

PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

Report on the Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia

House of Representatives Standing Committee on Health, Aged Care and
Sport

March 2018
CANBERRA

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Chair's Foreword

Approximately 2.4 million Australians smoke cigarettes daily and it has been estimated that two out of every three smokers will die prematurely due to their smoking. Given these stark figures, reducing the number of Australians who smoke is one of the nation's most important public health objectives.

This Committee has spent close to a year examining whether E-cigarettes could assist in meeting that objective.

The Standing Committee on Health, Aged Care and Sport has a long history of delivering consensus and bipartisan reports. On this occasion that has not been possible and I find myself in the unusual position as Chair of authoring a dissenting report.

The Committee has been presented with starkly conflicting views during this inquiry and I respect those Committee members who have formed different judgements to my own. I do, however, strongly disagree with the conclusions reached by the majority of my colleagues.

Australia has been a global leader in developing tobacco control policies such as plain packaging, advertising restrictions and anti-smoking mass media campaigns. This approach has been very successful — between 1991 and 2013 the proportion of Australians smoking daily dropped from 24 per cent to 12.8 per cent. In recent years, however, progress has stalled with the daily smoking rate only dropping from 12.8 per cent to 12.2 per cent between 2013 and 2016.¹ It is highly unlikely Australia will reach its 2018 target of reducing smoking to 10 per cent of the population.

In these circumstances, a new approach is needed for those smokers who have been unable to quit smoking using the assistance currently available. We need another weapon in the arsenal. The familiar hand-to-mouth movement and the

¹ Australian Institute of Health and Welfare, *National Drug Strategy Household Survey 2016*, p. 21.

'hit' of nicotine provided by E-cigarettes may appeal to those hardened smokers who have struggled to quit using traditional nicotine replacement therapies. While the evidence base regarding E cigarettes is still emerging, there are clear indications that E-cigarettes are significantly less harmful to human health than smoking tobacco cigarettes. If long term smokers who have been unable to quit smoking tobacco cigarettes switch to E-cigarettes, thousands of lives could be saved.

One medical researcher whom the Committee met in New Zealand put the choice starkly. If a patient has earnestly tried existing ways of quitting but failed, then knowing the consequences of that patient continuing to smoke, how could a medical practitioner morally and ethically not recommend they consider E-cigarettes?

Despite the potential health gains, Australia's public health community has been resistant to the idea of making nicotine E-cigarettes legally available. This stands in contrast to many of their counterparts in the United Kingdom and New Zealand who gave evidence to the Committee. While Australia should always set its own course, it was striking that similar organisations and experienced public health officials in those nations drew very different conclusions.

In part this is understandable; Australia has had considerable success in making smoking a less visible activity and reducing its appeal to young people. Many members of the public health community are concerned that legally available nicotine E-cigarettes may reverse these gains and make vaping, and by extension smoking, attractive to young people once more.

In those countries where nicotine E-cigarettes are legally available, however, there has not been an increase in youth smoking. In fact, smoking rates among young people continue to fall in jurisdictions where E-cigarettes are available.

Further, despite Australia's current restrictions on nicotine E-cigarettes, nicotine E-liquid can easily be purchased online from overseas. This unregulated 'black market' poses risks regarding product quality and safety, and could also see people under 18 years of age purchasing E-cigarettes and liquid for these devices online.

Australia's approach to E-cigarettes is also marked by inconsistency. E-cigarettes not containing nicotine are legally available in most states and, despite the domestic prohibition on sale and purchase, can be legally imported by individuals through the Therapeutic Goods Administration's Personal Importation Scheme with a prescription. There is also something obviously inconsistent about cigarettes being legally available while a less harmful nicotine product is not.

This is why in a dissenting report I argue that, in order to assist the millions of smokers struggling to quit tobacco smoking and improve their quality of life, nicotine E-cigarettes should be made available as consumer products. At the same time, regulatory restrictions should be imposed to limit the appeal of E-cigarettes to young people and non-smokers. This includes prohibiting the sale of E-cigarettes to people under 18 years of age and sales and marketing restrictions similar to those in place across the European Union (where E-cigarettes are legally available). Product safety and labelling requirements are also key regulatory considerations. At the same time, research into, and monitoring of, the health impacts of E-cigarettes and E-liquid should be undertaken in parallel, to inform future policy and regulatory decisions.

I would like to thank all the organisations, academics and agencies who participated in this inquiry, as well as the many individuals who shared their personal stories regarding their experiences using E-cigarettes. The Committee also heard from witnesses from the United Kingdom and I thank them for the insight they provided regarding the UK's experience with E cigarettes.

I would also like to extend the Committee's thanks to the members of the New Zealand Government, Parliament and public health community who kindly made time to meet with the Committee's delegation in New Zealand. Their willingness to share their expertise and experiences with the Committee in the spirit of cooperation continues to underpin the close relationship between Australia and New Zealand. In addition, I would like to thank Australia's High Commission to New Zealand for its assistance to the Committee.

The Committee has been again exceptionally well served by the Committee staff led by its Secretary, Stephanie Mikac. The Committee records its thanks for their work.

Finally, I would like to thank my Committee colleagues for their consideration of the evidence during this inquiry.

Mr Trent Zimmerman MP
Chair

Members

Chair

Mr Trent Zimmerman MP

Deputy Chair

Mr Steve Georganas MP

Members

Hon Damian Drum MP (until 19.12.17)

Dr Mike Freeland MP

Mr Andrew Laming MP

Ms Michelle Landry MP (from 6.02.18)

Mrs Lucy Wicks MP

Mr Tim Wilson MP

Mr Tony Zappia MP

Committee Secretariat

Ms Stephanie Mikac, Secretary

Ms Caitlin Cahill, Senior Research Officer (A/g Inquiry Secretary from 19.02.2018)

Mr Timothy Brennan, A/g Inquiry Secretary (until 16.02.2018)

Ms Carissa Skinner, Office Manager

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Terms of Reference

The Standing Committee on Health, Aged Care and Sport will inquire into and report on the use and marketing of electronic cigarettes (E-cigarettes) and personal vaporisers in Australia, in particular:

1. The use and marketing of E-cigarettes and personal vaporisers to assist people to quit smoking;
2. The health impacts of the use of E-cigarettes and personal vaporisers;
3. International approaches to legislating and regulating the use of E-cigarettes and personal vaporisers;
4. The appropriate regulatory framework for E-cigarettes and personal vaporisers in Australia; and
5. Any other related matter.

Abbreviations

AACS	Australasian Association of Convenience Stores
ACL	Australian Consumer Law
ACCC	Australian Competition and Consumer Commission
ADLRF	Australian Drug Law Reform Foundation
AIHW	Australian Institute of Health and Welfare
AMA	Australian Medical Association
AVATAR	Australian Vaping Advocacy, Trade and Research
CAH	Centre for Adolescent Health
CAP	Committee of Advertising Practice
CCA	Cancer Council Australia
CEO	Chief Executive Officer
COPD	Chronic Obstructive Pulmonary Disease
E-cigarette	Electronic Cigarette
ENDS	Electronic Nicotine Delivery Systems
EU	European Union
FDA	Food and Drug Administration
LFA	Lung Foundation Australia
MP	Member of Parliament
NAS	National Academy of Sciences

NHFA	National Heart Foundation of Australia
NHMRC	National Health and Medical Research Council
NNAA	New Nicotine Alliance Australia
NRT	Nicotine Replacement Therapy
NSW	New South Wales
NTS	National Tobacco Strategy
PHAA	Public Health Association of Australia
RACP	Royal Australasian College of Physicians
RANZCP	Royal Australian and New Zealand College of Psychiatrists
RCPL	Royal College of Physicians of London
RCTs	Randomised Controlled Trials
SA	South Australia
TGA	Therapeutic Goods Administration
TPD	Tobacco Products Directive
TSANZ	Thoracic Society of Australia and New Zealand
UK	United Kingdom of Great Britain
UKVIA	United Kingdom Vaping Industry Association
USA	United States of America
WA	Western Australia
WHO	World Health Organization
FCTC	Framework Convention on Tobacco Control

List of Recommendations

Recommendation 1

3.145 The Committee recommends that the National Health and Medical Research Council fund an independent and comprehensive review of the evidence relating to the health impacts of electronic cigarettes (E-cigarettes). This review should be updated every two years to take into account the findings of new research into E-cigarettes. Topics covered by the review should include:

- The effectiveness of E-cigarettes as an aid to help people quit smoking tobacco cigarettes;
- The health effects of ingredients commonly used in E-cigarette liquids. Following the review, any ingredients found to have significant negative impacts on human health should be prohibited from use in E-cigarette liquids;
- The likelihood that E-cigarettes will increase the number of young people using nicotine and the number of young people smoking;
- The health impacts of long term E-cigarette use;
- The relative health impacts of E-cigarettes as compared to tobacco products.

Recommendation 2

- 3.146 The Committee recommends that the Department of Health convenes an international meeting of health experts from similar economic jurisdictions to discuss different policy and legislative approaches to electronic cigarettes.

Recommendation 3

- 5.113 The Committee recommends a national approach be taken to the regulation of non-nicotine electronic cigarettes.

Recommendation 4

- 5.114 The Committee recommends that the Therapeutic Goods Administration continues to oversee the classification of nicotine and relevant exemptions, and the assessment of any electronic cigarette product as a therapeutic good.

Recommendation 5

- 5.115 The Committee recommends that the Australian Government establish a regulatory process for assessing and, if necessary, restricting colourings and flavourings used in electronic cigarettes.

1. Introduction

Background

- 1.1 The emergence of electronic cigarettes (E-cigarettes) in the past decade has required governments around the world to grapple with how to regulate this product.
- 1.2 The scale of the challenge facing governments can be seen in the growing number of E-cigarette users in the United States of America (USA) and in the United Kingdom of Great Britain (UK), which are already in the millions. Currently, the E-cigarette industry is estimated to be worth more than \$US 6 billion globally per annum.¹
- 1.3 In addition, the regulatory decisions facing governments are made more difficult by the lack of certainty regarding the health impacts of E-cigarettes. As the E-cigarette is a device that has only recently come into widespread use, there is limited, and often conflicting, research available in relation to the impact of E-cigarettes on smoking rates and the health implications of long term E-cigarette use.
- 1.4 In Australia there has, to date, been a precautionary approach taken to the regulation of E-cigarettes containing nicotine. The sale of nicotine E-cigarettes is prohibited unless approved as an aid to help people quit smoking and, so far, no E-cigarette has been approved for this purpose.
- 1.5 Internationally, the regulatory response to the emergence of E-cigarettes has been varied. In some countries there has been a similar approach taken to that of Australia, and the sale of some, or all, types of E-cigarettes is

¹ Royal College of Physicians of London, *Nicotine Without Smoke: Tobacco Harm Reduction*, 2016, p. 136.

prohibited. In contrast, other countries including the USA and the UK have opted to make E-cigarettes legally available.

About the Inquiry

Objectives and Scope

- 1.6 On 25 May 2017, the Minister for Health, the Hon Greg Hunt MP,² referred the *Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia* (the inquiry) to the Standing Committee on Health, Aged Care and Sport (the Committee).
- 1.7 As part of the inquiry, the Committee examined whether:
- E-cigarettes are effective in helping people to quit smoking;
 - Greater availability of E-cigarettes is likely to result in more young people taking up tobacco smoking; and
 - E-cigarettes should be regulated as a therapeutic good or as a consumer good.
- 1.8 The inquiry focussed on E-cigarettes and Personal Vaporisers, which are devices that heat a flavoured liquid (which may or may not include nicotine) to create a vapour which is inhaled by the user. These devices are referred to in this report as E-cigarettes, and the liquid they heat is referred to as an E-liquid. The process of using an E-cigarette is, following colloquial use, referred to as 'vaping'.
- 1.9 Heated tobacco products electrically heat tobacco to create a vapour, without burning the tobacco, to create smoke. While referred to occasionally during the inquiry, heated tobacco products are not generally considered a form of E-cigarette and were not a major focus of the inquiry.

