.

would disrupt the business model of big tobacco industry.[117] Mr Dimitriou presented on the personal and business aspects of the vaping industry as an e-cigarette user and Chairman of the Smoke-free Traders Association. In his view, the e-cigarette industry is a consumer-driven industry and '[o]ur entire business is about stealing Big Tobacco's customers'.[118] Mr Dimitriou also emphasised his desire to distance himself and the e-cigarette industry from the tobacco industry.[119]

[117] Mr Savvas Dimitriou, Managing Director, Vapoureyes Australia, *Committee Hansard*, 19 November 2020, p. 14.

[118] Vapoureyes Australia, *Submission 197*, p. 6.

[119] Mr Savvas Dimitriou, Managing Director, Vapoureyes Australia, *Committee Hansard*, 19 November 2020, pp. 13–14.

Chapter 6 - Regulatory approaches

6.1 During the course of the inquiry, evidence was provided to the committee on the relative strengths and weaknesses of a prescription-based model in comparison to other regulatory approaches.

6.2 It was argued by those in favour of a prescription-based model that this approach would avoid making e-cigarettes widely available to people who have never smoked or are non-smokers. It would also ensure that those seeking to quit smoking with the assistance of e-cigarettes would be required to access medical advice. These submitters drew attention to the importance of achieving an overall net harm reduction at the community level, not just for a particular group.

6.3 However, submitters concerned primarily with the harms associated with tobacco use, and the potentially lower harm of e-cigarettes for individuals, argued that liberalisation of e-cigarettes remains an important harm reduction strategy and may lead to a decrease in smoking prevalence. These submitters generally supported the treatment of e-cigarettes as a consumer good.

Evidence received on the prescription-based model

6.4 As previously noted, the Australian regulatory approach favours a prescription-based model. At the time of writing, the possession of nicotine for use in e-cigarettes without a prescription is illegal in all states and territories except South Australia.[1] E-cigarette users have, however, been able to source products online without a prescription.

6.5 If made final, the Therapeutic Goods Administration's (TGA) interim decision on nicotine scheduling would clarify the entry of nicotine in the Standard for the Uniform Scheduling of Medicines and Poisons (the Poisons Standard), with the principal effect that certain nicotine containing products for human use would require a prescription.[2]

6.6 The Australian Government's proposal to prohibit the importation of e-cigarettes containing nicotine would impose harsh penalties (of up to $222 000) on persons who import nicotine for use in e-cigarettes directly from

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1 Department of Health, *Submission 167*, p. 8.

2 TGA, *Notice of an interim decision to amend the current Poisons Standard*, 23 September 2020, https://www.tga.gov.au/resource/notice-interim-decision-amend-current-poisons-standard, (accessed 27 November 2020).

an overseas supplier without a valid import permit.[3] Instead, individuals may obtain e-cigarette products containing nicotine via a permit granted by the Department of Health to a doctor or medical supplier who would be able to import the goods using a courier service or by cargo service.[4]

Arguments in favour of a prescription-based model

6.7 The committee heard evidence that a prescription-based model appropriately restricts access to e-cigarettes containing nicotine, given that the long-term impacts of e-cigarette use are unknown. For example, the Queensland Nurses and Midwives' Union favoured a continued ban on the basis of the precautionary approach (like the Australian Association for Adolescent Health Ltd) until long-term research is able to rule out any long-term health consequences.[5]

6.8 A representative from the Department of Health noted that the proposed prescription-based scheme was part of a broader plan to reduce harm at the population level:

> …basically, there's really no evidence that e-cigarettes at a population level will lead to smoking cessation. Evidence at a population level is different to evidence at an individual level. So, while e-cigarettes may be helpful to some smokers individually in relation to smoking cessation, there's no evidence at a population level.[6]

6.9 The Royal Australasian College of Physicians (RACP) supported the view that e-cigarette usage should remain strictly regulated, noting that the long-term impacts of e-cigarettes and related products remained unclear at an aggregate level:

> …the current data [is] inadequate to inform the unequivocal impact of nicotine e-cigarettes on smoking rates, or the impact on the aggregate population health, including amongst populations who experience negative impacts across the social determinants, in that the effectiveness of e-cigarettes in smoking cessation is unclear.[7]

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3 TGA, *Prohibition in importing e-cigarettes containing vaporiser nicotine*, 17 November 2020, https://www.tga.gov.au/behind-news/prohibition-importing-e-cigarettes-containing-vaporiser-nicotine (25 November 2020).

4 TGA, *Prohibition in importing e-cigarettes containing vaporiser nicotine*, 17 November 2020, https://www.tga.gov.au/behind-news/prohibition-importing-e-cigarettes-containing-vaporiser-nicotine (25 November 2020).

5 Queensland Nurses and Midwives' Union, *Submission 210*, p. 3; and Australian Association for Adolescent Health Ltd, *Submission 264*, [p. 3].

6 Ms Sharon Appleyard, First Assistant Secretary, Department of Health, *Senate Community Affairs Legislation Committee Hansard*, 27 October 2020, p. 6.

7 RACP, *Submission 170*, p. 7.

6.10 The Australian Medical Association (AMA) agreed with this approach, noting that it 'strongly advocates for and supports a precautionary approach to the regulation of nicotine vaping products, and believes that the international experience supports this approach'.[8]

6.11 Emeritus Professor Simon Chapman, Emeritus Professor Mike Daube and Professor Matthew Peters advised the committee that 'the current access de facto free-for-all nicotine in Australia is allowing children easy access to vapable nicotine and carries significant quality and safety risks'.[9] They wrote in support of the prescription-based model and argued that it should remain in place until such a time as 'sufficient long term, high quality data may have accumulated to show that vapable nicotine poses an acceptable risk profile to allow it to be sold without prescription'.[10]

6.12 Similarly, Dr Khorshid advised the committee that:

> Really, the best part of a GP or prescription related model is that the prescription of the e-cigarette liquid would be accompanied by a conversation between the GP and the patient about their smoking, about other ways to quit and about the impacts of nicotine addiction on life and on their health.[11]

6.13 It was also argued that 'the obvious umpire in this matter should be the TGA'.[12] The George Institute for Global Health recommended that e-cigarette products be subject to the same rigorous assessments that the TGA applies to all other therapeutic products before they are made available to the Australian public, while the Lung Foundation submitted that 'all nicotine products for use as smoking cessation aids should be submitted to the TGA to review their safety and efficacy before they can be prescribed to Australians'.[13]

Arguments against a prescription-based model

6.14 Many witnesses and submitters argued that the prescription-based model for nicotine e-cigarette products was not evidence-based and was actually counterproductive.[14] For example, Legalise Vaping Australia argued:

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8 AMA, *Submission 183*, p. 2.

9 Emeritus Professor Simon Chapman, Emeritus Professor Mike Daube and Professor Matthew Peters, *Submission 195*, p. 30.

10 Emeritus Professor Simon Chapman, Emeritus Professor Mike Daube and Professor Matthew Peters, *Submission 195*, p. 30.

11 Dr Omar Khorshid, President, AMA, *Committee Hansard*, 19 November 2020, p. 48.

12 The George Institute for Global Health, *Submission* 267, [p. 1]; and Emeritus Professor Simon Chapman, Emeritus Professor Mike Daube and Professor Matthew Peters, *Submission 195*, p. 29.

13 Lung Foundation, *Submission 268*, p. 9.

14 See, for example, factasia, *Submission 45*, [p. 2]; National Retail Association, *Submission 156*, p. 2; Australian Tobacco Harm Reduction Association, *Submission 166*, pp. 23-24; Legalise Vaping

> Australia's health system is not prepared to prescribe nicotine, with GPs not knowing how to prescribe nicotine and pharmacies against stocking it. Australian vapers will go back to smoking cigarettes if vaping is only available as a prescription.[15]

6.15 Additionally, the International Network of Nicotine Consumer Organisations described the Australian Government's position as 'not sustainable' in light of recent evidence. It submitted:

> The Australian government's decision to delay the introduction of a risk proportionate regulation to enable people who use nicotine to access and to choose safer nicotine products whilst continuing to permit the free access to a known deadly combustible tobacco product is counterproductive. Justifying this decision by maintaining a lack of existing evidence a full fourteen years after the product entered the market is incompatible grounds to impose a precautionary de facto ban.[16]

6.16 Similarly to the RACP and AMA, the Australian Tobacco Harm Reduction Association (ATHRA) noted that it was 'not possible to quantify the population health impact of vaping with the available data', as health outcomes can 'take decades to appear'.[17] However, in contrast to their position, the ATHRA contended that studies of overall population benefit to date look promising:

> All modelling studies except one…indicate a substantial net public health benefit from vaping, such as life-years saved, and deaths averted, even after considering the potential harms such as harm from vaping and uptake by non-smokers.[18]

6.17 It was also argued that a prescription-based model is not proportionate to the risks associated with e-cigarette use.[19] Some submitters suggested that regulation as a consumer product would be a risk-proportionate approach.[20]

Australia, *Submission 173*, p. 3; Vapoureyes, *Submission 197*; p. 5; European Tobacco Harm Reduction Advocates, *Submission 202*, p. 1 and p. 9; TSG Franchise Management, *Submission 215*, [pp. 1-2]; International Network of Nicotine Consumer Organisations, *Submission 243*, p. 3; and Master Grocers Australia Independent Retailers, *Submission 276*, p. 3.

15 Legalise Vaping Australia, *Submission 173*, p. 3.

16 International Network of Nicotine Consumer Organisations, *Submission 243*, p. 3.

17 ATHRA, *Submission 166*, p. 12.

18 ATHRA, *Submission 166*, p. 13.

19 See, for example, Coalition of Asia Pacific Tobacco Harm Reduction Advocates, *Submission 38*, pp. 7-8; ATHRA, *Submission 166*, p. 7; Legalise Vaping, *Submission 173*, pp. 9-8; Aotearoa Vapers' Community Advocacy, *Submission 178*, p. 2; Juul Labs, *Submission 242*, pp. 3-4; International Network of Nicotine Consumer Organisations, *Submission 243*, p. 4; Mr Konstantinos Farsalino, *Submission 250*, [p. 2]; NSW Users and AIDS Association, *Submission 253*, pp. 2-6; and Vaping Trade Association of New Zealand, *Submission 263*, p. 5.

20 See, for example, factasia, *Submission 45*, pp. 2-3; National Retail Association, *Submission 156*, p. 3; Mr Clive Bates, *Submission 158*, pp. 6-7; ATHRA, *Submission 166*, pp. 3 and 5-6; Legalise Vaping,

6.18 We acknowledge the testimony from hundreds of individual submitters who have expressed the following reasons for their opposition to the prescription-based model:

- E-cigarettes have better health outcomes than smoking cigarettes and are an important strategy for harm minimisation.
- E-cigarettes provide a safer alternative to smoking tobacco, especially for those who are socially or economically disadvantaged or suffer from anxiety-related mental health issues.
- A prescription-based model would increase the burden on doctors' surgeries and pharmacies.
- Prohibition or increased restrictions on e-cigarettes are an infringement on freedom of choice.
- The prescription-based model would destroy the Australian e-cigarette industry, which encompasses a sizeable network of small and family-owned businesses across the country.[21]

6.19 These submitters indicated that should a prescription-based model be enforced it is likely that many of them will return to smoking combustible cigarettes (discussed earlier in Chapter 4). This same position was reaffirmed in thousands of form letters received by the committee.

6.20 Submitters noted that the enforcement of a prescription-based model through a prohibition on the importation of vaporiser nicotine could result in a growing black market in nicotine e-cigarette products.[22] The ATHRA advised the committee that the 'requirement for a prescription makes it far harder and more costly to access a much less harmful product' and 'the restricted access to legal vaping products has led to increasing black market sales which put users at risk from unsafe products'.[23] On this point, Professor Sweanor explained that limiting the availability of e-cigarette products is 'putting the safer alternative at a huge disadvantage'.[24]

Submission 173, p. 3; Vapoureyes, *Submission 197*, p. 2; Juddy Corp Pty Ltd, *Submission 227*, p. 2; NSW Users and AIDS Association, *Submission 253*, pp. 3-4; Vaping Trade Association of New Zealand, *Submission 263*, p. 5; and Progressive Public Health Alliance, *Submission 271*, p. 4.

[21] See, for example, Name withheld, *Submission 7*, [p. 2]; Mrs Yvette Hopkins, *Submission 9*, [p. 2]; Bowermann, *Submission 55*, [p. 1]; Name withheld *Submission 60*, [p. 1]; Name withheld, *Submission 201*, [p. 2]; Mrs Judith Wolters, *Submission 221*, [p. 1]; Ms Paula Foley, *Submission 332*, [p. 2]; and Mr Shaun Drew, *Submission 362*, [p. 1].

[22] See, for example, ATHRA, *Submission 166*, p. 5 and p. 24; Legalise Vaping, *Submission 173*, p. 4; Vapora, *Submission 226*, p. 2; Mr Konstantinos Farsalinos, *Submission 250*, p. 2; Liberal Democratic Party, *Submission 266*, p. 4; and Master Grocers Australia Independent Retailers, *Submission 276*, p. 3.

[23] ATHRA, *Submission 166*, pp. 5 and 24.

[24] Professor David Sweanor, Chair, Advisory Board for the Centre for Health Law, Policy and Ethics, University of Ottawa, *Committee Hansard*, 19 November 2020, p. 22.