Inquiry Conduct

- 1.10 On 26 May 2017, the Committee issued a media release that announced the commencement of the inquiry and called for submissions to be received by 6 July 2017. The Committee also invited submissions from: government agencies, public health organisations, business organisations, universities and research organisations.
- 1.11 The inquiry received 352 submissions and 45 exhibits, which are listed at Appendix A and B respectively.

² At the time Minister for Health and Sport; and currently the Minister for Health.

- 1.12 In addition, the Committee received three different form letters, which were letters provided by multiple participants with the same, or substantially similar, content. The first form letter was received from two participants, the second form letter was received from 1695 participants, and the third form letter was received from seven participants.
- 1.13 The Committee subsequently held three public hearings. In addition, the Committee held three private briefings with witnesses from the UK and later published the transcripts of these briefings.

Table 1.1 Public Hearings Held

Date	Place
12 July 2017	Sydney, NSW
8 September 2017	Canberra, ACT
5 October 2017	Melbourne, Vic

New Zealand Delegation

- 1.14 In addition to hearing from UK witnesses, the Committee undertook a delegation to New Zealand from 18 December to 20 December 2017.
- 1.15 The purpose of the delegation was for the Committee to gain an understanding of the issues encountered in New Zealand moving towards the legalisation of E-cigarettes.
- 1.16 During its visit to New Zealand the Committee met with:
- The Hon Jenny Salesa, Associate Minister of Health;
 - New Zealand Parliament Select Health Committee;
 - The Acting High Commissioner to New Zealand;
 - Ministry of Health, New Zealand;
 - The Technical Experts Advisory Group on Electronic Cigarettes;
 - New Zealand Cancer Society;
 - Action on Smoking and Health, New Zealand; and
 - Dr Natalie Walker and Dr Marjolein Verbiest from Auckland University.
- 1.17 Issues raised and discussed included:
- Proposed legislative changes to legalise nicotine E-cigarettes in New Zealand;

- Regulations relating to the sale and marketing of E-cigarettes, and the use of E-cigarettes in public places;
- E-cigarette use among specific demographics with high rates of tobacco smoking;
- Public health perspectives on the proposed legalisation of nicotine E-cigarettes; and
- The possible health impacts of E-cigarettes.

1.18 The policy context in New Zealand is discussed in more detail in Chapter 5. As delegation meetings were not transcribed, the delegation's findings are discussed in a general manner without attributing statements to individuals.

Figure 1.1 New Zealand Delegation



Mr Trent Zimmerman MP (Chair), Mr Steve Georganas MP (Deputy Chair) and Mr Tim Brennan (Inquiry Secretary) on the steps of the New Zealand Parliament in Wellington on 19 December 2017.

World Health Organization Guidelines

- 1.19 Several inquiry participants expressed concern at the appearance of tobacco industry representatives at public hearings during the inquiry.³ The Australian Medical Association (AMA) stated that:

... the AMA note and object in the strongest terms [to] the involvement of the tobacco industry in these proceedings ... The AMA, as a matter of policy, does not meet with or engage in discussions with the tobacco industry. The primary purpose of the tobacco industry is to make profit for shareholders through the sale of tobacco products. That they are diversifying into E-cigarettes does not exclude their commercial conflict of interest in these proceedings.⁴

- 1.20 Some inquiry participants were concerned that the appearance of tobacco industry representatives could be in breach of Australia's obligations under Article 5.3 of the *World Health Organization's Framework Convention on Tobacco Control*. The guidelines for implementing Article 5.3 (the Guidelines) state that Parties to the Convention⁵ 'need to be alert to any efforts by the tobacco industry to undermine or subvert tobacco control efforts'.⁶
- 1.21 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.'⁷ 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

³ Mr Michael Moore, Chief Executive Officer, Public Health Association of Australia, *Official Committee Hansard*, Melbourne, 5 October 2017, p. 14; Professor Bruce Thompson, Treasurer and Board Director, Finance, Risk and Audit Compliance, Thoracic Society of Australia and New Zealand, *Official Committee Hansard*, Melbourne, 5 October 2017, p. 1.

⁴ Dr Tony Bartone, Vice-President, Australian Medical Association, *Official Committee Hansard*, Melbourne, 5 October 2017, p. 8.

⁵ The Parties to the Convention are States, and other treaty making entities, where the Framework Convention is in force.

⁶ World Health Organization, *Guidelines for Implementation of Article 5.3*, www.who.int/fctc/guidelines/adopted/article_5_3/en/, Accessed 28 November 2017, p. 1.

⁷ World Health Organization, *Guidelines for Implementation of Article 5.3*, www.who.int/fctc/guidelines/adopted/article_5_3/en/, Accessed 28 November 2017, p. 4.

through public hearings, public notice of interactions [and] disclosure of records of such interactions to the public.’⁸

- 1.22 The Committee undertook the inquiry following established parliamentary practices and procedures and so sought the views of a wide range of organisations and individuals including government agencies, public health organisations, peak associations, and business organisations.
- 1.23 Representatives of the tobacco industry lodged submissions to the inquiry which were published on the inquiry webpage. In addition, representatives of the tobacco industry appeared at public hearings in Sydney and Melbourne. These 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.

Previous Inquiries and Reports

Health Committee Inquiry into the Plain Packaging Bill

- 1.24 On 22 August 2011, the Committee’s predecessor, the House Standing Committee on Health and Ageing tabled its advisory report on the *Inquiry into Tobacco Plain Packaging*.⁹ The report recommended that the House of Representatives pass the Tobacco Plain Packaging Bill 2011 and the Trade Marks Amendment (Tobacco Plain Packaging) Bill 2011.¹⁰
- 1.25 The Tobacco Plain Packaging Bill 2011 was designed to prevent tobacco advertising and promotion on the packaging of tobacco products in order to reduce the appeal of tobacco products to consumers and increase the effectiveness of mandated health warnings.¹¹ The House Standing Committee on Health and Ageing stated that Australia was a world leader in tobacco control and that ‘packaging plays a significant role in the

⁸ World Health Organization, *Guidelines for Implementation of Article 5.3*, www.who.int/fctc/guidelines/adopted/article_5_3/en/, Accessed 28 November 2017, p. 4.

⁹ House Standing Committee on Health and Ageing, ‘Inquiry into Tobacco Plain Packaging’, www.aph.gov.au/Parliamentary_Business/Committees/House_of_Representatives_Committees?url=haa/./billtobaccopackage/report.htm, Accessed 28 November 2017.

¹⁰ House Standing Committee on Health and Ageing, *Advisory Report on the Tobacco Plain Packaging Bill 2011 and the Trade Marks Amendment (Tobacco Plain Packaging) Bill 2011*, August 2011, p. xiii.

¹¹ House Standing Committee on Health and Ageing, *Advisory Report on the Tobacco Plain Packaging Bill 2011 and the Trade Marks Amendment (Tobacco Plain Packaging) Bill 2011*, August 2011, p. 5.

marketing of tobacco products’.¹² The House Standing Committee on Health and Ageing also stated that the tobacco industry has resisted tobacco control measures such as plain packaging but that ‘research has shown that over time many of these tobacco control measures have been effective in reducing the smoking rate’.¹³

1.26 The two bills received royal assent on 1 December 2011.¹⁴

Senate Inquiry into Vaporised Nicotine Products Bill

1.27 On 22 June 2017, the Senate referred the Vaporised Nicotine Products Bill 2017 to the Senate Community Affairs Legislation Committee for inquiry.

1.28 On 14 September 2017, the Senate Community Affairs Legislation Committee presented to the Senate its report which recommended that the ‘Senate does not pass the Bill until further scientific evaluation of the efficacy and safety of E-cigarettes and related products has been undertaken’.¹⁵

1.29 The Vaporised Nicotine Products Bill 2017 seeks to ‘exclude E-cigarettes from regulation by the Therapeutic Goods Administration in order to legalise E-cigarettes in Australia.’¹⁶

1.30 The Senate Community Affairs Legislation Committee found that:

Given the lack of a strong evidentiary basis surrounding E-cigarettes, the Committee supports the [Department of Health’s] precautionary approach, which is based on the need to consider the overall impact that E-cigarettes may have on population health, including smokers and non-smokers.¹⁷

¹² House Standing Committee on Health and Ageing, *Advisory Report on the Tobacco Plain Packaging Bill 2011 and the Trade Marks Amendment (Tobacco Plain Packaging) Bill 2011*, August 2011, p. 17.

¹³ House Standing Committee on Health and Ageing, *Advisory Report on the Tobacco Plain Packaging Bill 2011 and the Trade Marks Amendment (Tobacco Plain Packaging) Bill 2011*, August 2011, p. 18.

¹⁴ Parliament of Australia, ‘Tobacco Plain Packaging Bill 2011’, www.aph.gov.au/Parliamentary_Business/Bills_Legislation/Bills_Search_Results/Result?bId=r4613, ‘Trade Marks Amendment (Tobacco Plain Packaging) Bill 2011’, www.aph.gov.au/Parliamentary_Business/Bills_Legislation/Bills_Search_Results/Result?bId=r4614, Accessed 28 November 2017.

¹⁵ Senate Community Affairs Legislation Committee, *Vaporised Nicotine Products Bill 2017*, p. ix.

¹⁶ Senate Community Affairs Legislation Committee, *Vaporised Nicotine Products Bill 2017*, p. 1.

¹⁷ Senate Community Affairs Legislation Committee, *Vaporised Nicotine Products Bill 2017*, p. 14.

- 1.31 The Senate Community Affairs Legislation Committee also stated that it anticipates that the *Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia*:

... may assist in identifying an appropriate framework for the regulation of E-cigarettes. The Committee considers that any decisions regarding the regulatory framework for E-cigarettes should take into account the findings of that inquiry.¹⁸

South Australia Committee on E-cigarettes

- 1.32 On 17 June 2015, the South Australian House of Assembly passed a resolution to appoint a select committee to inquire into the appropriate legislative and regulatory controls on the sale, use, and advertising of E-cigarettes.¹⁹
- 1.33 In February 2016, the select committee released its final report and made 20 recommendations. The committee recommended setting restrictions on the sale, advertising, and public use of E-cigarettes that would bring E-cigarette regulation in line with tobacco regulation. In addition, the Committee's recommendations included: prohibiting the sale of products that may specifically appeal to children; packaging and labelling requirements; further research into the health impacts of E-cigarettes; and appealing to the Federal Government to more stringently enforce nicotine regulations.²⁰
- 1.34 In January 2017, the South Australian Government responded to the recommendations of the inquiry. The South Australian Government accepted the recommendations that could be implemented through the *Tobacco Products Regulation Act 1997 (SA)*.²¹ The South Australian Government also stated that recommendations dealing with prohibiting the sale of products that may appeal to children, packaging and labelling requirements, and the need for further research should be addressed through a national response.²²

¹⁸ Senate Community Affairs Legislation Committee, *Vaporised Nicotine Products Bill 2017*, p. 15.

¹⁹ South Australian House of Assembly, *Final Report of the Select Committee on E-cigarettes*, February 2016, p. 9.

²⁰ South Australian House of Assembly, *Final Report of the Select Committee on E-cigarettes*, February 2016, pp 12-14.

²¹ South Australian Government, *Submission 230*, p. 5.

²² South Australian Government, *Submission 230*, pp 6-7.

Therapeutic Goods Administration Rulings

- 1.35 On 23 March 2017, the Therapeutic Goods Administration (TGA) ruled on a proposal to exempt nicotine for use in E-cigarettes from Schedule 7 of the Poisons Standard. The proposed amendment included allowing a maximum nicotine concentration of 3.6 per cent, a maximum container size of 900 milligrams, and requiring safety and labelling standards for packaging.²³
- 1.36 The TGA ruled that the current scheduling of nicotine, which restricts access to the substance under the Poisons Standard, was appropriate. The TGA's reasons for choosing not to exempt nicotine from Schedule 7 of the Poisons Standard included:
- 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.²⁴

ACCC Enforcement

- 1.37 In June 2016, the Australian Competition and Consumer Commission (ACCC) commenced enforcement activity against three online E-cigarette retailers for 'making false and misleading representations that their products did not contain toxins and carcinogens contained in cigarettes when this was not the case.'²⁵

²³ Therapeutic Goods Administration, 'Scheduling Delegate's Final Decisions, March 2017: 2.1 Nicotine', www.tga.gov.au/book-page/21-nicotine-0, Accessed 28 November 2017.

²⁴ Therapeutic Goods Administration, 'Scheduling Delegate's Final Decisions, March 2017: 2.1 Nicotine', www.tga.gov.au/book-page/21-nicotine-0, Accessed 28 November 2017.

²⁵ Australian Competition and Consumer Commission (ACCC), *Submission 224*, p. 2; ACCC, 'ACCC Takes Action Against E-cigarette Suppliers for Alleged Misleading "No Toxic Chemicals"'

- 1.38 The ACCC commissioned independent testing which identified the presence of formaldehyde, acetaldehyde and acrolein. The ACCC stated that it was concerned consumers could be misled into 'believing that the use of those products would not expose them to harmful chemicals, cancer-causing chemicals or carcinogens like those contained in conventional tobacco cigarette smoke.'²⁶
- 1.39 Following admissions by the three companies involved, the Federal Court of Australia ordered these companies to pay pecuniary penalties. The ACCC has since written to over 30 E-cigarette suppliers reminding them of their responsibilities under Australian Consumer Law.²⁷

National Health and Medical Research Council Statement

- 1.40 On 3 April 2017, the National Health and Medical Research Council (NHMRC) released a CEO Statement on Electronic Cigarettes (the Statement). The Statement considered the potential health risks of E-cigarettes, the effectiveness of E-cigarettes as an aid to smoking cessation, the role of E-cigarettes in tobacco control policies, and the manufacturing quality of E-cigarettes.
- 1.41 The Statement's key findings included that:
- 'E-cigarettes may expose users to fewer toxic chemicals than conventional tobacco cigarettes; however the extent to which this reduces harm to the user has not been determined;'²⁸
 - E-cigarettes may expose users to toxins, heavy metals, and particulates at potentially unsafe levels;
 - There is insufficient evidence to determine whether E-cigarettes are effective in helping people quit smoking;
 - There is some evidence that E-cigarettes are associated with the uptake of smoking; and

Claims', www.accc.gov.au/media-release/accc-takes-action-against-e-cigarette-suppliers-for-alleged-misleading-%E2%80%9Cno-toxic-chemicals%E2%80%9D-claims, Accessed 28 November 2017.

²⁶ ACCC, *Submission 224*, p. 2.

²⁷ ACCC, *Submission 224*, pp 2-3.

²⁸ National Health and Medical Research Council (NHMRC), NHMRC CEO Statement: Electronic Cigarettes, April 2017, www.nhmrc.gov.au/files_nhmrc/file/publications/17072_nhmrc_-_electronic_cigarettes-web_final.pdf, Accessed 28 November 2017.

- Policy makers should act to minimise harm to users, bystanders, and vulnerable groups until ‘evidence of safety, quality and efficacy can be produced.’²⁹

National Academy of Sciences Review

- 1.42 In May 2016, the USA Food and Drug Administration (US FDA) issued a rule providing it with the authority to regulate the manufacturing, distribution, and marketing of tobacco products, including E-cigarettes. In order to support the regulatory work of the US FDA, the National Academy of Sciences (NAS) undertook a comprehensive review of the science relating to the public health risks and benefits of E-cigarettes.³⁰
- 1.43 The NAS Review identified more than 800 peer reviewed studies relating to the health impacts of E-cigarettes. The NAS Review considered health issues related to E-cigarettes including:
- The short and long-term health risks from regular E-cigarette use;
 - The effectiveness of E-cigarettes in assisting people to quit smoking; and
 - Whether E-cigarettes increase the likelihood of young people taking up smoking.³¹
- 1.44 On 23 January 2018, the NAS released its report entitled *Public Health Consequences of E-cigarettes*. The key findings of the report included that:
- E-cigarettes emit toxic substances but (in the most part) at lower levels than tobacco cigarettes;
 - There are health impacts from E-cigarette use but the long-term effect on mortality and morbidity is unknown;
 - E-cigarettes are likely to pose less risk to individuals than tobacco cigarettes;
 - E-cigarettes are likely to be effective in helping people to quit smoking;
 - E-cigarettes are likely to increase the likelihood of young people taking up smoking; and

²⁹ National Health and Medical Research Council (NHMRC), NHMRC CEO Statement: Electronic Cigarettes, April 2017, www.nhmrc.gov.au/files/nhmrc/file/publications/17072_nhmrc_-_electronic_cigarettes-web_final.pdf, Accessed 28 November 2017.

³⁰ Stratton, K., Kwan, L.Y., Eaton D.L., *Exhibit 24: Public Health Consequences of E-cigarettes*, National Academy of Sciences, p. ix.

³¹ Stratton, K., Kwan, L.Y., Eaton D.L., *Exhibit 24: Public Health Consequences of E-cigarettes*, National Academy of Sciences, p. ix.

- E-cigarettes are likely to result in a net public health benefit in the short-term but in the long-term (for example 50 years into the future) may have a negative public health impact.³²

Summary of Current Policy

- 1.45 In Australia, nicotine for use in E-cigarettes is classified as a poison and, therefore, nicotine E-cigarettes cannot be legally sold in Australia.³³ Despite this, if an E-cigarette product (regardless of whether it contains nicotine) can prove that it is a safe and effective aid to help people quit smoking it could be approved for sale as a therapeutic good. To date, however, no E-cigarette product has been approved for this purpose.³⁴
- 1.46 Non-nicotine E-cigarettes are regulated by the states and territories. The regulations relating to the sale, marketing, and use of E-cigarettes vary between states and territories. In most jurisdictions, non-nicotine E-cigarettes can be legally sold but the sale of these products is prohibited in Western Australia.³⁵
- 1.47 There is significant divergence in the approach to regulating E-cigarettes internationally; from complete prohibition, to prohibiting only nicotine E-cigarettes, to allowing the sale of all types of E-cigarette. Notably, nicotine E-cigarettes can be legally bought and sold in the USA, the European Union, and the UK.³⁶ Both New Zealand and Canada have also indicated that they intend to make legislative changes to legalise the sale of nicotine E-cigarettes.³⁷

Report Structure

- 1.48 Chapter 2 provides background and context to the issues discussed throughout the report. Issues discussed in Chapter 2 include: the

³² Stratton, K., Kwan, L.Y., Eaton D.L., *Exhibit 24: Public Health Consequences of E-cigarettes*, National Academy of Sciences, pp S-3 – S-8.

³³ Department of Health, *Submission 297: Attachment A*, p. 2.

³⁴ Department of Health, *Submission 297: Attachment A*, p. 1.

³⁵ Department of Health, *Submission 297: Attachment A*, pp 2-3.

³⁶ Department of Health, *Submission 297*, pp 6-7; Associate Professor Colin Mendelsohn, *Submission 258*, p. 18.

³⁷ Associate Professor Colin Mendelsohn, *Submission 258*, pp 17-18; Royal Australasian College of Physicians, *Submission 276*, p. 4.

development of E-cigarettes; types of E-cigarettes available; the prevalence of tobacco smoking and E-cigarette use in Australia and overseas; regulatory principles such as the precautionary principle and harm reduction; tobacco control policy in Australia; and E-cigarette regulations in Australia and internationally.

- 1.49 Chapter 3 discusses the health considerations relating to E-cigarettes, including: research on the effectiveness of E-cigarettes as a smoking cessation aid; the use of E-cigarettes as a substitute for smoking or in conjunction with smoking; the possibility that E-cigarettes could increase the likelihood of young people taking up smoking; the health impacts of long term E-cigarette use; and other potential risks such as battery explosions and nicotine poisoning.
- 1.50 Chapter 4 outlines personal accounts of E-cigarette use and discusses issues raised, such as the use of E-cigarettes as an aid to quit smoking and the health effects of switching from tobacco smoking to E-cigarette use.
- 1.51 Chapter 5 discusses the approaches taken to regulate E-cigarettes in Australia and overseas. In particular, Chapter 5 details: E-cigarette regulations in Australian states and territories; regulating E-cigarettes as a therapeutic good; the potential to regulate E-cigarettes as a consumer good; regulatory issues relating to the use of E-cigarettes in public places; labelling, packaging, marketing, and product safety regulations; taxation issues; the regulatory approaches to E-cigarettes internationally; and the proposed changes to E-cigarette regulation in New Zealand.

2. Setting the Scene

Background

- 2.1 In 2003,¹ the electronic cigarette (E-cigarette) was developed by the Chinese pharmacist Hon Lik, who was struggling to quit smoking and wanted to develop a machine that could provide nicotine in a way that would mimic the 'look, feel and hit of smoking.'² In 2004, the first commercial release of E-cigarettes took place in China and, by 2007, E-cigarettes had started to appear in the United Kingdom of Great Britain (UK).³
- 2.2 E-cigarettes use battery power to heat a liquid (known as E-liquid) and disperse an aerosol solution which is inhaled by the user.⁴ While technically an aerosol, the solution inhaled by the user is typically referred to as a vapour and this is the basis of the established terminology of E-cigarette use as 'vaping', and E-cigarette users as 'vapers'.⁵

¹ Ms Sarah Boseley, 'Hon Lik invented the E-cigarette to quit smoking – but now he's a dual user', *The Guardian*, 10 June 2015, <https://www.theguardian.com/society/2015/jun/09/hon-lik-e-cigarette-inventor-quit-smoking-dual-user>, Accessed 22 January 2018.

² Dr Alexander (Alex) David Wodak, President, Australian Drug Law Reform Foundation (ADLRF), *Official Committee Hansard*, Sydney, 12 July 2017, p. 9.

³ Public Health England, *Exhibit 1: E-cigarettes: An Evidence Update*, p. 15.

⁴ Public Health England, *Exhibit 1: E-cigarettes: An Evidence Update*, p. 15.

⁵ Public Health England, *Exhibit 1: E-cigarettes: An Evidence Update*, p. 15.