6.21 Mr Bates questioned how the proposed prescription-based model would affect smokers who wished to access e-cigarettes and submitted that the model would 'almost close this route to new switchers'.[25]

6.22 The National Retail Association also submitted that:

> …it defies common sense from a public health perspective that a regulatory model whereby products, in the form of cigarettes, contribute to the deaths of 21,000 Australians each year will continue to be freely available whilst less harmful ones, in the form of smoke free alternatives, would be less available.[26]

6.23 While the Lung Foundation did not support the use of e-cigarettes as a 'harm reduction smoking cessation method', it spoke out against the proposed rescheduling of nicotine under the Poisons Standard on the basis that this approach does not require the prescribed products to be assessed for safety, toxicity and health impacts. The Lung Foundation stated that the proposed rescheduling would provide 'implicit approval to the manufacturers and consumers of nicotine products' and that it would transfer 'responsibility for the safety, efficacy and physical impact of these products to the medical professionals prescribing, and possibly, dispensing the unapproved therapeutic nicotine products'.[27]

6.24 Some submitters noted that limiting the sale of e-cigarettes products to pharmacies would curtail Australia's fledgling vaping industry.[28] Legalise Vaping noted that:

> …people are using vaping to quit smoking, and vape shops are an integral part of this process. Not only do shops provide advice and instructions on vaping, they are employers and part of Australia's economy.[29]

6.25 The National Retail Association quantified this impact:

> Retail businesses are already struggling in an extremely difficult operating environment. The Department's proposed model locks out 20,000 small businesses and the 400,000 Australians these businesses employ. Instead the proposal grants a monopoly to big pharma companies.[30]

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[25] Mr Clive Bates, *Submission* 158, Appendix, p. 12.

[26] National Retail Association, *Submission 156,* p. 6.

[27] Lung Foundation, *Submission 268*, p. 9.

[28] See, for example, Mr Robert Adams, *Submission 65*, pp. 1-2; National Retail Association, *Submission 156*, p. 9; Professor Hall and Associate Professor Gartner, *Submission 159*, p. 12; ATHRA, *Submission 166*, p. 22; Legalise Vaping, *Submission 173*, pp. 3-4; and Juddy Corp Pty Ltd, *Submission 227*, p. 2.

[29] Legalise Vaping, *Submission 173*, p. 4

[30] National Retail Association, *Submission 156,* p. 6.

6.26 This view was supported by individuals who submitted their personal accounts of lived experiences using e-cigarettes. Many of these submitters expressed a preference for purchasing e-cigarettes and related products from local vaping stores.[31]

Obtaining a prescription

6.27 When questioned in relation to how many doctors currently prescribe nicotine e-cigarette products in Australia, Adjunct Professor John Skerritt, Deputy Secretary, Commonwealth Department of Health, advised the committee that '[i]t's about 10 at the moment'.[32]

6.28 Professor Skerritt explained that:

> It's minuscule, because at the moment there's this massive loophole whereby I could go online today and have it delivered to my home here in Canberra and not go to a GP.[33]

6.29 The Department of Health later clarified that, as at 27 November 2020, there were 14 medical practitioners prescribing nicotine containing e-cigarettes for smoking cessation. In addition:

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[31] See, for example, Mr Tom Morawetz, *Submission 2*, [p. 1]; Name withheld, *Submission 3*, [p. 1]; Name withheld, *Submission 7*, [p. 2]; Mr Shane Kerrigan, *Submission 8*, [p.1]; Ms Maureen Steele, *Submission 10*, [p. 2]; Name withheld, *Submission 12*, [p. 1]; Name withheld, *Submission 14*, [p. 1]; Name withheld, *Submission 24* [p. 2]; Mr Joshua Waters, *Submission 28*, [p. 1 and p. 4]; Mr Michael Sandic, *Submission 29*, [p. 3]; Mr Colin Mannings, *Submission 33* [p. 2]; Mr Deven Sporn, *Submission 34*, [p. 1]; Ms Sheryl Mulvey, *Submission 35*, [p. 1]; Mr Graeme Angrave, *Submission 37*, [p. 1]; Name withheld, *Submission 39*, [p. 1]; Mr Troy Jeppesen, *Submission 42*, [p. 1]; Mr Martin Kewish, *Submission 44*, [p. 1]; Name withheld, *Submission 48*, [p. 2]; Name withheld *Submission 52*, [pp. 1-2]; Name withheld *Submission 53*, [p. 1]; Mr Stuart Bowermann, *Submission 55*, [p. 1]; Mr Gerrad Geard, *Submission 57*, [p. 1]; Name withheld *Submission 59*, [p. 1]; Mrs Tiffany Kereopa, *Submission 63*, [p. 1]; Mr Robert Adams, *Submission 65*, [pp. 1-2]; Name withheld, *Submission 67*, [p. 3]; Mr Aaron Fisher, *Submission 80*, [pp. 1-3]; Mr Mark Watson, *Submission 84*, p. 1; Mrs Georgia Adams, *Submission 85*, p. 1; Mr John Walker, *Submission 106*, [p. 2]; Name withheld, *Submission 118*, [p. 1]; Ms Alison Paul, *Submission 125*, [p. 2]; Name withheld, *Submission 127*, [p. 2]; Mr Luke Oliver, *Submission 142*, [p. 1]; Dr David Mutch, *Submission 143*, [pp. 1-2]; Ms Deborah Smith, *Submission 144*, [p. 1]; Name withheld, *Submission 151*, [p. 2]; Name withheld, *Submission 168*, [p. 2]; Name withheld, *Submission 206*, [p. 1]; Mr Charles McCracken, *Submission 211*, [pp. 4-5]; Name withheld, *Submission 216*, [p. 2]; Ms Angela Gordon , *Submission 225*, [p. 3]; Ms Annette Huppatz, *Submission 265*, [p. 1]; Mr John Moore, *Submission 343*, [p. 1]; Ms Angela Hauke, *Submission 344*, [p. 1]; Mr George Teepa, *Submission 350*, [p. 1]; Mr Daniel Stewart, *Submission 387*, [p. 1]; Mr Malcolm Bodie, *Submission 391*, [p. 1]; Mr Anthony Wright, *Submission 392*, [p. 1]; Name withheld, *Submission 408*, [p. 1]; Name withheld, *Submission 410*, [p. 1]; Name withheld, *Submission 445*, [p. 1]; and Name withheld, *Submission 452*, [p. 2].

[32] Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, *Senate Community Affairs Legislation Committee Hansard*, 27 October 2020, p. 13.

[33] Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, *Senate Community Affairs Legislation Committee Hansard*, 27 October 2020, p. 13.

> From receipt of the first application for approval for Special Access Scheme B access to nicotine for inhalation products for smoking cessation on 22 June 2020 to date, the TGA has approved 15 applications by 12 separate medical practitioners. This represents supply on 15 separate occasions. As noted in evidence to the committee, these numbers reflect the fact that many individuals are importing nicotine products without medical oversight.[34]

6.30 Professor Skerritt explained that support information would be made available for doctors applying to be an authorised prescriber for nicotine and a consumer community-level campaign would be run.[35] Professor Skerritt described what such a campaign could entail:

> …the typical approaches that are used are working in partnership with consumer groups, whether it is a consumer health forum, whether it is other groups that have a reach into the target demographics. It will involve working together with mass media. It will also involve social media. Whether it will involve any paid media is a question still to be resolved.[36]

6.31 A further concern raised in relation to the prescription-based model is the willingness of doctors to prescribe, and pharmacists to dispense, nicotine e-cigarette products. For example, the RACP submitted that:

> There are potential medico-legal, ethical and professional responsibilities for the medical profession in taking on the prescribing role for a product unapproved by the TGA as a therapeutic product for smoking cessation, taking essentially a 'gatekeeper role' in lieu of regulation. The RACP contends that further consideration of the TGA's proposed regulatory changes in relation to the scheduling of nicotine is warranted, mainly around the mechanism of prescribing unapproved nicotine e-cigarette products and the need for development of evidence-based prescribing guidelines for such products. We suggest that further time is taken by the TGA to address these important concerns before implementation commences.[37]

6.32 Professor John Wilson expanded on this position:

> For doctors, there are risks in prescribing a wide range of commercial products outside usual standards of required scientific evidence of safety and effectiveness. Prescribing must align with the principles of evidence-based quality or the quality use of medicines framework. As doctors do not prescribe cigarettes, as they once did, it is most appropriate that the RACP recommends a do-no-harm approach to e-cigarettes. There are potential

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[34] Department of Health, answer to question on notice, 13 November 2020 (received 27 November 2020).

[35] Adjunct Professor John Skerritt, Deputy Secretary, Department of Health *Committee Hansard*, 13 November 2020, p. 6.

[36] Adjunct Professor John Skerritt, Deputy Secretary, Department of Health *Committee Hansard*, 13 November 2020, p. 6.

[37] RACP, *Submission 170*, p. 4.

> medico-legal, ethical and professional responsibilities for the medical profession in taking on the prescribing role for a product unapproved by the TGA as a therapeutic product for smoking cessation that contains what is still a highly addictive poison.[38]

6.33 Despite these concerns, Professor Skerritt advised the committee that:

> It's fair to say the AMA still oppose and do oppose the use of vaping products, except as an absolute last resort. But, in writing to us—and these submissions will be published on our website—the RACGP [Royal Australian College of General Practitioners] supports the proposed amendments. In other words, it supports the provision or the prescription-only model. The AMA accepts a proposal to down schedule nicotine to S4. The AMA regards this as an important move to ensure that patients see their doctor for advice on the most reliable and safe smoking cessation methods.[39]

6.34 Dr Khorshid, President, AMA, told the committee that the AMA supports the prescription model as an effective way to reduce access to e-cigarettes. However, Dr Khorshid acknowledged that 'doctors in general may be a little reticent to prescribe products that are not TGA approved'. To address this, he proposed that doctors be educated about how e-cigarettes may be used as well as product ingredients.[40]

6.35 Professor Matthew Peters, former President and Co-Chair of Electronic Cigarettes Working Party, Thoracic Society of Australia and New Zealand, told the committee that, while he would 'encourage every doctor, in every clinical interaction, to do something that is in the interests of the patient', he did not think that 'a GP should ever prescribe a dangerous product'. Professor Peters clarified that, in effect, his view was that general practitioners should not prescribe e-cigarettes as a first option.[41]

6.36 In contrast, the ATHRA submitted that the 'prescription proposal is complex and unworkable' due to the following reasons:

> **Vapers won't do it**. The current laws require vapers to have a prescription to import nicotine. ATHRA estimates that no more than 1-2% of vapers currently have a prescription.
>
> **Doctors won't do it.** There are less than a dozen GPs in Australia who are willing [to] write nicotine prescriptions and 520,000 vapers. Very few doctors understand vaping or know how to write a nicotine prescription.

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[38] Professor John Wilson, President, RACP, *Committee Hansard*, 19 November 2020, pp. 38-39.

[39] Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, *Committee Hansard*, 13 November 2020, p. 6.

[40] Dr Omar Khorshid, President, AMA, *Committee Hansard*, 19 November 2020, pp. 48-49.

[41] Professor Matthew Peters, former President and Co-Chair of Electronic Cigarettes Working Party, Thoracic Society of Australia and New Zealand, *Committee Hansard*, 19 November 2020, p. 29.

> **Pharmacists won't do it.** Pharmacists are not trained in vaping and cannot give advice to new users. The Pharmacy Guild does not support the sale of vaping products in pharmacies.
>
> **Manufacturers won't do it.** Most products are made by small to medium businesses which do not undertake the onerous regulatory process for every single product. The tobacco industry with its unlimited resources will take over the market.[42] [emphasis in original]

6.37 Professor Hall and Associate Professor Gartner argued that the reluctance of medical practitioners to prescribe nicotine for use in e-cigarettes makes it difficult for Australians to legally access nicotine e-cigarette products. As a result, 'Australians who want to use ENDS [electronic nicotine delivery systems] as a lower risk alternative to combustible cigarettes have to purchase them on the illicit market or illegally import nicotine purchased on the internet'.[43]

Risks from the black market

6.38 Many submitters argued that an unintended consequence of the prescription-based model would be to develop a black market for e-cigarette products and expose Australian e-cigarette users to harm as a result of accessing products through a black market.[44]

6.39 Mr Bates indicated that an unintended consequence of the precautionary approach is the creation of a black market. He stated:

> The problem is that, if you make these products more expensive, less accessible, less pharmacologically acceptable, harder to find and less appealing, the danger is that you simply end up with more smoking and black markets, and these risks are far greater than the risks that you're actually trying to defend against.[45]

6.40 Evidence provided to the committee indicated that a proportion of Australian e-cigarette users were currently accessing nicotine e-cigarette products without a prescription and are likely to continue to do so despite a prohibition of the importation of vaporiser nicotine.[46] The committee heard concerns that

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42 ATHRA, *Submission 166,* p. 24.

43 Professor Hall and Associate Professor Gartner, *Submission 159*, p. 12.

44 See, for example, ATHRA, *Submission 166*, p. 5 and p. 24; Legalise Vaping, *Submission 173*, p. 4; Vapora, *Submission 226*, p. 2; Mr Konstantinos Farsalinos, *Submission 250*, p. 2; Liberal Democratic Party, *Submission 266*, p. 4; and Master Grocers Australia Independent Retailers, *Submission 276*, p. 3.

45 Mr Clive Bates, *Committee Hansard*, 19 November 2020, p. 57.

46 See, for example, Mr Clive Bates, *Submission 158*, p. 9; Legalise Vaping, *Submission 173*, p. 4; Emeritus Professor Simon Chapman, Emeritus Professor Mike Daube and Professor Matthew Peters, *Submission 195*, p. 18; Juddy Corp Pty Ltd, *Submission 227*, p. 2; and Australian Lottery and Newsagents Association, *Submission 279*, pp. 2-3. Many submitters who wrote to the committee

enforcement of a prescription-based model would further foster the development of a black market:

> Prohibition has never stopped people. Illicit markets only increase dangers to consumers. The risks of tobacco alternatives, whatever they may be, are only amplified when consumers are forced to obtain them on the unregulated market, where products are made with substandard materials or in unsanitary conditions, have unknown constituents, and may be tainted with life-threatening ingredients.[47]

6.41 The risk from accessing e-cigarette products through unregulated providers was raised by a number of submitters. For example, Imperial Brands Australasia submitted that:

> Indeed, it may be anticipated that the nicotine black market would operate much like the illicit tobacco black market in that it may be more easily accessible for underage users, bypass health information on packaging, and present nicotine products with vastly more dangerous health risks than those manufactured by reputable regulated industries.[48]

6.42 Vapora informed the committee that 'black market dealers have little concern for the quality or safety of their products or the wellbeing of their customers'.[49]

6.43 It was also noted that Australians are likely to continue to access unregulated e-cigarette products through the black market and stated that this will lead to increased use of 'products containing unknown ingredients and ingredients linked to harm, including vitamin E acetate'.[50]

Regulation as a consumer good

6.44 A number of submitters called for e-cigarette products to be regulated as consumer goods.[51] It was argued that regulation as a consumer product would offer important consumer protections.[52] These submitters particularly highlighted that treatment of nicotine containing e-cigarettes as a consumer

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about their personal experiences with e-cigarettes reported such practices, but are not cited here for their own legal protection.