- 2.3 E-liquids may, but do not necessarily, contain nicotine. In addition, E-liquids typically contain food flavouring, propylene glycol, and vegetable glycerine.⁶
- 2.4 The first types of E-cigarette to become commercially available are known as *cigalikes*, as they physically resemble tobacco cigarettes. Cigalikes are often disposable, or alternatively they may feature a disposable E-liquid cartridge.⁷ Cigalikes deliver relatively small amounts of nicotine to the user, in part due to many of the particles in the vapour being too large to be absorbed by the lungs.⁸
- 2.5 Newer models of E-cigarettes are generally larger and do not resemble cigarettes as closely. These E-cigarettes are rechargeable and contain a tank that is designed to be refilled, enabling the vaper to experiment with different flavoured E-liquids.⁹ Tank system E-cigarettes have longer lasting batteries¹⁰ and deliver nicotine in smaller particles that can be better absorbed by the user.¹¹ Some tank systems allow the user to make adjustments to the power delivered by the battery and the temperature used to heat the E-liquid.¹²
- 2.6 As of 2016, cigalikes were the most popular style of E-cigarette in Russia and the United States of America (USA), while tank systems were the most popular type of E-cigarette in the UK.¹³
- 2.7 Initially, tobacco companies were not major players in the E-cigarette industry. From 2012 onwards, however, tobacco companies began purchasing existing E-cigarette companies or creating their own E-cigarette

⁶ Mr Savvas Dimitriou, Chairperson, Australian Vaping Advocacy, Trade and Research Inc (AVATAR), *Official Committee Hansard*, Melbourne, 5 October 2017, p. 40.

⁷ Public Health England, *Exhibit 1: E-cigarettes: An Evidence Update*, p. 15.

⁸ Stanton A. Glantz, David W. Bareham, *Exhibit 3: E-cigarettes: Use, Effects on Smoking, Risks and Policy Implications*, 2017, p. 5.

⁹ Stanton A. Glantz, David W. Bareham, *Exhibit 3: E-cigarettes: Use, Effects on Smoking, Risks and Policy Implications*, 2017, pp 4-5.

¹⁰ Mr Savvas Dimitriou, AVATAR, *Official Committee Hansard*, Melbourne, 5 October 2017, p. 38.

¹¹ Stanton A. Glantz, David W. Bareham, *Exhibit 3: E-Cigarettes: Use, Effects on Smoking, Risks and Policy Implications*, 2017, p. 5.

¹² Public Health England, *Exhibit 1: E-cigarettes: An Evidence Update*, p. 15; Associate Professor Colin Mendelsohn, Private Capacity, *Official Committee Hansard*, Sydney, 12 July 2017, p. 11.

¹³ Royal College of Physicians of London, *Nicotine Without Smoke: Tobacco Harm Reduction*, 2016, p. 136.

brands. Today all major tobacco companies have investments in the E-cigarette industry.¹⁴

- 2.8 For example, the tobacco company Philip Morris recently advertised in a number of UK newspapers that its 'New Year's Resolution' was to 'give up cigarettes' and stated that it had an 'ambition to stop selling cigarettes in the UK'.¹⁵
- 2.9 In addition, Philip Morris has stated that it is 'committed to a smoke-free future where electronic cigarettes and personal vaporisers will replace cigarettes'.¹⁶
- 2.10 Some public health agencies, however, cast doubt on the intentions behind this change of direction, with the Australian Medical Association (AMA) stating that in 'developed countries where there is increasing regulation, the business model is to move to other ways to maintain and grow nicotine addiction'.¹⁷
- 2.11 In addition, the Public Health Association of Australia stated that tobacco companies have shown little interest in selling E-cigarettes in the developing world. Instead, the tobacco companies have increased their sales of tobacco cigarettes in those countries where there is limited regulation and people may not 'understand the full dangers of tobacco'.¹⁸
- 2.12 To date, tobacco company investment has primarily been in developing the cigalike style of E-cigarette.¹⁹ In the UK, the refillable tank systems, which have the major share of the market, are predominantly produced by small to medium manufacturing companies.²⁰

¹⁴ Royal College of Physicians of London, *Nicotine Without Smoke: Tobacco Harm Reduction*, 2016, pp 136-137.

¹⁵ BBC, 'Philip Morris places anti-smoking advertisement in papers', <http://www.bbc.com/news/business-42539142>, Accessed 17 January 2018.

¹⁶ Mr Mark Powell, Manager, Public Policy, Philip Morris Limited, *Official Committee Hansard*, Melbourne, 5 October 2017, p. 43.

¹⁷ Dr Tony Bartone, Vice-President, Australian Medical Association, *Official Committee Hansard*, Melbourne, 5 October 2017, p. 8.

¹⁸ Mr Michael Moore, Chief Executive Officer, Public Health Association of Australia, *Official Committee Hansard*, Melbourne, 5 October 2017, p. 18.

¹⁹ Public Health England, *Exhibit 1: E-cigarettes: An Evidence Update*, p. 15; Associate Professor Colin Mendelsohn, *Official Committee Hansard*, Sydney, 12 July 2017, p. 11; Royal College of Physicians of London, *Nicotine Without Smoke: Tobacco Harm Reduction*, 2016, p. 137.

²⁰ Associate Professor Colin Mendelsohn, *Official Committee Hansard*, Sydney, 12 July 2017, p. 11.

- 2.13 The peak body for Australian E-cigarette retailers, Australian Vaping Advocacy, Trade and Research (AVATAR), advised that there are no local manufacturers of E-cigarette devices in Australia and approximately 90 per cent of E-cigarettes are imported from Europe, the USA, and China.²¹ In contrast, the majority of E-liquid sold by AVATAR members was produced in Australia and AVATAR described making E-liquid as ‘an easy process.’²²
- 2.14 In the UK, where E-cigarettes are legal, the industry grew from a value of £25 million in 2011 to £459 million in 2014.²³ In 2016, the value of sales of E-cigarettes globally was estimated to be \$US6.5 billion.²⁴

Smoking Rates in Australia

- 2.15 In 2016, about three million Australians, or 14.9 per cent of the population over 14 years of age, were current tobacco smokers and 2.4 million Australians (12.2 per cent) smoked daily.²⁵ Smoking rates in Australia have been on a ‘long term downward trend since 1991’ with the daily smoking rate halving between 1991 and 2016. Between 2013 and 2016, however, the daily smoking rate ‘only decreased slightly’ from 12.8 per cent to 12.2 per cent.²⁶
- 2.16 The decline in smoking rates has been driven by fewer people taking up smoking rather than existing smokers quitting.²⁷ Due to this, the smoking population is ageing. Between 2001 and 2016 the proportion of daily smokers over the age of 40 years rose from 44 per cent to 57 per cent.²⁸
- 2.17 The Department of Health advised that, in 2011, smoking was estimated to be responsible for the death of almost 19 000 Australians. Smoking is also estimated to account for 22 per cent of the total cancer burden in Australia.²⁹

²¹ Mr Savvas Dimitriou, AVATAR, *Official Committee Hansard*, Melbourne, 5 October 2017, p. 40.

²² Mr Savvas Dimitriou, AVATAR, *Official Committee Hansard*, Melbourne, 5 October 2017, p. 40.

²³ Royal College of Physicians of London, *Nicotine Without Smoke: Tobacco Harm Reduction*, 2016, p. 136.

²⁴ Royal College of Physicians of London, *Nicotine Without Smoke: Tobacco Harm Reduction*, 2016, p. 136.

²⁵ Australian Institute of Health and Welfare, *National Drug Strategy Household Survey 2016*, p. 21.

²⁶ Australian Institute of Health and Welfare, *National Drug Strategy Household Survey 2016*, p. 21.

²⁷ Australian Institute of Health and Welfare, *National Drug Strategy Household Survey 2016*, p. 21.

²⁸ Australian Institute of Health and Welfare, *National Drug Strategy Household Survey 2016*, p. 23.

²⁹ Department of Health, *Submission 297*, p. 10.

- 2.18 Until recently, smoking rates in the UK and the USA were significantly higher than in Australia, but in recent years the smoking rates in both countries have declined more rapidly than in Australia. In the USA, between 2010 and 2015, smoking rates dropped from 19.4 per cent to 15.1 per cent,³⁰ while in the UK the rate dropped from 20 per cent in 2012 to 15.5 per cent in 2016.³¹

Use of E-cigarettes

- 2.19 In its *National Drug Strategy Household Survey 2016* the Australian Institute of Health and Welfare (AIHW) stated the 'current use of E-cigarettes was relatively low in the general population with only 1.2 per cent of people aged 14 or older reporting that they currently use E-cigarettes'.³²
- 2.20 The AIHW also stated that 31 per cent of smokers had tried E-cigarettes in their lifetime. Younger smokers were more likely than older smokers to have tried E-cigarettes with 49 per cent of smokers aged 18 to 24 having tried E-cigarettes compared with 18.7 per cent of smokers aged 60 to 69.³³
- 2.21 A 2015-2016 study found that three per cent of the Queensland adult population were using E-cigarettes and that 10 per cent of the adult population had tried them during their life.³⁴
- 2.22 Rates of E-cigarette use are higher in the UK than in Australia. In 2015, 5.4 per cent of the population of the UK were E-cigarette users.³⁵ In 2017, among E-cigarette users in the UK, 52 per cent were ex-smokers, 45 per cent were smokers and 3 per cent had never smoked tobacco. The proportion of vapers who are ex-smokers has risen consistently since 2014.³⁶ E-cigarette use among youth in the UK is lower than in the general population with 87.7 per cent of youth having never used an E-cigarette and 2.6 per cent using E-cigarettes more than monthly.³⁷

³⁰ Counterfactual Consulting, *Submission 271*, p. 4.

³¹ Public Health England, *Submission 336.1*, p. 3.

³² Australian Institute of Health and Welfare, *National Drug Strategy Household Survey 2016*, p. 27.

³³ Australian Institute of Health and Welfare, *National Drug Strategy Household Survey 2016*, p. 27.

³⁴ Queensland Department of Health, *Submission 226*, p. 3.

³⁵ Public Health England, *Exhibit 1: E-cigarettes: An Evidence Update*, 2015, p. 27.

³⁶ Public Health England, *Submission 336.1*, p. 13.

³⁷ Public Health England, *Submission 336.1*, p. 14.

Regulatory Context

Guiding Principles – Harm Reduction and Precautionary Principle

- 2.23 The perspectives of many inquiry participants were informed by two key public health policy principles — *harm reduction* and the *precautionary principle*. Participants advocating for a continuation of current policy towards E-cigarettes tended to emphasise the precautionary principle, while participants advocating for greater availability of E-cigarettes tended to emphasise harm reduction principles.

Precautionary Principle

- 2.24 The Thoracic Society of Australia and New Zealand and Lung Foundation Australia defined the precautionary principle by stating that ‘if there is a suspected risk of harm and the scientific information is lacking, such that there is an absence of scientific consensus, then the burden of proof that it is not harmful falls on those wanting to progress the issue.’³⁸
- 2.25 Participants advocating for the use of the precautionary principle for the regulation of E-cigarettes highlighted the lack of long term evidence on the health impacts of E-cigarettes. Emeritus Professor Simon Chapman, Professor Mike Daube, David Bareham, and Associate Professor Matthew Peters (Emeritus Professor Chapman) highlighted the risks of flavouring chemicals used in E-cigarettes, stating ‘our knowledge of the impact of long term inhalation, many times a day over many years, of vapour arising from the heating of these chemicals is in its infancy.’³⁹
- 2.26 The AMA added that ‘the longitudinal research that is required to establish safety will take time, but until more definitive evidence on safety becomes available the precautionary principle should be applied to these products.’⁴⁰
- 2.27 In contrast, Associate Professor Coral Gartner and Professor Wayne Hall suggested that this approach sets the threshold of acceptable risk too high. Associate Professor Gartner and Professor Hall suggested the acceptable

³⁸ Thoracic Society of Australia and New Zealand and Lung Foundation Australia, *Submission 332*, p 2.

³⁹ Emeritus Professor Simon Chapman AO, Professor Mike Daube AO, David Bareham, and Associate Professor Matthew Peters, *Submission 313*, p. 36.