47 Competitive Enterprise Institute, *Submission 188*, [p. 2].

48 Imperial Brands Australasia, *Submission 294*, [p. 15].

49 Vapora, *Submission 226*, [p. 3].

50 Ms Ria Hopkins, *Submission 89*, [p. 2].

51 See, for example, factasia, *Submission 45*, pp. 2-3; National Retail Association, *Submission 156*, p. 3; Mr Clive Bates, *Submission 158*, pp. 6-7; ATHRA, *Submission 166*, pp. 3 and 5-6; Legalise Vaping, *Submission 173*, p. 3; Vapoureyes, *Submission 197*, p. 2; Juddy Corp Pty Ltd, *Submission 227*, p. 2; NSW Users and AIDS Association, *Submission 253*, pp. 3-4; Vaping Trade Association of New Zealand, *Submission 263*, p. 5; and Progressive Public Health Alliance, *Submission 271*, p. 4.

52 See, for example, National Retail Association, *Submission 156*, p. 3; ATHRA, *Submission 166*, p. 24; and Legalise Vaping, *Submission 173*, p. 3.

product in other regulatory regimes (such as the United Kingdom and Canada) has led to a decrease in smoking prevalence.[53]

Arguments against regulation of e-cigarettes as a consumer good

6.45 In contrast, the Australian Competition and Consumer Commission (ACCC) submitted that:

> The ACCC is aware that some stakeholders regard the ACL [Australian Consumer Law] as an appropriate mechanism to regulate e-cigarettes. However, the ACL's product safety provisions are limited in their application as they only provide for the restriction of supply in certain circumstances related to the physical safety of consumer goods, such as requirements regarding their design, construction or composition. They do not provide for health controls and cannot regulate user behaviour, nor provide for the enforcement of mandatory age restrictions to reduce uptake by children and young people.[54]

6.46 In discussing whether it would be more appropriate for the regulation of nicotine to fall under health legislation, as opposed to consumer legislation, Professor Chris Bullen stated:

> If the goal in Australia is also to improve public health, then the various regulatory levers available, such as taxation, packaging, contents, advertising, sales to minors, flavours, standards and so on, are in common with many consumer products, and could be invoked that way.[55]

6.47 Dr Rob Grenfell, Director, Health and Biosecurity, Commonwealth Scientific Industrial Research Organisation stated that '[i]f [e-cigarettes] were available freely to the community, that would mean that utilisation of that product would occur at higher rates'.[56]

6.48 Similarly, when questioned on the gateway impact of e-cigarette usage, Professor Banks told the committee:

> Our evidence indicates that we really do need to avoid widespread availability of e-cigarettes to people who have never smoked or who are non-smokers. One characteristic of consumer products is that they tend to be widely available. Even when we look at, say, tobacco or alcohol, where those products are widely available, and we try to target them to specific groups to avoid young people being exposed to them, we still have quite widespread exposure. If we want to avoid widespread exposure of people who are non-smokers to something, we probably need to avoid it being

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[53] See, for example, National Retail Association, *Submission 156*, p. 3; ATHRA, Submission 166, p. 2 and p. 9; and Legalise Vaping, *Submission 173*, p. 5.

[54] ACCC, *Submission 182*, p. 5.

[55] Professor Chris Bullen, answer to written question on notice QoN 002-02, 18 November 2020 (received 20 November 2020).

[56] Dr Rob Grenfell, Director, Health and Biosecurity, Commonwealth Scientific Industrial Research Organisation, *Committee Hansard*, 13 November 2020, p. 27.

> available as a consumer product. Even under current circumstances, in 2016 around 18 per cent of current daily e-cigarette users were in fact people who had never smoked. If you think of that broad view where we have actually restricted access now, we're already finding substantial use among people who have never smoked.[57]

6.49 Overall, experts were unable to quantify the impact the availability of nicotine e-cigarette products as a consumer good could have on overall smoking rates in Australia, including amongst young people.[58] Such conclusions would be reliant on 'a validated, dynamic model of population-wide smoking behaviours, disease, and mortality, with data on e-cigarette use inferred from populations elsewhere',[59] and such work is yet to be completed.

6.50 Dr Mendelson and Professor Hall argued that even if the evidence that e-cigarette use serves as a gateway to smoking were stronger, 'it would not justify a ban on the sale of nicotine to adult smokers because there are other ways of preventing adolescent vaping that do not require a ban'.[60] Measures to minimise risk of youth uptake are discussed further below.

Arguments in favour of regulation of e-cigarettes as a consumer good

6.51 Submitters pointed to the many benefits of regulating e-cigarette products as a consumer good, such as the opportunity for the Australian Government to collect significant revenue.[61] For example, the National Retail Association submitted that 'our economy could benefit substantially from government tax revenue, local economic activity and a reduction in the overall health bill'.[62] It was also argued that this revenue could be used to fund further harm reduction measures, such as education campaigns, research and enforcement.[63]

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[57] Professor Emily Banks, Epidemiology and Population Health, Australian National University, *Committee Hansard*, 13 November 2020, p. 27.

[58] For example, see ATHRA, *Submission 166*, p. 13; Emeritus Professor Simon Chapman, Emeritus Professor Mike Daube and Professor Matthew Peters, *Submission 195*, p. 21; Cancer Council, *Submission 194*, p. 8; and Vaping Trade Association of New Zealand, *Submission 263*, p. 15 and 23.

[59] Professor Emily Banks, answer to written question on notice, 13 November 2020 (received 20 November 2020).

[60] Dr Mendelson and Professor Hall, 'Does the gateway theory justify a ban on nicotine vaping in Australia?' *International Journal of Drug Policy*, vol. 78, 2020, p. 1, https://doi.org/10.1016/j.drugpo.2020.102712.

[61] See, for example, National Retail Association, *Submission 156*, p. 9; Vaping Trade Association of New Zealand, *Submission 263*, p. 35; and Legalise Vaping, *Submission 173*, p. 21.

[62] National Retail Association, *Submission 156*, p. 9.

[63] See, for example, Mr Andrew Thompson, *Submission 133*, [p. 4].

6.52 The committee heard that, as more of Australia's 2.3 million smokers transition to e-cigarette products,[64] 'the domestic market has the potential to grow to over $4 billion over the next decade'.[65]

6.53 Additionally, submitters argued that it is inappropriate for e-cigarette products which do not make therapeutic claims to be regulated by the TGA. For example, ATHRA submitted that:

> The TGA should not have a mandate over vaping products as they do not make therapeutic or medicinal claims. Low concentrations of nicotine should be exempt from the Poisons Standard.[66]

6.54 The committee received evidence that restricting how and where e-cigarette products could be obtained would limit access and minimise the risk of uptake amongst youth and non-smokers. Some submitters suggested that a balance could be struck by regulating e-cigarette products as consumer goods for adult smokers, while also restricting the access of young people by limiting how and where these products could be obtained.[67]

6.55 The ATHRA outlined three main strategies to minimise youth access. These include access control, marketing control and public information.[68] Specific measures proposed by submitters included:

- restricting sale of e-cigarette products to specialist vape shops, tobacconists, pharmacies, adult stores and other suitable outlets;[69]
- maintaining the current minimum age of sale for vaping products and e-liquids at 18 years, require strict proof of age at purchase points and via internet sales and improve enforcement;[70]
- responsible advertising to adult smokers, avoiding any appeal to youth and non-smokers;[71]

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64 Australian Institute of Health and Welfare, *Data tables: National Drug Strategy Household Survey 2019 – 2 Tobacco smoking supplementary tables*, 16 July 2020, Table 2.3.

65 National Retail Association, *Submission 156*, p. 9.

66 ATHRA, *Submission 166*, p. 24.

67 See, for example, Professor Hall and Associate Professor Gartner, *Submission 159*, pp. 12-13; ATHRA, *Submission 166*, pp. 3-4.

68 ATHRA, *Submission 166*, pp. 20-21.

69 See, for example, Mr Robert Adams, *Submission 65*, pp. 1-2; ATHRA, *Submission 166*, p. 21; Legalise Vaping, *Submission 173*, pp. 5 and 7; Mr Charles McCracken, *Submission 211*, [pp. 1-2]; Professor Hall and Associate Professor Gartner, *Submission 159*, p. 12.

70 See, for example, Mr Andrew Thompson, *Submission 133*, [p. 3]; National Retail Association, *Submission 156*, p. 4; Professor Hall and Associate Professor Gartner, *Submission 159*, p. 12; ATHRA, *Submission 166*, p. 5; Legalise Vaping, *Submission 173*, p. 9; and Australian Institute of Health and Welfare, *Submission 214*, p. 6. The Thoracic Society of Australia viewed this as ineffective, stating that that 'age restrictions are little deterrent in a retail environment'. For further information see Thoracic Society of Australia, *Submission 162* p. 5.

- packaging to restrict appeal to young people;[72] and
- restricting e-liquid brand and flavour names which appeal to youth.[73]

6.56 Professor Hall and Associate Professor Gartner suggested a similar approach, whereby e-cigarettes and related products would be allowed to be sold as a tightly regulated consumer good:

> We believe that the sale of ENDS that meet consumer safety standards to adults should be allowed under tight regulation. Nicotine would be supplied in child-resistant containers, promotions would be banned except at points of sale, such as specialist vape stores, tobacconists and/or pharmacies.[74]

6.57 Similarly, the RACP recommended regulatory controls on the sale, supply, use and promotion of e-cigarette devices to prevent an uptake in e-cigarette usage amongst youth. Specifically, the RACP recommended:

- The sale and supply of e-cigarettes (with or without nicotine) to minors, including access through personal importation scheme, must be prohibited and stringently enforced in all Australian states and territories.
- E-cigarettes must not be allowed to be promoted in a way that encourages their uptake or smoking initiation. Their sale and supply to minors must be prohibited in all Australian states and territories.
- The use of e-cigarettes should be banned in all areas that are designated to be smoke-free by all Australia's state and territory laws.[75]

Restrictions

6.58 The committee heard evidence from harm reduction proponents and e-cigarette critics that appropriate regulatory measures are required to protect Australian youth and non-smokers, and also to ensure product quality and safety for e-cigarette users. Broadly, these included:

- restrictions on sale and distribution;
- restrictions on promotion and advertising;
- packaging and product information;

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[71] See, for example, National Retail Association, *Submission 156*, p. 2 and p. 4; Professor Hall and Associate Professor Gartner, *Submission 159*, p. 4; and ATHRA, *Submission 166*, p. 7 and p. 21.

[72] See, for example, National Retail Association, *Submission 156*, p. 2; Professor Hall and Associate Professor Gartner, *Submission 159*, p. 13; ATHRA, *Submission 166*, p. 21; and Emeritus Professor Simon Chapman, Emeritus Professor Mike Daube and Professor Matthew Peters, *Submission 195*, p. 31.

[73] See, for example, the Coalition Asia Pacific Tobacco Harm Reduction Advocates, *Submission 38*, pp. 1 and 6; Dr Jongenelis, *Submission 66*, p. 5; and UK Vaping Industry Association, *Submission 236*, pp. 3-4.

[74] Professor Hall and Associate Professor Gartner, *Submission 159*, p. 7.

[75] RACP, *Submission 170*, p. 14.

- product quality and safety; and
- restrictions on the use of flavours and ingredients.

Restrictions on sale and distribution

6.59 Submitters proposed a number of restrictions on how and where e-cigarettes should be sold, including age restrictions on sales and limits on maximum volumes of e-liquid that can be sold.[76] In particular, the committee heard strong support for a minimum age of 18 years and strict age verification and enforcement.[77]

6.60 It was also argued that limits should be set on maximum concentrations of nicotine in e-liquid.[78] The committee heard that 'importation of high concentration nicotine is an increased risk to the individual due to the potential for accidental exposure to high doses of nicotine'.[79]

6.61 Dr Moller, Dr Kelso and Professor Jones proposed restricting the maximum concentration of nicotine to 36 mg/mL (3.6%) and limiting the maximum container volume to 50ml.[80]

6.62 As discussed earlier, the European Union regulates e-cigarettes that do not make therapeutic claims as consumer products, subject to a nicotine concentration limit of 20mg/ml and a bottle capacity of 10ml.[81] However, one submitter posited that 'by limiting the level of nicotine concentration available in e-cigarettes, the product became less efficacious for smokers as a smoking cessation aid, and more accessible to never-smokers'.[82]

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[76] See, for example, Mr Andrew Thompson, *Submission 133*, [p. 3]; National Retail Association, *Submission 156*, p. 4; Professor Hall and Associate Professor Gartner, *Submission 159*, p. 12; ATHRA, *Submission 166*, p. 5; Legalise Vaping, *Submission 173*, p. 9; Australian Institute of Health and Welfare, *Submission 214*, p. 6; Dr Judy Moller, Dr Celine Kelso and Professor Alison Jones, *Submission 220*, pp. 1 and 3-4; and Vaping Trade Association of New Zealand, *Submission 263*, p. 30.

[77] See, for example, Mr Andrew Thompson, *Submission 133*, [p. 3]; National Retail Association, *Submission 156*, p. 4; Professor Hall and Associate Professor Gartner, *Submission 159*, p. 12; ATHRA, *Submission 166*, pp. 4-5; Legalise Vaping, *Submission 173*, p. 9; and Australian Institute of Health and Welfare, *Submission 214*, p. 6.