⁴⁰ Australian Medical Association, *Submission 289*, p. 3.

level of risk is context dependent. Therefore, an acceptable risk of poisoning from tap water would be very low as people presume the water they drink will be safe. In contrast, smokers are already engaged in a very high risk activity and so would accept 'some uncertainty about the absolute risk [of E-cigarettes] given the known risks of smoking.'⁴¹

- 2.28 Public Health England stated that personal opinions on whether E-cigarettes should be available:

... [comes] down to one's attitude to the precautionary principle ... rather than waiting 20 years to get definitive evidence, we have to make the best decision on the evidence that's available now, and that points us towards cautious use of E-cigarettes.⁴²

Harm Reduction

- 2.29 The Royal College of Physicians of London (RCPL) stated that, in 2007, it adopted harm reduction as part of its tobacco control policy. The RCPL described tobacco harm reduction approaches as being:

... predicated on the principle that smokers smoke primarily because they are addicted to nicotine; that nicotine addiction, of itself, is not a major health hazard and that the harms from smoking arise primarily from the many toxins in tobacco smoke; and hence that in addition to encouraging all smokers to quit if possible, tobacco control policies should encourage those who continue to smoke to switch to a less hazardous source of nicotine.⁴³

- 2.30 Professor Gerry Stimson illustrated the concept of harm reduction by providing the example of driving motor vehicles. Driving is an inherently risky activity but rather than prohibiting it, governments seek to reduce the risk of harm through road rules and safety regulations.⁴⁴ Professor Stimson also suggested Australia had experienced public health benefits from using a harm reduction approach to other drug policy issues; for instance in the use of needle and syringe exchanges, safer injecting facilities, and the prescription of methadone.⁴⁵

⁴¹ Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 282.1*, p. 3.

⁴² Professor John Newton, Director of Health Improvement, Public Health England, *Official Committee Hansard*, Canberra, 18 October 2017, p. 10.

⁴³ Royal College of Physicians of London, *Submission 280*, p. 1.

⁴⁴ Professor Gerry Stimson, *Submission 287*, pp 1-2.

⁴⁵ Professor Gerry Stimson, *Submission 287*, p. 1.

- 2.31 Dr Alex Wodak stated that the introduction of harm reduction strategies in Australia has generally been accompanied by ‘acrimonious debate’.⁴⁶ Dr Wodak suggested that opposition to harm reduction strategies was often based on the risk compensation hypothesis which suggests that if you lower the risk of an activity, then more people will undertake that activity. Dr Wodak suggested that ‘we should always look for the possibility of risk compensation but it rarely happens.’⁴⁷
- 2.32 Associate Professor Colin Mendelsohn described E-cigarettes as meeting many of the criteria for an ‘ideal tobacco harm reduction product’.⁴⁸ Associate Professor Mendelsohn stated that E-cigarettes were able to deliver nicotine ‘without the vast majority of harmful constituents of tobacco smoke, and provide the behavioural and sensory aspects of the smoking ritual.’⁴⁹
- 2.33 The Department of Health stated that its regulatory response to E-cigarettes as outlined in the *National Tobacco Strategy 2012-2018* (NTS) was based on the principles of harm minimisation which ‘includes the three pillars of demand reduction, supply reduction and harm reduction’.⁵⁰ The Public Health Association of Australia (PHAA) emphasised the importance of the combination of these three principles and critiqued the idea that the increased availability of E-cigarettes would minimise harm. The PHAA stated:
- ... this argument is based on highly selective use of the evidence, coupled with a fundamental misunderstanding of a comprehensive harm minimisation strategy. This includes not only harm reduction but also reduction in demand and supply—two elements that are explicitly rejected by many advocates of electronic cigarettes.⁵¹
- 2.34 The Department of Health added that the effects of E-cigarette availability on non-smokers should also be considered in relation to the potential for E-cigarettes to minimise harm. The Department of Health stated:

⁴⁶ Dr Alexander (Alex) David Wodak, ADLRF, *Official Committee Hansard*, Sydney, 12 July 2017, p. 1.

⁴⁷ Dr Alexander (Alex) David Wodak, ADLRF, *Official Committee Hansard*, Sydney, 12 July 2017, p. 16.

⁴⁸ Associate Professor Colin Mendelsohn, *Submission 258*, p. 4.

⁴⁹ Associate Professor Colin Mendelsohn, *Submission 258*, p. 4.

⁵⁰ Department of Health, *Submission 297*, p. 10.

⁵¹ Professor Michael Moore, Chief Executive Officer, Public Health Association of Australia, *Official Committee Hansard*, Melbourne, 5 October 2017, p. 14.

... for nearly 90 per cent of the population that are not currently smoking, it is not a harm minimiser ... to open a pathway that would start exposing them to nicotine. That's not harm minimisation; it's quite a harm increase.⁵²

- 2.35 Emeritus Professor Chapman referred to products, including asbestos filters and light or low tar cigarettes, as previous examples of products that have been marketed as reducing harm but were not subsequently shown to be less harmful. Emeritus Professor Chapman stated that 'the long history of failure [of harm reducing products] and the consequences of again promoting false hopes must give all responsible authorities strong pause for consideration.'⁵³
- 2.36 The Department of Health suggested that E-cigarettes create 'a numbers game' where governments must balance 'the risk of people starting smoking versus [the] hope that a number will stop smoking at the other end of their life — adults versus teenagers and young adults'. The Department of Health added that due to this need to balance these competing concerns, the World Health Organization has advised against making E-cigarettes available in countries with low rates of smoking.⁵⁴

Tobacco Control Policy in Australia

- 2.37 The Department of Health described Australia as a 'global leader' in tobacco control,⁵⁵ and Public Health England stated that it has 'huge respect for what [Australia has achieved] in the area of tobacco control in the past—things like plain packaging.'⁵⁶
- 2.38 The Department of Health stated that the Australian Government's approach to tobacco control has a 'strong evidence base' and is undertaken

⁵² Dr Lisa Studdert, Acting Deputy Secretary, Department of Health, *Official Committee Hansard*, Canberra, 8 September 2017, p. 16.

⁵³ Professor Simon Chapman AO, Professor Mike Daube AO, David Bareham, and Associate Professor Matthew Peters, *Submission 313*, p. 23.

⁵⁴ Dr John Skerritt, Deputy Secretary, Department of Health, *Official Committee Hansard*, Canberra, 8 September 2017, pp 16-17.

⁵⁵ Dr Lisa Studdert, Department of Health, *Official Committee Hansard*, Canberra, 8 September 2017, p. 3.

⁵⁶ Professor John Newton, Public Health England, *Official Committee Hansard*, Canberra, 18 October 2017, p. 7.

in partnership with non-government health organisations.⁵⁷ Key elements of Australia's tobacco control policy include:

- Regular, staged increases in the excise for tobacco products;
- Education campaigns and programs;
- Plain packaging for tobacco products;
- Graphic health warnings on tobacco product labels;
- Prohibiting tobacco advertising and promotion;
- Providing support for smokers to quit.⁵⁸

2.39 Australia's approach to tobacco control is outlined in the NTS, which sets out priority areas for action and was developed with the objective of 'reducing the prevalence of smoking and its associated health, social and economic costs, and the inequalities it causes.'⁵⁹ The nine priority areas for action outlined in the NTS are:

- Protect public health policy, including tobacco control policies, from tobacco industry interference;
- Strengthen mass media campaigns to: motivate smokers to quit and recent quitters to remain quit; discourage uptake of smoking; and reshape social norms about smoking;
- Continue to reduce the affordability of tobacco products;
- Bolster and build on existing programs and partnerships to reduce smoking rates among Aboriginal and Torres Strait Islander people;
- Strengthen efforts to reduce smoking among populations with a high prevalence of smoking;
- Eliminate remaining advertising, promotion and sponsorship of tobacco products;
- Consider further regulation of the contents, product disclosure and supply of tobacco products and alternative nicotine delivery systems;
- Reduce exceptions to smoke-free workplaces, public places and other settings; [and]
- Provide greater access to a range of evidence-based cessation services to support smokers to quit.⁶⁰

⁵⁷ Dr Lisa Studdert, Department of Health, *Official Committee Hansard*, Canberra, 8 September 2017, p. 3.

⁵⁸ Department of Health, *Submission 297*, p. 9.

⁵⁹ Department of Health, *Submission 297*, p. 10.

⁶⁰ Intergovernmental Committee on Drugs, *National Tobacco Strategy 2012-2018*, p. 12.

Regulation of E-cigarettes in Australia

- 2.40 In Australia, the regulation of E-cigarettes 'is a shared responsibility between the Commonwealth, state and territory governments'⁶¹ and different regulations apply to nicotine and non-nicotine E-cigarettes.
- 2.41 Nicotine E-cigarettes are regulated through the Poisons Standard which classifies nicotine as a poison. The Poisons Standard is a legislative instrument under the *Therapeutic Goods Act 1989 (Cwlth)* and is 'given legal effect ... through relevant state and territory legislation'.⁶²
- 2.42 States and territories are able to make their own laws to determine the availability of poisons and medicines but, in the majority of cases, classify these substances in accordance with the Poisons Standard. In the case of nicotine, 'the commercial supply of nicotine for use in E-cigarettes is prohibited by legislation in all states and territories'.⁶³
- 2.43 There are exemptions in the Poisons Standard for the use of nicotine in tobacco; for veterinary purposes; and as a therapeutic good (such as in nicotine replacement therapies).⁶⁴
- 2.44 All products that claim to be able to assist people to quit smoking are considered therapeutic goods and must be authorised for use by the Therapeutic Goods Administration (TGA). The TGA stated that it is 'unable to confirm or deny' whether it has received any applications for an E-cigarette product.⁶⁵ To date the TGA has not approved any E-cigarette product for use as a therapeutic good.⁶⁶
- 2.45 The TGA also oversees the Personal Importation Scheme which enables the importation of nicotine for personal use. People may legally import nicotine through the Personal Importation Scheme if they have a prescription from a general practitioner, are importing no more than a three month supply, and

⁶¹ Department of Health, *Submission 297*, p. 6.

⁶² Department of Health, *Submission 297: Attachment A*, p. 1.

⁶³ Department of Health, *Submission 297: Attachment A*, pp 1- 2.

⁶⁴ Therapeutic Goods Administration (TGA), 'Scheduling Delegate's Final Decisions, March 2017', www.tga.gov.au/book-page/21-nicotine-0, Accessed 7 November 2017.

⁶⁵ Mr John Skeritt, Department of Health, *Official Committee Hansard*, 8 September 2017, Canberra, p. 14.

⁶⁶ Department of Health, *Submission 297: Attachment A*, p. 1.

it is lawful in their state or territory (in Queensland, for instance, this is specifically prohibited).⁶⁷

- 2.46 E-cigarettes that do not contain nicotine and do not make therapeutic claims (such as aiding people to quit smoking) are governed by the legislation and regulation of the states and territories. Currently there is significant variation in how non-nicotine E-cigarettes are regulated in the states and territories. The sale of non-nicotine E-cigarettes is legal in most states and territories but is prohibited in Western Australia;⁶⁸ other regulations relating to where E-cigarettes can be used and how they can be marketed differ between jurisdictions. The relevant regulations in each jurisdiction are considered in more detail in Chapter 5.

International Approaches to Regulation

- 2.47 The World Health Organization Framework Convention on Tobacco Control (FCTC), to which Australia is a Party, commits 'nations to implementing a range of demand and supply-side tobacco control measures'.⁶⁹
- 2.48 In 2014, a FCTC report stated that in countries with very low rates of tobacco smoking, the use of E-cigarettes will not result in reductions in the rates of disease and mortality caused by smoking.⁷⁰ The Department of Health also advised that the 'FCTC has repeatedly invited Parties to the Convention to consider regulating and/or prohibiting [E-cigarettes]'.⁷¹

⁶⁷ Department of Health, *Submission 297: Attachment A*, p. 2; Dr John Skerritt, Department of Health, *Official Committee Hansard*, Canberra, 8 September 2017, p. 9; Queensland Department of Health, *Submission 226*, p. 6.