[78] See, for example, Dr Moller, Dr Kelso and Professor Jones, *Submission 220*; and Miss Dianna Nguyen, *Submission 232*, p. 4.

[79] Dr Moller, Dr Kelso and Professor Jones, *Submission 220*, p. 3.

[80] Dr Moller, Dr Kelso and Professor Jones, *Submission 220*, p. 1.

[81] See Medicines and Healthcare products Regulatory Agency (MHRA), *E-cigarettes: regulation for consumer products*, 25 November 2020, https://www.gov.uk/guidance/e-cigarettes-regulations-for-consumer-products (accessed 30 November 2020).

[82] Nicovape Pty Ltd, *Submission 283*, p. 8.

6.63 Professor Hall and Associate Professor Gartner cautioned that nicotine e-cigarette products should not be sold by generalist retailers:

> Nicotine solutions should be supplied in child-resistant containers and no promotion allowed except at licensed points of sale. These should be restricted to specialist vape stores, tobacconists, adult stores and/or pharmacies to minimise youth access. All nicotine products should be stored behind the counter.[83]

6.64 Professor Chris Bullen and Associate Professor Natalie Walker highlighted the model used by New Zealand as 'an example of sensible regulation around vaping'.[84] In particular, general stores and other businesses which do not specialise in e-cigarettes can sell e-cigarette products, but are restricted to tobacco, mint, menthol flavours only, while specialist vape shops are exempt from a number of these restrictions.

6.65 Professor Beaglehole also commended the New Zealand model. He stated:

> The New Zealand Government treats vaping as a consumer issue with the potential to reduce the harm from smoked cigarettes by encouraging switching to less harmful products. From a public health perspective this is a sensible approach, given the enormity of the burden of death and disease caused in New Zealand by smoked cigarettes. The legislation attempts to balance the aims of encouraging adult cigarette smokers to switch while protecting young people from vaping.[85]

6.66 The National Retail Association put forward a draft Responsible Retailers Code of Conduct for Smoke-Free Products to guide retailers in relation to age verification, product information and promotion. The code proposed that retailers:

- Never sell vape products to anyone under the age of 18 or anyone purchasing on their behalf. Proof of age is to be requested if a customer is perceived to be under 25 years old.
- Ensure any nicotine components are clearly labelled or available for the product.
- Avoid claiming any health benefits from the use of vape products.[86]

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[83] Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 159*, p. 12.

[84] Professor Chris Bullen and Associate Professor Natalie Walker, *Submission 163*, [p. 2].

[85] Professor Robert Beaglehole, answer to written question on notice QoN 001-02, 18 November 2020 (received 22 November 2020).

[86] National Retail Association, *Submission 156*, p. 5.

Restrictions on promotion and advertising

6.67 A number of submitters argued in favour of restricting advertising of e-cigarette products to adult smokers.[87] In addition, it was argued that vendors should be prohibited from making claims about the safety and efficacy of e-cigarettes as a smoking cessation method.[88]

6.68 The Department of Health highlighted its concern that the widespread advertising and promotion of products via digital media and other communication platforms was being used to increase the appeal of e-cigarettes to youth.[89]

6.69 Dr Jongenelis expressed concern that widespread advertising and availability of e-cigarettes in the United States 'led to substantial increases in youth use'.[90] She advised the committee that 'Australia can very much avoid having to throw that money at intervention later on by just taking the right steps now to prevent that from even happening in the first place'.[91]

6.70 Associate Professor Gartner also expressed her opposition to 'any kind of replication of the US situation which allowed aggressive marketing or advertising of these products, because it could increase vaping amongst young people'.[92]

6.71 While the ATHRA was supportive of restrictions on marketing specifically targeted at young people, it submitted that 'blanket bans on advertising prevent responsible, targeting [of] advertising to adult smokers to educate them about these products'.[93]

6.72 Mr Ben Youdan also advised that, in his opinion, there was a need to strike a balance between 'clear, directed messages to adult smokers about switching, without it necessarily being over-medicalised, and ensuring that they have good information about the products'.[94]

6.73 Similarly, Dr Mendelsohn commented that the 'promotion should be about switching from smoking to vaping'. He likened advertising for e-cigarettes to that used for alcohol:

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87 See, for example, RACP, *Submission 170*, p. 3; National Retail Association, *Submission 156*, pp. 2 and 4; Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 159*, p. 4; and ATHRA, *Submission 166*, pp. 7 and 21.

88 Mr Andrew Thompson, *Submission 133*, [p. 4].

89 Department of Health, *Submission 167*, p. 19.

90 Dr Jongenelis, *Committee Hansard*, 19 November 2020, p. 51.

91 Dr Jongenelis, *Committee Hansard*, 19 November 2020, p. 51.

92 Associate Professor Gartner, *Committee Hansard*, 13 November 2020, p. 32.

93 ATHRA, *Submission 166*, pp. 8 and 20.

94 Mr Ben Youdan, *Committee Hansard*, 13 November 2020, p. 45.

> We need to learn from that in developing a policy for the advertising of vaping. But if we think vaping is a life-saving alternative for people who can't quit, we need to make sure that adult smokers are aware of it and that we provide the information and target any messaging to them.[95]

Packaging and product information

6.74 The committee heard evidence that 'regulations such as child-proof packaging and appropriate labelling of e-liquids should be put in place'.[96] A number of jurisdictions, including Canada, the European Union, the United Kingdom and the United States, have introduced measures to include child resistant requirements for e-liquids, such as the requirement for:

- labelling to include risk-proportionate health messages regarding toxicity and addictiveness;
- a full list of e-liquid ingredients;
- advice to keep out of the reach of children; and
- advice on overdose management.

6.75 Dr Moller, Dr Kelso and Professor Jones advised that 'packaging should avoid cartoon-style imagery and be required to contain warnings about nicotine and the unknown health risks of flavouring molecules'.[97]

Product quality and safety

6.76 As discussed earlier, e-liquids contain a wide range of substances of varying concentration and, at present, there is very little to guarantee the accuracy of any ingredients listed on their labels. The committee heard evidence that a number of measures should be put in place to ensure product safety and quality.[98] These included establishing quality and safety standards in relation to the devices, electrical safety and e-liquids. One submitter called for the committee to '[r]egulate THR [tobacco harm reduction] product quality and safety standards in-line with consumer product guidelines'.[99]

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[95] Dr Mendelsohn, Board Member, ATHRA, *Committee Hansard*, 13 November 2020, p. 78.

[96] Ms Diane Gorman, *Submission 100*, p. 2. See also Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 159*, p. 4; ATHRA, *Submission 166*, p. 21; ACCC, *Submission 182*, p. 2; Dr Moller, Dr Kelso and Professor Jones, *Submission 220*, pp. 1 and 3-4; and Australian Capital Territory Government, *Submission 288*, p. 1.

[97] Dr Moller, Dr Kelso and Professor Jones, *Submission 220*, p. 2.

[98] See, for example, factasia, *Submission 45*, [p. 2]; Mr Keith Riseley, *Submission 92*, p. 2; National Retail Association, *Submission 156*, p. 4; Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 159*, p. 12; ATHRA, *Submission 166*, p. 5; Legalise Vaping, *Submission 173*, p. 9; Australian Institute of Health and Welfare, *Submission 214*, p. 6; Dr Moller, Dr Kelso and Professor Jones, *Submission 220*, pp. 1 and 3-4; Vaping Trade Association of New Zealand, *Submission 263*, p. 30.

[99] Name Withheld, *Submission 286*, p. 2.

6.77 Mr Konstantinos Farsalino proposed a number of principles that should be followed to create a regulatory framework for e-cigarettes. In particular, he submitted that regulation should be realistic and ensure product quality. However, he warned against setting unreasonably high quality standards as this 'creates a competitive advantage for tobacco cigarettes, while the regulation should aim for the opposite'.[100]

6.78 The RACP recommended that e-cigarette product packaging and labelling requirements should be implemented, including disclosure of all ingredients and their concentrations in e-liquid, child-resistant packaging, plain packaging rules and health warning labels.[101]

6.79 In addition, Dr Khorshid discussed the need for the regulation of product quality and safety standards in order to strengthen the prescription-based model:

> Any process that was designed to make nicotine based e-cigarette products available on prescription would ideally include some further regulation to ensure that the products are reliable, that their sources are reliable, that you can believe the quantities of nicotine and whatever other products are within their products so that both the consumer and the doctor know what's actually being ingested.[102]

Restrictions on the use of flavours and other ingredients

6.80 Some evidence before the committee expressed concern about possible risks from e-liquid flavourings,[103] while other submitters cited various flavours as a key part of the experience of using e-cigarettes.[104]

6.81 Submitters who supported the sale of flavoured e-liquids emphasised the importance of flavourings as part of the appeal of e-cigarettes for adult smokers. The ATHRA stated that:

> Flavours are an integral part of vaping and make it more appealing as an alternative for adult smokers. Flavours facilitate initiation of vaping for current smokers, reduce the likelihood of relapse and increase quit rates compared to non-flavoured or tobacco flavoured e-liquids.[105]

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100 Mr Konstantinos Farsalino, *Submission 250*, [p. 2].

101 RACP, *Submission 170*, p. 4.

102 Dr Omar Khorshid, President, AMA, *Committee Hansard*, 19 November 2020, p. 49.

103 See, for example, Coalition of Asia Pacific Harm Reduction Advocates, *Submission 38*, p. 7; Dr Jongenelis, *Submission 66*, p. 6; National Retail Association, *Submission 156*, p. 3; Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 159*, p. 12; Department of Health, *Submission 167*, pp. 18-19; RACP, *Submission 170*, p. 17; ACCC, *Submission 182*, p. 2; and Dr Moller, Dr Kelso and Professor Jones, *Submission 220*, p. 2.

104 See, for example, factasia, *Submission 45*, p. 1; ATHRA, *Submission 166*, p. 28; Aotearoa Vapers' Community Advocacy, *Submission 178*, [p. 2]; and Vapora, *Submission 226*, p. 2.

105 ATHRA, *Submission 166*, p. 28.

6.82 Despite the popularity of such flavours, the RACP was concerned that the health impacts of inhaling heated flavoured chemicals is unknown and has not been well studied and may pose a risk to health.[106] The ACCC noted that '[c]hildren are vulnerable and may be attracted to e-liquids marketed, scented, and flavoured as novelty scents and flavours', which could lead to accidental nicotine poisoning.[107]

6.83 Other submitters were also concerned that novelty flavours and targeted marketing could lead to an uptake in e-cigarette usage among young people.[108] Dr Moller, Dr Kelso and Professor Jones noted that many e-juices had flavours and associated name titles that seemed deliberately marketed to youth:

> There are a wide variety of e-liquid brands and flavours available to individuals. A recent study analysing flavours available on the Dutch market examined 20,000 differently named e-liquids and identified 213 different flavouring molecules.…Amongst the many thousands of flavouring names available some, for example, Oba Oba, Unicorn Vomit, Beast, and Drgn Spit etc do not clearly identify or even suggest a flavour. It is likely that these e-liquids are deliberately designed to entice young individuals and all names which do not clearly indicate a flavour-type should be banned in Australia.[109]

6.84 It is noted that the UK Vaping Industry Association has guidelines around its members' sale of flavours, which limit such marketing towards youth:

> The UKVIA [UK Vaping Industry Association] has issued guidance to members which aims to strike the right balance between innovative and appealing products which support adult smokers in the transition to a less harmful alternative, whilst not appealing to anyone who does not already smoke or vape or anyone who is under 18. These guidelines state that members must not use flavour names or descriptors that are particularly appealing to youths, or are associated with youth culture, including popular language or expressions, or names which are reminiscent of confectionary disproportionally appealing to children.[110]

6.85 In concluding their analysis of the role of flavoured e-liquids on youth uptake of e-cigarettes, Professor Hall and Associate Professor Gartner argued that this issue should be monitored by government and health bodies into the future:

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[106] RACP, *Submission 170*, p. 17.

[107] ACCC, *Submission 182*, p. 2.

[108] See, for example, Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 159*, p. 11, Department of Health, *Submission 167*, pp. 18-19; New South Wales Government, *Submission 171*, p. 2; Cancer Council, National Heart Foundation of Australia and Australian Council on Smoking and Health, *Submission 194*, p. 5; and Dr Moller, Dr Kelso and Professor Jones, *Submission 220*, p. 2.

[109] Dr Moller, Dr Kelso and Professor Jones, *Submission 220*, p. 2.

[110] UK Vaping Industry Association, *Submission 236*, p. 3.

> We should monitor sales and ENDS [electronic nicotine delivery systems] use among young people. If certain types of flavours are associated with increased use among non-smoking youth, then we should restrict the use of these flavoured products to minimise their attractiveness to non-smoking young people.[111]

[111] Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 159*, p. 12.

Chapter 7 - Chair's view

7.1 This inquiry held heightened significance due to the Australian Government's future regulatory direction for e-cigarettes in Australia. On 23 September 2020, the Therapeutic Goods Administration (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). The proposed changes, if finalised, would mean that e-cigarette products containing nicotine could only be supplied with a doctor's prescription.

7.2 The Australian Government has also signalled its intention to make regulations prohibiting the importation of nicotine e-cigarettes products, except where permission is granted by the Department of Health to a doctor or medical supplier to import the goods using courier or cargo services.

7.3 We understand that, taken together, the import regulations and rescheduling of nicotine in the Poisons Standard will require individuals to source nicotine e-cigarette products via a medical practitioner. The proposed changes would also impose harsh penalties of up to $222 000 for those who import nicotine for use in e-cigarettes directly from an overseas supplier without a valid import permit.

7.4 We recognise that debate around e-cigarette regulation is characterised by two competing philosophies: the precautionary principle and harm reduction. These were discussed at length in Chapter 5.

7.5 In summary, divergent views were held by medical experts, public health organisations, academics, government agencies and the general public in relation to the appropriate regulatory approach for e-cigarettes. Proponents for a prescription-based model of regulation argued that this would prevent the widespread availability of e-cigarettes to people who have never smoked or are non-smokers and the associated harms that could arise. Those in favour of a prescription-based model generally placed greater emphasis on a precautionary approach: that is, e-cigarettes should be discouraged or prohibited until there is further evidence available regarding their safety and efficacy.

7.6 In contrast, an overwhelming majority of submitters argued that nicotine e-cigarette products should be made readily available in Australia to assist people who have unsuccessfully tried other ways to quit smoking. These submitters argued that e-cigarettes could play an important harm reduction role and may lead to a decrease in smoking prevalence.

7.7 We acknowledge the genuine need to protect the health of children and young people. Nonetheless, the Australian Government also has a responsibility to protect the health of adult smokers. It is clear that risk-proportionate regulation of e-cigarettes is essential in order to reduce smoking and avoid uptake amongst youth and non-smokers. We have carefully considered the evidence provided and proposes 10 recommendations which aim to protect children and non-smokers, while making e-cigarettes appropriately available to adults for the purposes of significantly reducing the harm associated with smoking.

Reducing harm

7.8 The committee heard two major claims for e-cigarettes: namely, e-cigarettes increase smoking cessation, and are safer to use in the long term than combustible cigarettes.

7.9 Evidence considered in Chapter 5 of this report overwhelmingly showed that while debate can, and should, continue about the precise level of risk associated with the use of e-cigarettes, the current evidence is that e-cigarettes are significantly safer for users than combustible cigarettes. Indeed, the committee heard no evidence suggesting that e-cigarette use is more harmful than combustible cigarettes. In addition, the experiences and observations of e-cigarette users indicated that e-cigarettes have helped individuals to stop smoking combustible cigarettes and provided a range of benefits to users, including increased financial stability, lifestyle and health improvements.[1]

7.10 There is also a growing body of empirical evidence which suggests e-cigarettes are an effective tool in helping people quit smoking combustible cigarettes. While there remain some gaps in the evidence about how effective e-cigarettes are as a smoking cessation aid, the numerous personal accounts received demonstrate that thousands of Australians have used e-cigarettes to successfully quit smoking. However, we accept that where a therapeutic claim is made in relation to e-cigarettes, the product should be rigorously assessed for safety and efficacy by the TGA.

7.11 Some members of the public health community expressed concern that any easing of the current restrictions that apply to e-cigarettes may result in an uptake amongst youth and non-smokers. However, we accept the evidence that the 'common liability' hypothesis is a plausible explanation for the relationship between e-cigarettes and smoking initiation: that is, young people who experiment with risky behaviours are simply more likely to try smoking combustible cigarettes. Furthermore, a number of overseas jurisdictions have found that e-cigarettes are not a gateway to smoking. The New Zealand

[1] The benefits of e-cigarette use were reported extensively in hundreds of submissions and thousands of form letters received from individuals. Chapter 4 addresses these personal accounts in detail.

Ministry of Health notes '[t]here is no international evidence that vaping products are undermining the long-term decline in cigarette smoking among adults and youth, and may in fact be contributing to it'.[2] Similarly, Public Health England reported in 2018 that '[d]espite some experimentation with these devices among never smokers, e-cigarettes are attracting very few young people who have never smoked into regular use'.[3]

7.12 The small risk that e-cigarette use may lead some young people who would not otherwise have smoked to take up smoking must be weighed against the substantial and immediate benefits from helping smokers to quit. It must also be weighed against the benefit of diverting some young people away from smoking combustible cigarettes.

7.13 In our view, e-cigarettes present an opportunity to significantly accelerate already declining smoking rates and thus address the leading cause of preventable illness and death in Australia. We recognise that the long-term health impacts of e-cigarettes are not fully known given that e-cigarettes have not had a long history of use. However, e-cigarettes are substantially less harmful—by around 95 per cent—than combustible cigarettes.

A smoke-free Australia by 2027

7.14 Over the past two decades, tobacco reduction strategies have resulted in a substantial decrease in smoking rates in Australia. Despite this, tobacco use still accounts for significant number of deaths in Australia, with tobacco smoking killing about 15 500 people annually.[4] This harm largely results from burning tobacco and inhalation of smoke into the lungs, not from nicotine use.

7.15 While daily adult smoking levels have fallen across Australia, the rates of decline have slowed over the period from 2013 to 2019[5] and there remain increased smoking rates across remote communities and people living in the lowest socioeconomic areas.[6] In these circumstances, a new approach is needed

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2 New Zealand Ministry of Health, *Position statement on vaping*, 3 September 2020, https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/vaping-smokefree-environments-and-regulated-products/position-statement-vaping (accessed 28 November 2020).

3 Public Health England, *Evidence review of e-cigarettes and heated tobacco products 2018: A report commissioned by Public Health England*, February 2018, p. 13.

4 Cancer Council Australia, *Smoking and tobacco control*, https://www.cancer.org.au/about-us/policy-and-advocacy/position-statements/smoking-and-tobacco-control (accessed 28 November 2020).

5 Australian Institute of Health and Welfare, *National Drug Strategy Household Survey 2019*, 16 July 2020, p. 6.

6 For example, the *National Drug Strategy Household Survey 2019* reported that people in remote and very remote areas were twice as likely as those in major cities to smoke daily (19.2% compared with 9.8%) and people living in the lowest socioeconomic areas were about 3.7 times as likely as those in the highest socioeconomic areas to smoke daily (19.0% compared with 5.1%).

for those smokers who have been unable to quit combustible cigarettes using the assistance currently available, including nicotine patches, gum, medical interventions, counselling and alternative medicine.

7.16 E-cigarettes do not use combustion and are widely accepted to be less harmful than combustible cigarettes. Significant numbers of smokers worldwide are switching to e-cigarettes, with an estimated 520 000 Australians having used e-cigarettes in the past year.[7] This demonstrates that, despite the strict controls applied to e-cigarettes in Australia,[8] consumers are seeking e-cigarettes as an alternative to smoking. Notably, Australia is the only country to adopt a prescription-based model for the supply of e-cigarette products containing nicotine.[9] This stands in contrast with New Zealand and United Kingdom, where the harm reduction benefits of e-cigarette use have been acknowledged and e-cigarettes legislated as consumer goods.[10]

7.17 We believe that the Australian Government's current goal of 10 per cent smoking prevalence by 2025 would be strengthened by the adoption of a smoke-free target in Australia by 2027. To achieve this target, daily smoking prevalence must fall to minimal levels and tobacco access and supply must be significantly reduced. It is our view that e-cigarette products have the potential to make a significant contribution to a smoke-free 2027 target.

7.18 Australia has been a global leader in tobacco control for decades and has achieved significant, long term reductions in smoking prevalence. However, these achievements are at risk with smoking prevalence no longer falling as fast as it has previously. The estimated $137 billion costs of smoking require a more ambitious target, such as that adopted by comparable countries such as New Zealand and United Kingdom. An associated policy platform will also be required to achieve this target, given the current target is not likely to be met on the basis of current policy settings.

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7 Australian Institute of Health and Welfare, *National Drug Strategy Household Survey 2019*, 16 July 2020, p. 9; Australian Tobacco Harm Reduction Association, *Over 500,000 vapers in Australia now, according to Government study*, 22 July 2020, https://www.athra.org.au/blog/2020/07/22/over-500000-vapers-in-australia-now-according-to-government-study/ (accessed 1 December 2020).

8 As discussed in Chapter 2, the possession, supply and/or sale of nicotine for use e-cigarettes is currently illegal in Australia, unless exempt in specific circumstances and when accessed by patients on prescription.

9 Department of Health, answer to question taken on notice, 13 November 2020 (received 27 November 2020).

10 E-cigarette products that make therapeutic claims are regulated separately in both jurisdictions.

Recommendation 1

7.19 We recommend the Australian Government set a target of reducing smoking prevalence and tobacco availability to minimal levels, making Australia a smoke-free nation by 2027.

Recommendation 2

7.20 We recommend the Australian Government revise its current tobacco control measures to include harm reduction strategies with a strong focus on e-cigarettes to ensure that Australia is a smoke-free nation by 2027.

Prescription-based model

7.21 Australia's regulatory approach currently favours a prescription-based model. As such, the possession of nicotine for use in e-cigarettes without a prescription is currently illegal in all states and territories except South Australia. The Australian Government has justified its regulatory approach by citing the precautionary principle. This is despite the growing consensus around the role of e-cigarettes in tobacco harm reduction.

7.22 Evidence received by the committee raised serious questions about whether a prescription-based model would serve the interests of the Australian community. For example, at present there are only 14 medical practitioners in Australia who are prescribing nicotine e-cigarette products for smoking cessation.

7.23 The committee heard that the requirement to obtain a medical prescription for nicotine e-cigarette products places an onerous and inappropriate burden on those wishing to access a less harmful alternative to smoking. Critics of the prescription-based model highlighted the unwillingness of doctors to prescribe nicotine, and the potentially devastating impact on the e-cigarette industry including an extensive network of small businesses across Australia. These submitters also argued that the further restrictions on e-cigarette products would drive up demand for unsafe black market products and see increased rates of smoking.

7.24 This inquiry also highlighted the fact that many medical practitioners lack an understanding of e-cigarettes, particularly in relation to their use by smokers as a smoking cessation aid.

Risk-proportionate regulation

7.25 The committee heard compelling arguments that e-cigarettes, complemented by an appropriately robust and enforced regulatory framework, offer the potential for significant health benefits. In particular, a regulated e-cigarette market would help improve product safety and provide more effective controls over e-cigarette marketing and promotion, particularly to non-smokers. Submitters also argued that the e-cigarette industry could support the creation of a number of jobs in Australia.

7.26 While complete cessation of all tobacco and nicotine use is the best action smokers can take to improve their health, for smokers who are unable to quit smoking the next best option is supporting a transition to nicotine products that are substantially less harmful. We consider that the Australian Government could strengthen its current tobacco control measures with harm reduction strategies that allow less harmful, smoke-free alternatives to combustible cigarettes, including e-cigarettes, to be made readily available to the 2.3 million Australians who still smoke.

7.27 Throughout the inquiry, it was argued that nicotine e-cigarette products were substantially different to combustible cigarettes, both in relation to their features and their impact on consumers. While combustible cigarettes contain tobacco and produce carbon monoxide, tar and smoke, nicotine e-cigarettes do not contain tobacco and heat up nicotine e-liquid rather than burning it. As such, nicotine e-cigarette products should be regulated differently to combustible cigarettes.

7.28 The growing weight of independent scientific evidence strongly supports providing Australian adult smokers a choice to legally access, purchase and use less harmful smoke-free e-cigarette products.

7.29 After analysing the various arguments about the relative strengths and weaknesses of a prescription-based model in comparison to other regulatory approaches, we conclude that regulating e-cigarette products with a nicotine concentration of less than 50mg/mL as a consumer good would constitute risk-proportionate regulation. Furthermore, we recognise the need for appropriate advertising restrictions and robust product quality and safety standards to ensure e-cigarettes support a comprehensive tobacco harm reduction strategy in Australia.

7.30 Evidence presented to the committee indicated that e-liquid flavours play a critical role in attracting and retaining smokers, directly contributing to tobacco harm reduction and declining smoking rates. While it is clear that flavours play an important role in adult e-cigarette use, we believe there is a need to limit flavoured e-liquids that may specifically appeal to youth.

7.31 The committee received evidence that the regulation of e-cigarette products as a consumer good would create an opportunity for the Australian Government

to collect taxation revenues. We are of the view that e-cigarettes that do not contain tobacco should not be subject to tobacco excise tax. However, e-cigarette products that contain nicotine should be subject to a nicotine excise tax. We recognise that price is an important factor in encouraging smokers to use e-cigarettes. In light of the emerging consensus around the role of e-cigarettes in tobacco harm reduction, the Australian Government should endeavour to maintain their affordability, while directing associated revenue toward further tobacco harm reduction interventions (such as effective enforcement to reduce the uptake of e-cigarette use amongst youth).

7.32 In Australia, the current regulatory framework draws on existing laws that may apply to tobacco products, poisons, therapeutic goods, consumer goods and industrial chemicals. However, regulatory approaches to e-cigarettes vary between states and territories. We believe this inconsistency should be addressed through the development of a nationally consistent approach to the regulation of e-cigarettes.

Recommendation 3

7.33 We recommend the Australian Government defer implementation of the following decisions and proposals until a whole-of-government approach is agreed by the Commonwealth, state and territory governments in relation to the regulation of e-cigarettes:

- **the final decision of the delegate of the Secretary of the Department of Health to amend the current Poisons Standard in relation to nicotine; and**
- **the proposal by the Australian Government to prohibit the importation of e-cigarettes containing vaporiser nicotine (nicotine in solution or in salt or base form) and nicotine-containing refills unless on prescription from a doctor.**

Recommendation 4

7.34 We recommend the Australian Government request the Therapeutic Goods Administration review the scheduling of nicotine with a view to exempting concentrations of nicotine below 50mg/mL from the Poisons Standard.

Recommendation 5

7.35 We recommend the Australian Government legalise the sale, possession and use of nicotine e-cigarette products as a consumer product up to a maximum nicotine concentration of 50mg/mL.

Recommendation 6

7.36 We recommend the Australian Government consult with state and territory governments with a view to establishing a nationally consistent regulatory framework for the sale, possession and use of nicotine e-cigarette products which:

- **prohibits the sale of e-cigarettes to persons under the age of 18;**
- **prohibits the sale of novelty e-cigarettes that may specifically appeal to minors;**
- **restricts the maximum volume of nicotine-containing e-liquid for sale in one refill container to 250ml;**
- **prohibits advertising and marketing which makes therapeutic claims for products that have not been approved by the Therapeutic Goods Administration;**
- **prohibits advertising and marketing which targets young people and non-smokers;**
- **establishes product quality and safety standards;**
- **establishes requirements for packaging and product information (including child-safe packaging and health warnings);**
- **restricts where e-cigarette products can be purchased;**
- **prohibits general retailers from promoting the sale of e-cigarette products;**
- **prohibits general retailers from selling e-cigarette devices (but not pre-mixed e-liquids); and**
- **establishes 'specialist vape retailers' as a special class of retailer which are exempt from the restrictions that apply to general retailers.**

Recommendation 7

7.37 We recommend the Australian Government consider options for the taxation of nicotine e-cigarette products, including the creation of a nicotine excise tax. At the same time, any taxation should ensure e-cigarettes remain an affordable alternative to combustible cigarettes.