⁶⁸ Victorian Department of Health and Human Services, 'E-cigarette reforms: factsheet', www2.health.vic.gov.au/about/publications/factsheets/e-cigarette-reforms-factsheet, Accessed 7 December 2017; ACT Health, 'Electronic Cigarettes', www.health.act.gov.au/public-information/public-health/tobacco-and-smoke-free/electronic-cigarettes, Accessed 7 December 2017; Tasmanian Department of Health and Human Services 'Electronic Cigarettes', www.dhhs.tas.gov.au/publichealth/tobacco_control/electronic-cigarettes, Accessed 27 November 2017; Northern Territory Government, 'Electronic Cigarettes', <https://nt.gov.au/wellbeing/healthy-living/smoking/electronic-cigarettes>, Accessed 7 November 2017; Department of Health, *Submission 297: Attachment A*, p. 3.

⁶⁹ Department of Health, *Submission 297*, p. 9.

⁷⁰ World Health Organization, 'Electronic Nicotine Delivery Systems', July 2014, p. 11, http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10-en.pdf, Accessed 13 November 2017.

⁷¹ Department of Health, *Submission 297*, p. 9.

- 2.49 The Department of Health stated that ‘there is currently no international consensus on the most appropriate regulatory framework for E-cigarettes.’⁷² Regulatory approaches to E-cigarettes include regulating them as ‘tobacco products, poisons, medicines (including medical devices) and consumer products.’⁷³ Nicotine E-cigarettes cannot be sold in nine countries and the sale of all E-cigarettes is prohibited in 27 countries.⁷⁴
- 2.50 In contrast, nicotine E-cigarettes can be legally purchased in the European Union (EU), the UK, and the USA. In the EU and the UK, E-cigarettes are regulated through the Tobacco Products Directive (TPD). The TPD: requires manufacturers to disclose information about the content of E-liquids; requires E-cigarette packaging to contain health warnings; places restrictions on E-cigarette advertising; and limits the volume and concentration of nicotine available in E-liquid solutions.⁷⁵
- 2.51 In the USA, nicotine E-cigarettes are regulated as a tobacco product by the Food and Drug Administration (US FDA). The US FDA regulates the ‘manufacture, import, packaging, labelling, advertising, promotion, sale, and distribution of E-cigarettes.’⁷⁶
- 2.52 The Governments of Canada and New Zealand have proposed legislative changes to regulate the sale of E-cigarettes as consumer products. In both countries, E-cigarette products that make therapeutic claims, such as being able to assist people to quit smoking, will be regulated as medicines.⁷⁷

Concluding Comment

- 2.53 Australia has a strong record as a global leader in the field of tobacco control and has often been at the forefront of implementing measures designed to reduce the appeal of smoking. This strong approach to tobacco control has made an important contribution to the significant decline in the number of

⁷² Department of Health, *Submission 297*, p. 6.

⁷³ Department of Health, *Submission 297*, p. 6.

⁷⁴ Cancer Council Australia and the National Heart Foundation of Australia, *Submission 295*, p. 13; Associate Professor Colin Mendelsohn, *Submission 258*, p. 16.

⁷⁵ Royal College of Physicians of London, *Submission 280*, p. 4.

⁷⁶ Department of Health, *Submission 297*, p. 7.

⁷⁷ Associate Professor Colin Mendelsohn, *Submission 258*, p. 18; Royal Australasian College of Physicians, *Submission 276*, p. 4.

smokers in Australia since the 1990s. Nevertheless, with approximately three million Australians still smoking, it is clear that more may be done.

- 2.54 Despite being a relatively new product, electronic cigarettes (E-cigarettes) are already being used by a significant number of people. Just over one per cent of Australians are currently using E-cigarettes and over 30 per cent of smokers have tried an E-cigarette at least once. In the United Kingdom of Great Britain, where nicotine E-cigarettes are legally available, rates of E-cigarette use are higher with more than five per cent of the population currently using E-cigarettes.
- 2.55 During the inquiry, there was substantial discussion about the appropriate use of the precautionary principle and harm reduction approach in public health policy. Both the precautionary principle and harm reduction approach have been used in the past to underpin decisions that have resulted in positive health outcomes.

3. Smoking and Vaping: Health Considerations

Overview

- 3.1 The increasing use of electronic cigarettes (E-cigarettes) is a relatively recent phenomenon and this creates a challenge for researchers and policy makers seeking to evaluate the public health impact of E-cigarettes. Potential health risks from the use of E-cigarettes include impacts on: lung health, adolescent brain development, and maternal and fetal health during pregnancy.¹
- 3.2 In addition, there may be health impacts from the use of E-cigarettes that are yet to become apparent. The potential health impacts of E-cigarette use, the possibility of additional and as yet unknown effects, and the health risks relative to the known impacts of smoking are all factors that require balanced consideration by policy makers.
- 3.3 E-cigarettes have been described as a potential smoking cessation aid to assist those smokers who have been unable to quit using other methods.² While some studies have found evidence suggesting that E-cigarettes may help smokers to quit,³ other studies have found that E-cigarettes were ineffective as a smoking cessation aid.⁴

¹ Thoracic Society of Australia and New Zealand and Lung Foundation Australia (TSANZ and LFA), *Submission 332*, p. 9; Centre for Adolescent Health, *Submission 256*, p. 5.

² New Nicotine Alliance Australia (NNAA), *Submission 222*, pp 3-4.

³ Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 282.1*, p. 9.

⁴ Emeritus Professor Simon Chapman AO, Professor Mike Daube AO, David Bareham, and Associate Professor Matthew Peters, *Submission 313*, pp 11-12.

- 3.4 Another key issue for public health policy makers is whether E-cigarettes could create a new pathway into smoking for young people.⁵ There are conflicting views on whether the evidence suggests there is an association between E-cigarette availability and the increased likelihood of young people trying and taking up smoking.⁶

E-cigarettes and Smoking

- 3.5 In Australia, any product that claims to assist smokers to quit smoking must be approved by the Therapeutic Goods Administration (TGA) prior to sale. To date, 'no E-cigarettes have yet been approved by the TGA as smoking cessation aids'.⁷

Consumer Perspective

- 3.6 The New Nicotine Alliance Australia (NNAA), an organisation representing E-cigarette users, stated that 'the big difference between E-cigarettes and other nicotine replacement options is that the E-cigarette simulates smoking'. The NNAA added that E-cigarettes were also able to provide nicotine to the user faster than nicotine replacement therapies (NRT).⁸
- 3.7 The Committee received many submissions from individuals who recounted their personal stories of using E-cigarettes. In most cases, these submissions were from people who had successfully used E-cigarettes to quit smoking tobacco. Mr Ben Grotegoed, in an account mirrored by other participants, described his experience of unsuccessfully trying to quit smoking using other methods before turning to E-cigarettes. Mr Grotegoed stated:

I've tried [nicotine] patches and gum and spray all with varying degrees of success. However nothing I've tried has kept me off the dreaded smokes for any longer than a month or two. About three years ago I took up vaping ... I can count the number of cigarettes I've had in the three years [since] on one hand.⁹

⁵ Department of Health, *Submission 297*, p. 1.

⁶ Mr Maurice Gerard Swanson, Chief Executive Officer, National Heart Foundation of Australia (WA Division), *Official Committee Hansard*, Canberra, 8 September 2017, p. 11; Royal College of Physicians of London, *Submission 280*, p. 2.

⁷ Department of Health, *Submission 297*, p. 1.

⁸ Dr Attila Danko, President, NNAA, *Official Committee Hansard*, Sydney, 12 July 2017, p. 6.

⁹ Mr Ben Grotegoed, *Submission 91*, p. 1.

- 3.8 The personal accounts of the individual vapers who provided submissions to the inquiry are considered in more detail in Chapter 4.

Public Health Perspective

- 3.9 The Department of Health stated that available evidence on the use of E-cigarettes to help people to quit smoking ‘does not allow any firm conclusions to be drawn as to whether E-cigarettes may help most smokers quit smoking or prevent them from doing so.’¹⁰
- 3.10 This view was shared by many Australian public health bodies. The Royal Australasian College of Physicians (RACP) stated that ‘the evidence base is unable to support or refute the role E-cigarettes play in smoking cessation.’¹¹ The Thoracic Society of Australia and New Zealand (TSANZ) agreed, stating that ‘we would advise caution with respect to the idea that electronic cigarettes promote smoking cessation. They may actually do so; the problem is we just don’t know.’¹²
- 3.11 The Australian Medical Association (AMA) described the ‘efficacy and safety of E-cigarettes as cessation aids [as] an area of rapidly emerging evidence’ and stated that ‘it is not unusual for two contradictory articles on E-cigarettes to be released in one week.’¹³
- 3.12 State government agencies in New South Wales,¹⁴ Queensland,¹⁵ South Australia,¹⁶ Tasmania,¹⁷ Victoria,¹⁸ and Western Australia¹⁹ also agreed that there was insufficient evidence to support the use of E-cigarettes as smoking cessation devices. These government agencies also supported the role of the TGA and the National Health and Medical Research Council (NHMRC) as

¹⁰ Department of Health, *Submission 297*, p. 2.

¹¹ Royal Australasian College of Physicians (RACP), *Submission 276*, p. 2.

¹² Professor Bruce Thompson, Treasurer and Board Director, Finance, Risk and Audit Compliance, TSANZ, *Official Committee Hansard*, Melbourne, 5 October 2017, p. 1.

¹³ Australian Medical Association, *Submission 289*, p. 4.

¹⁴ New South Wales Health, *Submission 333*, p. 1.

¹⁵ Queensland Department of Health, *Submission 226*, p. 4.

¹⁶ South Australian Government, *Submission 230*, p. 2.

¹⁷ Tasmanian Government, *Submission 182*, p. 2.

¹⁸ Quit Victoria, *Submission 328*, p. 1.

¹⁹ Government of Western Australia, *Submission 292*, p. 2.

the appropriate bodies to assess the evidence relating to E-cigarettes and smoking cessation.

- 3.13 The Department of Health also drew attention to the World Health Organization's statement that the 'scientific evidence regarding the effectiveness of [E-cigarettes] as a smoking cessation aid is scant and of low certainty, making it difficult to draw credible inferences.'²⁰

Research on E-cigarettes and Smoking Cessation

The Cochrane Review

- 3.14 Many inquiry participants referred to a study on the effectiveness of E-cigarettes as smoking cessation aids undertaken by Cochrane. Cochrane undertakes 'systematic reviews of primary research in human health care and health policy'.²¹
- 3.15 The Cochrane Review (the Review) considered 24 studies looking at the effectiveness of E-cigarettes at assisting people to quit smoking. Of these studies, 22 did not follow participants for a long period of time or did not 'directly compare the effectiveness of E-cigarettes with other possible smoking cessation aids'.²² The two remaining studies were Randomised Controlled Trials (RCTs) that followed participants for at least six months and were considered to 'provide the best evidence'.²³
- 3.16 The two RCTs found that people using E-cigarettes containing nicotine were more successful in quitting smoking than people using E-cigarettes without nicotine.²⁴ The Review was not able to determine whether E-cigarettes were more effective in helping people to quit smoking than nicotine patches.²⁵ Overall the Review rated the confidence in the result as low due to the small

²⁰ Department of Health, *Submission 297*, p. 3.