Research

7.38 The current evidence demonstrates that e-cigarettes are substantially less harmful than combustible cigarettes. To improve public health, it is clear e-cigarette regulation needs to balance the risks of e-cigarettes with their potential benefits. We believe there is a need for continued research to regularly review and evaluate the health impacts of e-cigarettes. In particular, submitters pointed to the limited evidence on the impact of the long-term use of e-cigarettes and the lack of scientific consensus regarding the efficacy of e-cigarettes as a smoking cessation aid. This research should be made publicly available for consumers and health professionals.

7.39 We also note that the Joint Committee on Law Enforcement is currently inquiring into public communications campaigns targeting demand for drugs and substance abuse. The Joint Committee on Law Enforcement's report has the potential to add to this body of knowledge.

Recommendation 8

7.40 We recommend the Australian Government continue to fund independent research into e-cigarette use and related products, particularly in relation to the:

- **impact of Australia's tobacco control measures on smoking rates and patterns and use of e-cigarettes by adults and young people;**
- **health impacts of long term e-cigarette use;**
- **effectiveness of e-cigarettes as an aid to help people quit smoking combustible cigarettes;**
- **short and long term health effects of ingredients commonly used in e-liquids, including but not limited to: vaporiser nicotine, propylene glycol and vegetal glycerine; and**
- **safety of e-liquid flavours for inhalation.**

Recommendation 9

7.41 We recommend the Australian Government report annually on the state of its research into e-cigarette use and related products.

Recommendation 10

7.42 We recommend the Australian Government establish an online hub for making the findings of its research into e-cigarette use and related products readily available to the public and health professionals.

Senator Hollie Hughes
Chair

Senator the Hon Matthew Canavan

Appendix 1
Submissions, answers to questions on notice and additional documents

Submissions

1 *Name Withheld*
2 Mr Tom Morawetz
3 *Name Withheld*
4 Mr James Reid
5 Mr Richard Pruen
6 Mr Alan Beard
7 *Name Withheld*
8 Mr Shane Kerrigan
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11 Mr Tony Barron
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15 Mr Grant Clark
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22 *Name Withheld*
23 Miss Kerri Shannon
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25 *Name Withheld*
26 *Name Withheld*
27 Mr Don Brooke
28 Mr Joshua Waters
29 Mr Michael Sandic
30 Mr Matthew Barton
31 Dr Richard Watkins
32 *Name Withheld*
33 Mr Colin Mannings
34 Mr Deven Sporn
35 Ms Sheryl Mulvey

36 Mr Lewis Johnson
37 Mr Graeme Angrave
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42 Mr Troy Jeppesen
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44 Mr Martin Kewish
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46 Mr Chris Hansen
47 *Name Withheld*
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51 Mr Adam Metelmann
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54 Mr Matthew Landau
55 Mr Stuart Bowerman
56 Ms Shayne O'Neill
57 Mr Gerrad Geard
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61 Mr Dan Jackson
- 61.1 Supplementary to submission 61

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65 Mr Robert Adams
66 Dr Michelle Jongenelis
67 *Name Withheld*
68 Mr Michael Gorman
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75 Mr Samuel cahir
76 Mr Bill Stewart
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83 Ms Trina Macleod
84 Mr Mark Watson
85 Mrs Georgia Adams
86 Ms Bonnie Schultz
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88 *Name Withheld*
89 Ms Ria Hopkins
90 Mr Logan Evans
91 *Name Withheld*
92 Mr Keith Riseley
93 *Name Withheld*
94 Mr Sam Macartney
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98 *Name Withheld*
99 Institute of Economic Affairs
100 Ms Dianne Gorman
101 *Name Withheld*
102 Ms Samantha Barratt
103 Mr Paul Marshall
104 Professor Peter Hajek
105 *Name Withheld*
106 Mr John Walker
107 Mr Aaron Fornarino
108 Mr Paul Montague
109 Mr John Richardson
110 Ms Amy Trezise
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112 *Name Withheld*
113 Ms Penelope Turner
114 Mr Daniel Perfect
115 *Name Withheld*
116 *Name Withheld*
117 Mr Damien Noonan
118 *Name Withheld*
119 Mr John Littlewood
120 Mr Michael Johnsen MP, Nationals Member for Upper Hunter (NSW)

121 Mr Ken McNaughton
122 *Name Withheld*
123 Mr Glenn Thompson
124 Mr Michael Stewart
125 Ms Alison Paul
126 Mr Shail Akhil
127 *Name Withheld*
128 *Name Withheld*
129 Professor Kenneth Warner
130 Professor John Britton
131 *Name Withheld*
132 Mr Nicholas Dean
133 Mr Andrew Thompson
- 133.1 Supplementary to submission 133

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135 Mr Bob Ludlow
136 *Name Withheld*
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138 Mr John Walker
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143 Dr David Mutch
144 Ms Deborah Smith
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150 Mr Foo Bar
151 *Name Withheld*
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155 Taxpayers Protection Alliance
156 National Retail Association
157 Professor Emily Banks, ANU Research School of Population Health
158 Mr Clive Bates
159 Professor Coral Gartner & Professor Wayne Hall
160 Professor Ron Borland PhD FASSA
161 Professor David Sweanor
162 The Thoracic Society of Australia and New Zealand

163 Professor Chris Bullen and Associate Professor Natalie Walker
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165 Ampol
166 Australian Tobacco Harm Reduction Association
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170 The Royal Australasian College of Physicians
171 NSW Government, NSW Health
172 Miss Alice Pierce
173 Legalise Vaping Australia
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176 TSG Burpengary
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178 Aotearoa Vapers' Community Advocacy (AVCA)
179 Mr Robert Pestell
180 PodVapes Pty Ltd
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183 Australian Medical Association (AMA)
184 *Name Withheld*
185 Dr Nicholas Cope
186 World Vapers Alliance
187 Mr Adam Hazebroek
188 Competitive Enterprise Institute
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190 *Name Withheld*
191 *Name Withheld*
192 *Name Withheld*
193 *Name Withheld*
194 Cancer Council, National Heart Foundation of Australia and Australian Council on Smoking and Health
195 Emeritus Professor Simon Chapman AO PhD, Emeritus Professor Mike Daube AO and Professor Matthew Peters AM MD
- Professor Ann McNeill response to submission 195
- Professor Jamie Brown response to submission 195
- Professors Chapman, Daube and Peters response to Professor Ann McNeill and Jamie Brown
- Ben Youdan, Professors Bullen and Beaglehole response to Dr Ball

196 Mr Rodney Bambridge
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199 Mr Philip Foo
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204 Mr Ben Johnson
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208 Tasmanian Small Business Council
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210 Queensland Nurses & Midwives' Union
211 Mr Charles McCracken
212 Mr Iain Carson
213 *Name Withheld*
214 Australian Institute of Health and Welfare
215 TSG Franchise Management
216 *Name Withheld*
217 British American Tobacco Australia
218 *Name Withheld*
219 Mr Adam Hickmott
220 Dr Moller, Dr Kelso and Professor Jones
221 Mrs Judith Wolters
222 National Asthma Council Australia
223 Centre of Research Excellence Indigenous Sovereignty and Smoking
224 Ms Rachael James
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227 Juddy Corp Pty Ltd
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232 Miss Diana Nguyen
233 *Name Withheld*
234 Mr George Sale
235 *Name Withheld*
236 UK Vaping Industry Association
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238 Property Rights Alliance
239 Mr Chris Baxter
240 Consumer Advocates for Smoke-free Alternatives Association

241 New York University School of Global Public Health
242 Juul Labs
243 The International Network of Nicotine Consumer Organisations (INNCO)
244 Professor Ann McNeill
245 Cigarettes Tobacco Cigars (CTC) Pty Ltd
246 Tasmanian Government
247 Consumer Healthcare Products (CHP) Australia
248 Mr Terry Barnes
- 248.1 Supplementary to submission 248

249 Mr Norbert Zillatron Schmidt
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258 Nurses' Professional Association of Queensland
259 The Royal Children's Hospital
260 Hospitality NT
261 Orygen
262 Miss Tessa Miller
263 Vaping Trade Association of New Zealand
264 Australian Association for Adolescent Health Ltd
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266 Liberal Democrats
267 The George Institute for Global Health
268 Lung Foundation Australia
269 Dr David Outridge
270 Tasmanian Hospitality Association
271 Progressive Public Health Alliance
272 Professor Renee Bittoun
273 Asthma Australia
274 Australian Health Promotion Association
275 Public Health Association of Australia
276 MGA Independent Retailers
277 Mr Patrick Cameron
278 Stroke Foundation
279 Australian Lottery and Newsagents Association
280 Cignall Pty Ltd
281 *Name Withheld*
282 Mrs Linda Foster

283 Nicovape Pty Limited
284 *Name Withheld*
285 *Name Withheld*
286 *Name Withheld*
287 Australian Hotels Association
288 ACT Government
289 Cancer Society of New Zealand
290 Mr Brian Osterio
291 Mr Robert Rogers
292 National Aboriginal Community Controlled Health Organisation
293 Mr Paul Clarence
294 Imperial Brands Australasia
295 Mr Wayne Betts
296 Mr Christopher Boreham-Carna
297 Mr Travis Hinds
298 Mr Duncan McLaren
299 Ms Lyn Bennetts
300 Mr Dan Tarasenko
301 Ms Pam Mulholland
302 Mr Troy Luff
303 Mr Damien Noonan
304 Mr Angelo Ferlauto
305 Ms Kaye Matthews
306 Mr Vince McDevitt
307 Ms Sheryl Mulvey
308 Mr Alpha Centauri
309 Mr Paul Briton
310 Mr Sam Whitehead
311 Mr Paul Webster
312 Ms Naomi Groenendyk
313 Mr Chris Blanch
314 Mr Keith Lewis
315 Ms Donna Garrett
316 Mr Jacent Hipworth
317 Mr Caleb Maher
318 Mr Dan Lucas
319 Mr Stuart Vanderplank
320 Mr Craig Brown
321 Mr Robert Finlay
322 Mr Graeme Fritz
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324 Mr Max Gorvel
325 Mr Troy Smith

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356 Mr Bunny Lim
357 Mr Edwin Seward
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359 Mr Chris O'Connor
360 Ms Lauren Chalmers
361 Mr Michael Byrne
362 Mr Shaun Drew
363 Ms Sheila Marsh
364 Mr Mark Temple
365 Mr Marvin Petilla
366 Mr David Ormsby
367 Mr Michael Oltmanns

368 Mr Gerard McLinden
369 Mr Christopher Merry
370 Mr Adam Grace
371 Mr Chris Cassidy
372 Mr Gary Russell
373 Ms Tracey Fawdry
374 Mr Howard Randell
375 Ms Tara Orr
376 Mr Brad Martens
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380 Mr Shane Robison
381 Mr Peter Sharman
382 Mr Gary McGrath
383 Mr Cliff Chandler
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391 Mr Malcolm Bodie
392 Mr Anthony Wright
393 Mr Ben McBeth
394 Mr Stafford Lumsden
395 Ms Michele Bailey
396 Mr Craig Farquharson
397 Ms Cheryl Bennett
398 Mr Francis M
399 Mr Simon Wells
400 Mr Christiaan van Schalkwyk
401 Mr Jock Mac
402 Mr Brad Hendry
403 Professor Jamie Brown
404 Professor Tony Blakely, Professor Nick Wilson, Dr Jennifer Summers and Dr Driss Ait Ouakrim
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431 Mr Wayne Jones
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461 Philip Morris Limited
462 The Royal Australian & New Zealand College of Psychiatrists
463 Mr Stephen Meredith
464 Mr Anthony Burns
465 Ms Jannah Jaeger
466 Mr Richard Higgins
467 Mr Russell Fuller
468 Ms Pam Wright
469 Mr Louis Upton
470 Mr Mark Eaton
471 Mr Bernd Tendera
472 Mr Craig Jessica
473 Ms Lauren Minahan
474 Mrs Susan Quinn
475 Ms Lesley-Ann Atkins
476 Mr Matthew Driscoll
477 Mr Caleb Garfinkel
478 Ms Adrienne Adams
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488 Ms Traci
489 Mr John Sharpin
490 Mr Adam Pritchard
491 Herschel Baker
492 Ms Justine Davey
493 Mr Dave D
494 Mr Rob Gordon
495 Australian Vaping Association

496 Ms Phaedra Barrett
497 Ms Fiona Smith
498 Mr Jeremy Allen
499 Mr Keith Ballantyne
500 Mr Angus McKimm
501 Ms Kate Moloney
502 Mr Shayne Billings
503 Mr Patrik Hartwig
504 Mr Adrian Cross
505 Ms Rebecca Holloway
506 Ms Kelly Bennett
507 Mr Dave King
508 Ms Carol Brock
509 Mr Elijah Wolf
510 Mr Roy Lang
511 Mr Jason Mackay
512 Mr Tim Best
513 Mr George Briscoe
514 Mr Spencer Myers
515 Ms Sally Beeston
516 Dr Stephen Elsom
517 Mr Patrick O'Brien
518 Ms Lorraine Douglas-Smith
519 Mr Peter Pfkasterer
520 Ms Angela Rundberg
521 Mr Paul Meredith
522 Ms Kathy Willis
523 Mr Ben Weidner
524 Ms Anna Wiseman
525 Mr Derek Gibbs
526 Mr Matt Reeks
527 Mr Nathan Alphonso
528 Ms Deborah Kovas
529 Mr Steve Matsoukas
530 Mr Keith Belding
531 Mr Mario
532 Mr James Brogmus
533 Mr Scott Cleary
534 Mr Darren Reilly
535 Mr Dan Barreda
536 Mr Robert Mathieson
537 Mr John Sullivan
538 Mr Andrew Roberts

539 Mr Wayne Devitt
540 Mr Darren Evans
541 Ms Arlene Alpar
542 Mr Martin Haggas
543 Peta Zenveld
544 Mr John Reid
545 Dr Glenda Smith
546 Ms Emmy Ryan
547 Ms Nicole Hoschke
548 Dr Joe Kosterich
549 Mr John Telford
550 Mr Michael Rafferty
551 Ms Kylie Basford
552 Jean Lam
553 Mr Roberto Arrastia
554 Mr Merv Stephens
555 Mr Alex Bloom
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559 Mr Fredrik Storronning
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567 Mr Daniel Skinner
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576 Ms Toni Brownlie
577 Ms Diane Iveson
578 Ms Susy Argall
579 Ms Deborah McLeod
580 Mr Jeremy Cottom
581 Mr Michael King

582 Mr Samuel Shilson-Josling
583 Mr Christos Hatzinikolaou
584 Mr Marcel Maldonado
585 Mr Eric Wang
586 Mr Jure Selin
587 Jan Melksham
- 587.1 Supplementary to submission 587

588 Mr Keith Spackman
589 Kel Morgan
590 Mr Jeffrey Miceli
591 Mr Alan Edwards
592 Mr Troy Bullock
593 Mr Chris Muir
594 Mr Dominic Johns
595 Mr Peter Smithard
596 Mr Peter Burtonclay
597 Mr John Heffernan
598 Mr Peter Morris
599 Mr James Pawlowski
600 Ms Joanne Mills
601 Bobbie Harlow
602 Ms Bianca Spencer
603 Mr Jarrod Turner
604 Mr John McMahon
605 Mr Adam Cross
606 Chris Jackson
607 Mr Monty Dean
608 Ms Torhild Parkinson
609 Mr Frank Halmi
610 Ms Leeanne Sanderson
611 Ms Kristine Curnow
612 Mr Brian French
613 National Health and Medical Research Council (NHMRC)
614 Ms Natalie Carosi
615 Mr David Lucas
616 Mr Daniel Tippmann
617 Ms Rachael James
618 Ms Sharon Easton
619 Mr Michael Gayner
620 Mr Ben Duggan
621 Mr Oliver Walsh
622 Ms Anna Glare
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624 Mr Ian Thomas
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626 Mr Philippe Lamarque
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628 Mr Rhys Miller
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642 Mr Warrick Allwood
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644 Mr Mark Senden
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647 Mr Scott Morton
648 Ms Tammy Pope
649 Mr Dion McGrath
650 Ms Glynis Cole
651 Mr Tim Hewitt
652 Mr Brett Riley
653 Ms Lisa Barry
654 Ms Marianne Forrest
655 Boon Tan
656 Mr Darryl Knight
657 Mr Matthew Baker
658 Mr Kristofer Brown
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661 Mr Stephen Thomas
662 Mr Simon Garnock-Jones
663 Jo Ebsary
664 Mr Ian Ryan
665 Mr Todd Yorke
666 Ms Melanie Niemann

667 Mr Joshua Marien
668 Mr Peter Everett
669 Mr Ryan Smith
670 Mr Carl Fairhurst
671 Mr Philip Johnson
672 Mr Shimon Maymon
673 Mr John McCormack
674 Mr David Nuka
675 Mr Phil Sharman
676 Mr Foster Johnston
677 Mr Craig Duncombe
678 Mr Chris Owen
679 Ms Julie Ashworth
680 Mr Murray Fox
681 Mr Paul Gerber
682 Mr Jason Harton
683 Mr Greg Cain
684 Mr Barry McRae
685 Ms Jenny McGrath
686 Ms Anna Muller
687 Ms Lynda Watts
688 Mr Bill Gonch
689 Tass Caliskan
690 Mr Andrew Baker
691 Mr Mark Walsh
692 Mr David Milne
693 Mr Nelson Silva
694 Ms Deborah Kingdom
695 Mr Reece Alexander
696 Mr Mark Hansen
697 Ms Mereana Bambridge
698 Mr Geoffrey Willis
699 Ms Loretta Cashell
700 Mr David Miller
701 Mr Ian McIntyre
702 Mr Dale Mills
703 Mr Martin Clarke
704 Mr Matthew Wall
705 Mr Geoff Grant
706 Mr Darren Martin
707 Mr Danny Brvenik
708 Florian Johnen
709 Mr Rodney Waldron

710 Ms Sonya Harmon
711 Ms Yasmin Palmer
712 Mr Alan Andersen
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717 Mr Bruce Chapman
718 Mr Keith Gibbs
719 Mr Justin Eckersley
720 Mr Simon Basham
721 Mr Peter Rankin
722 Mr Scott Stevenson
723 Mr Murray Bell
724 Mr Kees Struik
725 Mr John Archer
726 Mr James Fowle
727 Mr Ben Genn
728 Ms Mary Anne White
729 Mr Adam Hemmling
730 Mr Pieter Rossouw
731 Mr Nick Chapman
732 Mr Raymond Saliba
733 Mr Phillip Redway
734 Ms Jodie Devlin
735 *Name Withheld*
736 Mr Kevin Gillespie
737 Kim Sedgman
738 Mr Christopher Thomas
739 Mr Steven Gribble
740 Ms Dianne May
741 Ms Kirsty Gray
742 Mr Eric Madjeric
743 Mr Gary de Graaf
744 Mr Kiley Thorndyke
745 Frazer Watson
746 Kerry Paynter
747 Mr Gerard Gouault
748 Ms Barbara Beavis
749 Mr Hugh Shepherd
750 Mr Geoff Smith
751 Dr Nathaniel Milani
752 Mr Alistair Passmore

753 Mr Jon Simpfendorfer
754 Mr Rob Carrie
755 Mr Greg Day
756 Mr Jaxon Campbell
757 Mr Jeremy Harris
758 Mr Jarrod Page
759 Ms Tanya Daly
760 Mr Cliff Roberts
761 Mr Kian Lai
762 Mr Jem Lowther
763 Ms Joy Chapple
764 Arpit Juneja
765 Ms Donna Waters
766 Ms Tanya Farrell
767 Mr James Harvey
768 Mr Michael Langdon
769 Mr Anthony Nutter
770 Mr Dan O'Connell
771 Mr Stephen Salmon
772 Mr Dale Sweet
773 Ms Jenny O'Neill
774 Ms Sue Tapara
775 Mr David Perdreau
776 Ms Eileen McFadden
777 Mr Dave Mitchell
778 Dr Ted Arnold
779 Mr Andrew Morrison
780 Mr Brett Streader
781 Ms Diana van Hamburg
782 Mr Brad Gibson
783 Ms Rachel Parnell
784 Mr David Stew
785 Ms Zoe Dior
786 Mr Justin Donelly
787 Mr Greg Wilcox
788 Mr Stewart Thistlethwaite
789 Mr Nick van Stekelenburg
790 Mr Mark Cooney
791 Issam Kadamani
792 Mr Craig Wood
793 Ms Gina Rockett
794 Mr Joshua Bucello
795 Mr Neil Cozens

796 Mr Wei Hong
797 Mr Peter Zivadinovic
798 Mr Tom Parry
799 Sam Boscolo
800 Ms Sherry Dowie
801 Mr Michael Sibbes
802 Mr Danny Organa
803 Mr Jack Fairless
804 Mr Chad Dunlevie
805 Mr Michael Gunning
806 Mr Peter Matheson
807 Ms Deb Hayes
808 Mr Dwayne May
809 Mrs Nina Rantanen
810 Mr Joe Londino
811 Mr Mark Robbins
812 Mr John Vidakovic
813 Ms Jan Ruzans
814 Mr Pete Dreyer
815 Ms Sue Mcleod
816 Marcelle Maxwell
817 Ms Carol Cala
818 Mr Timothy Scherger
819 Ms Belinha Radford
820 Professor Riccardo Polosa
821 Mr Mark Rattenbury
822 Mr Gary Gill
823 Ms Brenda Zuj
824 Ms Susan Hunt
825 Ms Lyndal O'Bryan
826 Mr Donald Lampre
827 Mr Paul Chambers
828 Ms Christiana de Chaeney
829 Ms Georgina Myles
830 Mr Ben Madsen
831 Ms Karen Rullis
832 Ms Marion Freimuth
833 Ms Heidi-Lauren Knuth
834 Professor Robert Beaglehole
835 Jan Deimel
836 Ms Lisa Beswick
837 Mr Ryan Ollier
838 Mr Paul Ackers

839 Mr Andrew Boyd
840 Cory Annetts
841 Mr Paul Healy
842 Ms Bev Tovey
843 Mr Andrew Lisle
844 Ms Barbara S
845 Mr Tony Lloyd
846 Mr Peter Kelly
847 Mr Michael Unterweger
848 Mr Brendan Pelly
849 Ms Anne-Marie Sullivan
850 Ms Marie Guenette
851 Mr Rick Andrews
852 Ms Suzanne Vaughan
853 Dr Carolyn Beaumont
854 Mr Scott McMahon
855 Ms Karen Fry
856 Mr Ken Barr
857 *Name Withheld*
858 *Name Withheld*
859 *Name Withheld*
860 Ms Diana Horne
861 *Name Withheld*
862 Mr Anthony Ryan
863 *Name Withheld*
864 Mr Joel Nicolosi
865 *Name Withheld*
866 Ms Debbie Cowley
867 Mr Christos Stefanidis
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876 *Name Withheld*
877 Mr Paul Wrigley
878 *Name Withheld*
879 *Name Withheld*
880 *Name Withheld*
881 Ms Deborah Holding

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Answers to Questions on Notice

1 Ms Dianne Gorman - Senator Henderson - question on notice from the public hearing on 13 November 2020 (received 16 November 2020)
2 Dr Michelle Jongenelis - Senator Sheldon - written questions on notice QoN01-QoN08 - 19 November 2020 (received 19 November 2020)
3 Dr Coral Gartner - Senator Sheldon - Prescription of nicotine in e-cigarettes - written question on notice QoN008-01 - 18 November 2020 (received 19 November 2020)
4 Dr Coral Gartner - Senator Sheldon - Treatment of nicotine for e-cigarettes - written question on notice QoN008-02 - 18 November 2020 (received 19 November 2020)
5 Dr Coral Gartner - Senator Sheldon - Taxation treatment for e-cigarettes - written question on notice QoN008-03 - 18 November 2020 (received 19 November 2020)
6 Dr Coral Gartner - Senator Sheldon - The likely effect of applying the same taxation treatment or any additional taxes on e-cigarettes - written question on notice QoN008-04 - 18 November 2020 (received 19 November 2020)
7 Mr Christopher Snowdon - Senator Sheldon - written questions on notice QoN01-QoN08 - 19 November 2020 (received 20 November 2020)
8 Professor John Britton - Senator Sheldon - written questions on notice QoN01-QoN08 - 19 November 2020 (received 20 November 2020)
9 Professor Peter Hajek - Senator Sheldon - written questions on notice QoN01-QoN08 - 19 November 2020 (received 20 November 2020)

10 Professor Chris Bullen - Senator Sheldon - Increase in the use of e-cigarettes - written question on notice QoN002-01 - 18 November 2020 (received 20 November 2020)

11 Professor Chris Bullen - Senator Sheldon - Regulation of nicotine - written question on notice QoN002-02 - 18 November 2020 (received 20 November 2020)

12 Professor Chris Bullen - Senator Sheldon - Regulation on nicotine through the Therapeutic Goods Administration - written question on notice QoN002-03 - 18 November 2020 (received 20 November 2020)

13 Professor Chris Bullen - Senator Sheldon - Regulation on nicotine through the Australian Competition & Consumer Commission - written question on notice QoN002-04 - 18 November 2020 (received 20 November 2020)

14 Professor Kenneth E. Warner, PhD - Senator Sheldon - written questions on notice QoN01-QoN08 - 19 November 2020 (received 20 November 2020)

15 Australian Tobacco Harm Reduction Association - Senator Sheldon - written questions on notice QoN01-QoN08 - 19 November 2020 (received 20 November 2020)

16 Professor Wayne Hall PhD AM FASSA FHMS - public hearing on 13 November 2020 (received on 20 November 2020)

17 Australian Council on Smoking and Health - Senator Hughes - written questions on notice QoN013-01-QoN013-02 - 19 November 2020 (received 20 November 2020)

18 CAPHRA - Senator Sheldon - written questions on notice QoN01-QoN08 - 19 November 2020 (received 20 November 2020)

19 Professor Coral Gartner - Senator Sheldon - written questions on notice QoN01-QoN08 - 19 November 2020 (received 20 November 2020)

20 Dr David Mutch - Senator Sheldon - written questions on notice QoN01-QoN08 - 19 November 2020 (received 20 November 2020)

21 Professor Emily Banks - Senator Hughes - Additional evidence on continuing regular smoking in relation to e-cigarette use - public hearing on 13 November 2020 (received on 20 November 2020)

22 Professor Emily Banks - Senator Sheldon - Evidence on smoking in young people in Australia - public hearing on 13 November 2020 (received on 20 November 2020)

23 Professor Emily Banks - Senator Hughes - Eligibility criteria, consideration of nicotine dose and exclusion of data from specific study - public hearing on 13 November 2020 (received on 20 November 2020)

24 Professor Emily Banks - Senator Siewert - Evidence on why young people move from e-cigarettes to smoking - public hearing on 13 November 2020 (received on 20 November 2020)

25 Professor Emily Banks - Senator Henderson - Evidence on the likely impact on smoking prevalence in Australia of increased smoking in young people

resulting from use of e-cigarettes - public hearing on 13 November 2020 (received on 20 November 2020)

26 Dr Michelle Jongenelis - Senator Hughes - written questions on notice QoN013-01-QoN013-02 - 19 November 2020 (received 20 November 2020)

27 Professor Ron Borland - Senator Sheldon - View about the tax treatment of nicotine for e-cigarettes - written question on notice QoN007-01 - 19 November 2020 (received 21 November 2020)