²¹ Cochrane, 'What is Cochrane evidence and how can it help you?' www.cochrane.org/what-is-cochrane-evidence, Accessed 1 December 2017.

²² Department of Health, *Submission 297*, p. 3.

²³ Cochrane, 'Can electronic cigarettes help people stop smoking and are they safe to use for this purpose?' www.cochrane.org/CD010216/TOBACCO_can-electronic-cigarettes-help-people-stop-smoking-and-are-they-safe-use-purpose, Accessed 1 November 2017.

²⁴ Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 282*, p. 2.

²⁵ Cochrane, 'Can electronic cigarettes help people stop smoking and are they safe to use for this purpose?' www.cochrane.org/CD010216/TOBACCO_can-electronic-cigarettes-help-people-stop-smoking-and-are-they-safe-use-purpose, Accessed 1 November 2017.

number of studies.²⁶ The Review added that more studies of E-cigarettes and smoking cessation were needed, some of which were already underway.²⁷

- 3.17 Associate Professor Coral Gartner and Professor Wayne Hall stated that the two RCTs considered by the Review used first generation *cigalike*²⁸ E-cigarettes that ‘are known to be less effective at delivering nicotine than the modern tank devices that are now predominantly used by vapers.’²⁹
- 3.18 Professor Martin McKee suggested that in one of the RCTs ‘it is likely that that the effectiveness of E-cigarettes was overstated’ due to the inconsistencies between how E-cigarette users and NRT users were provided with the materials to take part in the trial.³⁰

National Academy of Science Review

- 3.19 The United State of America’s (USA) National Academy of Sciences (NAS) considered the effectiveness of E-cigarettes in assisting people to quit smoking. The review was undertaken on behalf of the USA Food and Drug Administration and published in January 2018. The NAS Review classified the evidence relating to the effectiveness of E-cigarettes in assisting people to quit smoking as *limited evidence*³¹. This classification suggests there is sufficient evidence to conclude that E-cigarettes may be effective as smoking cessation aids but that this conclusion is subject to significant uncertainty.³²
- 3.20 The 2018 NAS Review identified three RCTs and stated that the results of these trials suggest that E-cigarettes have a ‘possible though not definitively

²⁶ Associate Professor Colin Mendelsohn, *Submission 258*, p. 8.

²⁷ Cochrane, ‘Can electronic cigarettes help people stop smoking and are they safe to use for this purpose?’ www.cochrane.org/CD010216/TOBACCO_can-electronic-cigarettes-help-people-stop-smoking-and-are-they-safe-use-purpose, Accessed 1 November 2017.

²⁸ Cigalikes are a type of E-cigarette that physically resembles a tobacco cigarette and is often disposable or uses a disposable liquid container as opposed to the refillable containers for E-liquids used by tank system E-cigarettes.

²⁹ Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 282*, p. 2.

³⁰ Professor Martin McKee, *Submission 291*, p. 3.

³¹ The 2018 NAS review defines limited evidence as: ‘supportive findings from fair-quality studies or mixed findings with most favouring one conclusion. A conclusion can be made, but there is significant uncertainty due to chance, bias, and confounding factors.’ National Academy of Science, *Exhibit 24a: Public Health Consequences of E-cigarettes: Conclusions by Level of Evidence*, p. 2.

³² Stratton, K., Kwan, L.Y., Eaton D.L., *Exhibit 24: Public Health Consequences of E-cigarettes*, National Academy of Sciences, p. S-7.

positive association with quitting smoking'.³³ Two of the RCTs found nicotine E-cigarettes to be a more effective smoking cessation aid than non-nicotine E-cigarettes and the 2018 NAS Review also stated that the 'substantial body of RCT evidence demonstrating the efficacy of nicotine replacement products ... provided plausibility for the role of nicotine in enhancing the likelihood of smoking cessation.'³⁴

- 3.21 The 2018 NAS Review stated that the only RCT comparing E-cigarettes with NRTs had found no statistically significant difference in the quit rates between E-cigarette and NRT users.³⁵ The 2018 NAS Review stated that there was insufficient evidence to determine whether E-cigarettes were more or less effective than NRTs as a smoking cessation aid.³⁶
- 3.22 The 2018 NAS Review drew attention to the discrepancy between the results from the RCTs and the results of meta-analyses of observational studies published prior to 2016. Two of these meta-analyses (El Dib, and Kalkhoran and Glantz; discussed below) found a negative association between E-cigarettes and quitting smoking. The 2018 NAS Review stated that this discrepancy contributed 'to the uncertainty about the overall effect of E-cigarettes on cessation'.³⁷
- 3.23 The 2018 NAS Review highlighted that studies published prior to 2016 may have included E-cigarette users who either vaped infrequently or continued smoking while using E-cigarettes (dual users). Due to the possibility that this may have affected the results of these studies, as well as the rapid evolution of E-cigarette technology, the 2018 NAS Review gave greater weight to studies published recently.³⁸

³³ Stratton, K., Kwan, L.Y., Eaton D.L., *Exhibit 24: Public Health Consequences of E-cigarettes*, National Academy of Sciences, p. 17-15.

³⁴ Stratton, K., Kwan, L.Y., Eaton D.L., *Exhibit 24: Public Health Consequences of E-cigarettes*, National Academy of Sciences, p. 17-15.

³⁵ Stratton, K., Kwan, L.Y., Eaton D.L., *Exhibit 24: Public Health Consequences of E-cigarettes*, National Academy of Sciences, p. 17-15.

³⁶ Stratton, K., Kwan, L.Y., Eaton D.L., *Exhibit 24: Public Health Consequences of E-cigarettes*, National Academy of Sciences, p. 17-15.

³⁷ Stratton, K., Kwan, L.Y., Eaton D.L., *Exhibit 24: Public Health Consequences of E-cigarettes*, National Academy of Sciences, p. 17-16.

³⁸ Stratton, K., Kwan, L.Y., Eaton D.L., *Exhibit 24: Public Health Consequences of E-cigarettes*, National Academy of Sciences, p. 17-16.

- 3.24 The 2018 NAS Review found that in recently published studies there was an association between the frequency of E-cigarette use and the likelihood of successfully quitting smoking. The 2018 NAS Review stated:

Based on ... the strong, consistent body of evidence from higher-quality studies published more recently that overcome measurement limitations of studies published in the past, [the NAS] concluded that there was *moderate evidence*³⁹ that more frequent use of E-cigarettes is associated with quitting smoking.⁴⁰

Other Studies on E-cigarettes and Smoking Cessation

- 3.25 Emeritus Professor Simon Chapman, Professor Mike Daube, David Bareham, and Associate Professor Matthew Peters (Emeritus Professor Chapman) highlighted a review undertaken by El Dib which considered eight longitudinal cohort studies that followed smokers over a long period to assess the effectiveness of different methods of quitting smoking. Emeritus Professor Chapman stated that this review indicated that there was ‘a potential suppression of chances in successful quitting when people use [E-cigarettes].’⁴¹ The El Dib review, however, also reported a number of limitations in the cohort studies and stated they provided ‘very low-certainty evidence from which no credible inferences can be drawn.’⁴²
- 3.26 Overall, looking at both RCTs and longitudinal cohort studies, the El Dib review concluded that based on available evidence it was not possible to ‘verify nor exclude the hypothesis’ that E-cigarettes were more effective than

³⁹ The 2018 NAS Review defines moderate evidence as: ‘several supportive findings from fair-quality studies with few or no credible opposing findings. A general conclusion can be made, but limitations, including chance, bias, and confounding factors, cannot be ruled out with reasonable confidence.’ *Exhibit 24a: Public Health Consequences of E-cigarettes: Conclusions by Level of Evidence*, p. 2.

⁴⁰ Stratton, K., Kwan, L.Y., Eaton D.L., *Exhibit 24: Public Health Consequences of E-cigarettes*, National Academy of Sciences, p. 17-17.

⁴¹ Emeritus Professor Simon Chapman AO, Professor Mike Daube AO, David Bareham, and Associate Professor Matthew Peters, *Submission 313*, p. 11.

⁴² El Dib, R., Suzumura, E.A., Aki, E.A., Gomaa, H., Agarwal, A., Chang, Y., Prasad, M., Ashoorion, V., Heels-Ansdell, D., Maziak, W., Guyatt, G., ‘Electronic Nicotine Delivery Systems and/or Electronic Non-Nicotine Delivery Systems for Tobacco Smoking Cessation or Reduction: A Systematic Review and Meta-Analysis, *BMJ Open*, 2017, 7.

other nicotine replacement strategies. The review also stated there was a need for more ‘well designed trials in this field’.⁴³

- 3.27 Professor Martin McKee and the RACP highlighted a meta-analysis of 20 studies by Kalkhoran and Glantz which, ‘while subject to caveats’ found that E-cigarette users had a 28 per cent lower rate of quitting than those that did not use E-cigarettes.⁴⁴ Associate Professor Mendelsohn was, however, critical of the ‘poor methodology’ of the Kalkhoran and Glantz review stating it included studies that were too different to be compared, did not consider different types of E-cigarettes or different frequency of use, and used selective inclusion and reporting of studies.⁴⁵
- 3.28 Associate Professor Gartner and Professor Hall drew attention to a population based study in the USA.⁴⁶ This study looked at the results from a 2014-2015 national survey of tobacco use and found that E-cigarette users attempted to quit smoking, and succeeded at quitting smoking at higher rates than other smokers. The study also found that there was a statistically significant increase in the overall rate of smokers quitting smoking between 2010-2011 and 2014-2015 (from 4.5 per cent to 5.6 per cent).⁴⁷
- 3.29 Another population study of 5863 English smokers who had attempted to quit smoking in the past year without using professional support found that those who had used E-cigarettes were more likely to quit than those who used NRT or no quitting aids.⁴⁸
- 3.30 Emeritus Professor Chapman highlighted that as cross-sectional population surveys only collect data from a single moment in time they are unable to

⁴³ El Dib, R., Suzumura, E.A., Aki, E.A., Gomaa, H., Agarwal, A., Chang, Y., Prasad, M., Ashoorion, V., Heels-Ansdell, D., Maziak, W., Guyatt, G., ‘Electronic Nicotine Delivery Systems and/or Electronic Non-Nicotine Delivery Systems for Tobacco Smoking Cessation or Reduction: A Systematic Review and Meta-Analysis, *BMJ Open*, 2017, 7.

⁴⁴ Professor Martin McKee, *Submission 291*, p. 3; RACP, *Submission 276*, p. 2.

⁴⁵ Associate Professor Colin Mendelsohn, *Submission 258*, p. 8.

⁴⁶ Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 282.1*, p. 9.

⁴⁷ Zhu, S.H., Zhuang, Y.L., Wong, S., Cummins S.E., Tedeschi, G.J., ‘E-cigarette Use and Associated Changes in Population Smoking Cessation: Evidence from US Current Population Surveys’, *The BMJ*, 2017, 358.