28 Professor Ron Borland - Senator Sheldon - Taxation treatment for e-cigarettes - written question on notice QoN007-02 - 19 November 2020 (received 21 November 2020)

29 Professor Ron Borland - Senator Sheldon - The likely effect of applying the same taxation treatment or any additional taxes on e-cigarettes - written question on notice QoN007-03 - 19 November 2020 (received 21 November 2020)

30 Professor Robert Beaglehole - Senator Sheldon - written questions on notice QoN001-01-QoN001-04 - 18 November 2020 (received 22 November 2020)

31 Professor Michelle Jongenelis - Senator Griff - Statements made by Adjunct Professor John Skerritt of the Therapeutic Goods Administration - written question on notice QoN016-01 - 20 November 2020 (received 22 November 2020)

32 Australian Council on Smoking and Health - Senator Hughes - written questions on notice QoN013-01-QoN013-02 - 19 November 2020 (received 23 November 2020)

33 Australian Council on Smoking and Health - Senator Griff - Statements made by Adjunct Professor John Skerritt of the Therapeutic Goods Administration - written question on notice QoN016-01 - 20 November 2020 (received 23 November 2020)

34 National Retail Association - Senator Sheldon - written questions on notice QoN004-01 - QoN004-19 - 18 November 2020 (received 23 November 2020)

35 Thoracic Society of Australia - Senator Hughes - Evidence on vaping being less harmful than tobacco smoking - written question on notice QoN013-01 - 19 November 2020 (received 24 November 2020)

36 Thoracic Society of Australia - Senator Hughes - Direct or indirect support received from the Pharmaceutical industry - written question on notice QoN013-02 - 19 November 2020 (received 24 November 2020)

37 Professor Emily Banks - Senator Canavan - Evidence on e-cigarette use in never smokers - public hearing on 13 November 2020 (received on 24 November 2020)

38 Professor Ron Borland - Senator Sheldon - written questions on notice QoN01-QoN08 - 19 November 2020 (received 24 November 2020)

39 Professor David Sweanor - written questions on notice QoN01-QoN08 - 19 November 2020 (received 24 November 2020)

40 National Drug and Alcohol Research Centre - Senator Sheldon - written questions on notice QoN01-QoN08 - 19 November 2020 (received 25 November 2020)

41 Professor Emily Banks - Senator Griff - Statements made by Adjunct Professor John Skerritt of the Therapeutic Goods Administration QoN016-01 - 20 November 2020 (received 25 November 2020)

42 Professor Wayne Hall - Senator Sheldon - written questions on notice QoN01-QoN08 - 18 November 2020 (received 25 November 2020)

43 Professor Simon Chapman - Senator Hughes - Direct or indirect support received from the Pharmaceutical industry - written question on notice QoN020-01 - 25 November 2020 (received 25 November 2020)

44 Vapoureyes - Senator Hughes - Direct or indirect support received from the Pharmaceutical industry - written question on notice QoN020-01 - 25 November 2020 (received 25 November 2020)

45 Professor Wayne Hall - Senator Hughes - Direct or indirect support received from the Pharmaceutical industry - written question on notice QoN020-01 - 25 November 2020 (received 25 November 2020)

46 Mr James Reid - Senator Hughes - Direct or indirect support received from the Pharmaceutical industry - written question on notice QoN020-01 - 25 November 2020 (received 25 November 2020)

47 Professor Chris Bullen & Associate Professor Natalie Walker - Senator Sheldon - written questions on notice QoN01-QoN08 - 19 November 2020 (received 25 November 2020)

48 Dr Alex Wodak AM - Senator Hughes - Direct or indirect support received from the Pharmaceutical industry - written question on notice QoN020-01 - 25 November 2020 (received 25 November 2020)

49 TSG Lloyds & TSG Claremont Plaza - Senator Sheldon - written questions on notice QoN01-QoN08 - 19 November 2020 (received 25 November 2020)

50 Professor Coral Gartner - Senator Hughes - Direct or indirect support received from the Pharmaceutical industry - written question on notice QoN020-01 - 25 November 2020 (received 25 November 2020)

51 The Royal Australian and New Zealand College of Psychiatrists - Senator Hughes - written questions on notice QoN013-01-QoN013-02 - 19 November 2020 (received 25 November 2020)

52 The Royal Australian College of General Practitioners - Senator Hughes - written questions on notice QoN013-01-QoN013-02 - 19 November 2020 (received 25 November 2020)

53 Factasia - Senator Sheldon - written questions on notice QoN01-QoN08 - 19 November 2020 (received 25 November 2020)

54 Ms Dianne Gorman - Senator Hughes - Direct or indirect support received from the Pharmaceutical industry - written question on notice QoN020-01 - 25 November 2020 (received 25 November 2020)

55 Royal Australasian College of Physicians - Senator Hughes - Evidence on vaping being less harmful than tobacco smoking - written question on notice QoN013-01 - 19 November 2020 (received 25 November 2020)

56 Royal Australasian College of Physicians -Senator Hughes - Direct or indirect support received from the Pharmaceutical industry - written question on notice QoN013-02 - 19 November 2020 (received 25 November 2020)

57 Australian Medical Association - Senator Hughes - written questions on notice QoN013-01-QoN013-02 - 19 November 2020 (received 25 November 2020)

58 National Retail Association - Senator Sheldon - written questions on notice QoN01-QoN08 - 19 November 2020 (received 25 November 2020)

59 Emeritus Professor Mike Daube - Senator Hughes - Direct or indirect support received from the Pharmaceutical industry - written question on notice QoN020-01 - 25 November 2020 (received 25 November 2020)

60 Mr Clive Bates - Senator Sheldon - written questions on notice QoN01-QoN08 - 19 November 2020 (received 25 November 2020)

61 Mr Clive Bates - Senator Hughes - Direct or indirect support received from the Pharmaceutical industry - written question on notice QoN020-01 - 25 November 2020 (received 25 November 2020)

62 Australian Tobacco Harm Reduction Association - Senator Hughes - Direct or indirect support received from the Pharmaceutical industry - written question on notice QoN020-01 - 25 November 2020 (received 26 November 2020)

63 Ms Hayley Dekker - Senator Hughes - Direct or indirect support received from the Pharmaceutical industry - written question on notice QoN020-01 - 25 November 2020 (received 26 November 2020)

64 Professor Hayden McRobbie - Senator Sheldon - Taxation treatment of nicotine for e-cigarettes - written question on notice QoN005-01 - 18 November 2020 (received 26 November 2020)

65 Professor Hayden McRobbie - Senator Sheldon - Taxation treatment for e-cigarettes - written question on notice QoN005-02 - 18 November 2020 (received 26 November 2020)

66 Professor Hayden McRobbie - Senator Sheldon - The likely effect of applying the same taxation treatment or any additional taxes on e-cigarettes - written question on notice QoN005-03 - 18 November 2020 (received 26 November 2020)

67 Professor Emily Banks - Senator Hughes - Evidence on delivery of nicotine - written questions on notice QoN019-01 - 25 November 2020 (received 30 November 2020)

68 Professor Emily Banks - Senator Hughes - Evidence on e-cigarettes for smoking cessation - written questions on notice QoN019-02 - 25 November 2020 (received 30 November 2020)

69 Professor Emily Banks - Senator Hughes - Evidence on e-cigarette use in never smokers - written questions on notice QoN019-03 - 25 November 2020 (received 30 November 2020)

70 Department of Health - Senator Canavan - Involvement of a health care professional in smoking cessation attempts - public hearing on 13 November 2020 (received on 30 November 2020)

71 Department of Health - Senator Canavan - Number of prescriptions for e-cigarettes - public hearing on 13 November 2020 (received on 30 November 2020)

72 Department of Health - Senator Henderson - Summary of the most recent research that identifies the harm of e-cigarettes - public hearing on 13 November 2020 (received on 30 November 2020)

73 Professor Emily Banks - Senator Hughes - Direct or indirect support received from the Pharmaceutical industry - written question on notice QoN020-01 - 25 November 2020 (received 1 December 2020)

74 AMPOL - public hearing on 13 November 2020 (received on 1 December 2020)

75 AMPOL - Senator Sheldon - written questions on notice QoN01-QoN08 - 19 November 2020 (received 1 December 2020)

76 AMPOL - Senator Hughes - Direct or indirect support received from the Pharmaceutical industry - written question on notice QoN020-01 - 25 November 2020 (received 1 December 2020)

77 AMPOL - Senator Sheldon - written questions on notice QoN003-1-QoN003-11 - 18 November 2020 (received 1 December 2020)

78 CSIRO - Senator Hughes - Direct or indirect support received from the Pharmaceutical industry - written question on notice QoN020-01 - 25 November 2020 (received 2 December 2020)

79 Emeritus Professor Mike Daube & Emeritus Professor Simon Chapman - Senator Griff - Harm reduction strategies - written question on notice QoN015-01 - 20 November 2020 (received 25 November 2020)

80 Emeritus Professor Mike Daube & Emeritus Professor Simon Chapman - Senator Griff - Views regarding vaping health claims - written question on notice QoN014-02 - 20 November 2020 (received 25 November 2020)

81 Emeritus Professor Mike Daube & Emeritus Professor Simon Chapman - Senator Griff - Risks from taking a more relaxed approach to vaping in Australia - written question on notice QoN014-04 - 20 November 2020 (received 25 November 2020)

82 Emeritus Professor Mike Daube & Emeritus Professor Simon Chapman - Senator Griff - Evidence on tobacco companies - written question on notice QoN015-05 - 20 November 2020 (received 25 November 2020)

83 Emeritus Professor Mike Daube & Emeritus Professor Simon Chapman - Senator Griff - Smoking rates - written question on notice QoN014-06 - 20 November 2020 (received 25 November 2020)

84 Emeritus Professor Mike Daube & Emeritus Professor Simon Chapman - Senator Griff - Statements made by Adjunct Professor John Skerritt of the Therapeutic Goods Administration - written question on notice QoN014-09 - 20 November 2020 (received 25 November 2020)

85 Emeritus Professor Mike Daube & Emeritus Professor Simon Chapman - Senator Griff - Overseas approaches to vaping - written question on notice QoN015-07 - 015-08 - 20 November 2020 (received 25 November 2020)

86 Australian Council on Smoking and Health - Senator Siewert - Speech by David Davies - public hearing on 19 November 2020 (received on 23 November 2020)

87 Professor Ron Borland - Senator Sheldon - Declaration in regard to any financial associations with the tobacco, vaping and nicotine industries - public hearing on 13 November 2020 (received 16 November 2020) and response from Professor Simon Chapman (received 9 December 2020)

88 Professor Ron Borland - Senator Hughes - Direct or indirect support received from the Pharmaceutical industry - written question on notice QoN020-01 - 25 November 2020 (received 4 December 2020)

89 Australian Border Force - Senator Hughes - Direct or indirect support received from the Pharmaceutical industry - written question on notice QoN020-01 - 25 November 2020 (received 7 December 2020)

90 New Zealand Ministry of Heath - Senator Hughes - written questions on notice QoN017-01-QoN017-04 - 23 November 2020 (received 9 December 2020) and response from Emeritus Professor Daube to QoN017-01 (received on 15 December 2020)

Additional Information

1 Opening Statement from Mr Maurice Swanson OAM MPH BSc - Public Hearing on 19 November 2020

Appendix 2
Public hearings

Friday, 13 November 2020
Committee Room 2S1
Parliament House
Canberra

Department of Health

- Dr Bernie Towler, Principal Medical Officer
- Ms Sharon Appleyard, First Assistant Secretary
- Ms Caroline Edwards, Associate Secretary

Therapeutic Good Administration

- Adjunct Professor John Skerritt, Deputy Secretary
- Ms Jenny Francis, Principal Legal and Policy Adviser

Australian Border Force

- Dr Bradley Armstrong, Group Manager
- Mr Matthew Duckworth, Assistant Secretary Customs and Trade Policy

Professor Emily Banks, Australian National University Research School of Population Health, Private capacity

Commonwealth Scientific and Industrial Research Organisation

- Dr Rob Grenfell, Director
- Dr Malcolm Riley, Group Leader

Professor Hayden McRobbie, University of New South Wales, Private capacity

Professor Ron Borland, University of Melbourne, Private capacity

Professor Coral Gartner, University of Queensland, Private capacity

Professor Wayne Hall, University of Queensland, Private capacity

Professor Robert Beaglehole, University of Auckland, Private capacity

Professor Chris Bullen, University of Auckland, Private capacity

Ampol

- Mr Todd Lydell, Head of Government Affairs
- Ms Martine Cooper, General Manager

Individual panel discussion (via videoconference):

- Ms Dianne Gorman
- Mr James Reid
- Ms Hayley Dekker Lennon

Australian Tobacco Harm Reduction Association

- Dr Alex Wodak, Director
- Dr Colin Mendelsohn, Board Member

Thursday, 19 November 2020

York Room, Level 1
77 York Street
Sydney

Emeritus Professor Simon Chapman AO PhD FASSA Hon FFPH (UK), Private capacity

Emeritus Professor Mike Daube, Curtin University, Private capacity

Vapoureyes Australia

- Mr Savvas Dimitriou, Managing Director

Professor David Sweanor, University Ottawa, Private capacity

Australian Council on Smoking and Health

- Professor Kingsley Faulkner, President
- Mr Maurice Swanson OAM MPH BSc, Chief Executive Officer

Thoracic Society of Australia and New Zealand

- Professor Matthew Peters, Former President and Co-Chair of Electronic Cigarettes Working Party

Royal Australian College of General Practitioners

- Professor Nick Zwar, Chair of RACGP Smoking Cessation guideline Expert Advisory Group

Royal Australian and New Zealand College of Psychiatrists

- Associate Professor John Allan, President

Royal Australasian College of Physicians

- Professor John Wilson AM, President

Australian Medical Association

- Dr Omar Khorshid, President

Dr Michelle Jongenelis, University of Melbourne, Private capacity

Mr Clive Bates, Private capacity