⁴⁸ Public Health England, *Exhibit 1: E-cigarettes: An Evidence Update*, p. 48.

show causality and therefore they could not prove that E-cigarette use had caused a change in smoking rates.⁴⁹

Smoking Among At-Risk Groups

3.31 Professor Ron Borland highlighted that smoking rates remain high among at-risk groups even in countries like Australia who have ‘done virtually everything on the tobacco control agenda that targets smokers and the social conditions influencing use.’⁵⁰ Professor Borland added ‘it is not clear how much further progress can be made [to reduce smoking among at-risk groups] without large new initiatives designed to make it easier to give up smoking.’⁵¹

3.32 Emeritus Professor Ian Webster stated that there were ‘rusted on’ smokers who had been unable to quit and among this group there was an over-representation of:

... Aboriginal and Torres Strait Islanders, people with enduring mental illnesses, people with established chronic diseases, persons with alcohol and other drug dependence, homeless people and people from socially deprived backgrounds.⁵²

3.33 Professor Borland commented that people in at-risk groups were just as likely as other smokers to attempt to quit but were less likely to be successful in their quit attempts.⁵³ Professor Borland explained:

... a major factor in the increasing divergence in smoking rates between those living relatively privileged lives and those whose lives are psychologically or socially impoverished is almost entirely due to greater difficulty staying quit. The most likely explanation for this is that the rewarding aspects of smoking are relatively more important to these people than others, perhaps because of the lower levels of alternative rewards ... the use of a nicotine substitute that provides much of the psychological effects obtained from smoking, is more likely to result in increased quit success.⁵⁴

⁴⁹ Emeritus Professor Simon Chapman AO, Professor Mike Daube AO, David Bareham, and Associate Professor Matthew Peters, *Submission 313*, p. 11.

⁵⁰ Professor Ron Borland, *Submission 216*, p. 7.

⁵¹ Professor Ron Borland, *Submission 216*, p. 7.

⁵² Emeritus Professor Ian Webster, *Submission 65*, p. 2.

⁵³ Professor Ron Borland, *Submission 216*, p. 8.

⁵⁴ Professor Ron Borland, *Submission 216*, p. 19.

- 3.34 The Royal Australian and New Zealand College of Psychiatrists (RANZCP) stated that 70 per cent of people with schizophrenia and 61 per cent of people with bipolar disorder smoke.⁵⁵ The RANZCP added that ‘people living with mental illness are not only more likely to smoke, but they also tend to smoke more heavily than people without mental disorders.’⁵⁶
- 3.35 Professor Con Stough and Associate Professor Luke Downey stated that ‘a processing deficit (called the P50) observed in patients with schizophrenia may be significantly ameliorated by nicotine and is one of the reasons why smoking rates are so high in patients with schizophrenia.’⁵⁷
- 3.36 The RANZCP stated that the rate of smoking among people with mental disorders has not gone down and that in cases where there are ‘factors that are impacting on someone’s ability or willingness to quit smoking, [that is] where harm reduction can have a role.’⁵⁸ The RANZCP also indicated that it would support a ‘comprehensive approach [that] should include the proportional regulation of E-cigarettes and vaporisers.’⁵⁹
- 3.37 The RANZCP added that E-cigarettes had the potential to provide an option for people who were financially struggling due to the cost of cigarettes, stating that:

With continued increases in the tobacco excise, keeping E-cigarettes and vaporisers at a low cost would not only encourage uptake of these devices over more harmful products, but would also present financial benefits for vulnerable groups of people which may present flow-on benefits for public health.⁶⁰

Substituting E-cigarettes for Tobacco

- 3.38 Some vapers⁶¹ choose to use E-cigarettes over the long term without the intention of stopping, effectively using E-cigarettes to quit smoking without quitting nicotine use. For example, Dr Attila Danko of the NNAA stated that

⁵⁵ Royal Australian and New Zealand College of Psychiatrists (RANZCP), *Submission 294*, p. 1.

⁵⁶ RANZCP, *Submission 294*, p. 1.

⁵⁷ Professor Con Stough and Associate Professor Luke Downey, *Submission 324*, p. 2.

⁵⁸ Dr Shalini Arunogiri, Chair, Faculty of Addiction Psychiatry, RANZCP, *Official Committee Hansard*, Canberra, 8 September 2017, p. 16.

⁵⁹ RANZCP, *Submission 294*, p. 1.

⁶⁰ RANZCP, *Submission 294*, p. 4.

⁶¹ Vapers is the commonly used term for E-cigarette users.

‘nicotine is important for me to function, to be happy, to enjoy life and trying to reduce it and stop it is about as important to me as trying to reduce and stop caffeine ... it is not important at all to me.’⁶²

- 3.39 The NNAA stated that quit smoking rates are stalling as remaining smokers are ‘a hard core of smokers that either gain so much benefit and enjoyment out of smoking or else are so deeply addicted that we do need this disruptive technology.’⁶³ The NNAA described E-cigarettes as a plausible tobacco substitute for smokers because it replicated the sensation of smoking. The NNAA explained:

Almost all smokers have given up for long enough in the past for the hold of addiction to be broken, but most smokers get tempted back to smoking time and time again. Why? Because we enjoyed it. We gained pleasure from it. Vaping works because it recognises and acknowledges that people gain pleasure from smoking, and replaces it with something not only far safer, but more pleasurable.⁶⁴

- 3.40 Associate Professor Mendelsohn observed that substituting E-cigarettes for smoking has been found to have significant short term health benefits, including improved lung function, reduced asthma symptoms, reduced blood pressure and improved cardiovascular health.⁶⁵ Associate Professor Mendelsohn added that ‘it is common sense to me that that would lead onto long term benefits but, of course, we do not have that data.’⁶⁶
- 3.41 The 2018 NAS Review found that there was *conclusive evidence*⁶⁷ that the complete substitution of tobacco cigarettes with E-cigarettes reduced users’ exposure to toxicants and carcinogens. In addition, the 2018 NAS Review

⁶² Dr Attila Danko, NNAA, *Official Committee Hansard*, Sydney, 12 July 2017, pp 6-7.

⁶³ NNAA, *Submission 222*, p. 3.

⁶⁴ NNAA, *Submission 222*, pp 3-4.

⁶⁵ Associate Professor Colin Mendelsohn, Private Capacity, *Official Committee Hansard*, Sydney, 12 July 2017, pp 10-11.

⁶⁶ Associate Professor Colin Mendelsohn, *Official Committee Hansard*, Sydney, 12 July 2017, p. 11.

⁶⁷ The 2018 NAS Review defines conclusive evidence as: ‘many supportive findings from good-quality controlled studies (including randomised and non-randomised controlled trials) with no credible opposing findings. A firm conclusion can be made, and the limitations to the evidence, including change, bias, and confounding factors, can be ruled out with reasonable confidence.’ *Exhibit 24a: Public Health Consequences of E-cigarettes: Conclusions by Level of Evidence*, p. 2.

found that there was *substantial evidence*⁶⁸ that this reduced short term negative health impacts for several of the body's organ systems.⁶⁹

- 3.42 Associate Professor Gartner and Professor Hall stated that, for smokers who have difficulty quitting, moving to a less harmful source of nicotine may be much easier than quitting entirely. Associate Professor Gartner and Professor Hall added that E-cigarettes may also:

... assist some smokers to become smoke-free who would never quit smoking in the absence of an acceptable substitute. It is arguably unethical and unjust to deny smokers who have great difficulty ending their nicotine addiction from using less harmful alternatives while we continue to allow them ready access to the most harmful nicotine products (combustible tobacco cigarettes).⁷⁰

- 3.43 Emeritus Professor Webster stated that for smokers who have been unable to quit using other available methods there was a case for the use of E-cigarettes as a nicotine substitute 'deployed as part of a wider support program to help the patient cease smoking.' Professor Webster added that:

... nicotine substitution has been accepted internationally, over many years, as an appropriate addition to the therapeutic repertoire for dependent smokers to cease smoking. [E-cigarettes with] nicotine solution at low dose levels [are] a biologically plausible and reasonable extension of this approach.⁷¹

Dual Smoking and Vaping

- 3.44 Some smokers may begin using E-cigarettes while continuing to smoke cigarettes; this is referred to as 'dual using'. The NHMRC stated that '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.'⁷²

⁶⁸ The 2018 NAS Review defines substantial evidence as: 'several supportive findings from good-quality observational studies or controlled trials with few or no credible opposing findings. A firm conclusion can be made, but minor limitations, including chance, bias, and confounding factors, cannot be ruled out with reasonable confidence.' *Exhibit 24a: Public Health Consequences of E-cigarettes: Conclusions by Level of Evidence*, p. 2.

⁶⁹ Stratton, K., Kwan, L.Y., Eaton D.L., *Exhibit 24: Public Health Consequences of E-cigarettes*, National Academy of Sciences, p. S-7 – S-8.

⁷⁰ Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 282*, p. 10.

⁷¹ Emeritus Professor Ian Webster, *Submission 65*, p. 3.

⁷² National Health and Medical Research Council, *Submission 167*, p. 2.

- 3.45 The Department of Health stated that while dual use of tobacco and E-cigarettes may:
- ... reduce daily consumption of cigarettes, available evidence suggests that the health benefits of this reduced consumption may be minimal at best. Several large cohort studies have shown little evidence of reduced mortality in smokers who reduce cigarette consumption, and no association between smoking reduction and a decline in all-cancer risk.⁷³
- 3.46 Associate Professor Mendelsohn suggested that when smokers reduce their cigarette consumption without E-cigarettes they ‘unconsciously smoke more intensely to maintain their nicotine levels’, thus undermining potential health benefits. In contrast, dual users, who receive nicotine from E-cigarettes, do not smoke more intensely and can experience health benefits when reducing cigarette consumption, including improvements in chronic obstructive pulmonary disease symptoms, blood pressure, asthma and lung function.⁷⁴
- 3.47 In contrast, Emeritus Professor Chapman cautioned that using E-cigarettes to reduce consumption of tobacco cigarettes without completely quitting was unlikely to result in health benefits. Emeritus Professor Chapman drew attention to a Norwegian study that followed 51 210 people for over 20 years and found that smokers who reduced their cigarette consumption by more than 50 per cent did not reduce their risk of premature death.⁷⁵
- 3.48 The Queensland Department of Health advised that two thirds of adults in Queensland who were using E-cigarettes were also smoking tobacco cigarettes. Dual use was most common among people aged between 30 to 44 years.⁷⁶ The Queensland Department of Health was concerned that dual use could result in smokers maintaining their tobacco smoking.⁷⁷
- 3.49 Emeritus Professor Chapman stated that in 2014 the proportion of E-cigarette users who continued smoking tobacco cigarettes was 93 per cent in the USA, 83 per cent in France, and 60 per cent in the United Kingdom of

⁷³ Department of Health, *Submission 297*, p. 4.

⁷⁴ Associate Professor Colin Mendelsohn, *Submission 258*, p. 9.

⁷⁵ Emeritus Professor Simon Chapman AO, Professor Mike Daube AO, David Bareham, and Associate Professor Matthew Peters, *Submission 313*, p. 31.

⁷⁶ Queensland Department of Health, *Submission 226*, p. 3.

⁷⁷ Queensland Department of Health, *Submission 226*, p. 8.

Great Britain (UK).⁷⁸ Emeritus Professor Chapman highlighted that the proportion of smokers in the UK who have tried to quit smoking had dropped from 42.5 per cent in 2007 to 30.9 per cent in 2016 and suggested that dual users may find it more difficult to quit ‘as they do not actually view themselves as smokers’.⁷⁹

- 3.50 The Australian Drug Law Reform Foundation stated that in many cases smokers would continue smoking while using E-cigarettes during a transitional period before entirely quitting smoking. This transitional period could take ‘weeks or years’.⁸⁰ Associate Professor Mendelsohn agreed that ‘dual use is a normal part of quitting’ and that the rate of dual use of E-cigarettes and tobacco was similar to that of NRT and tobacco.⁸¹
- 3.51 Associate Professor Gartner and Professor Hall drew attention to the limitations of cross-sectional surveys of dual use of smoking and vaping as these studies cannot discern the reason people are dual using. Associate Professor Gartner and Professor Hall commented that longitudinal studies have found that dual users do not make fewer quit attempts than other smokers and that the proportion of dual users who quit smoking increases over time.⁸²
- 3.52 The 2018 NAS Review stated that on average dual users do not smoke fewer cigarettes than other smokers but it is possible that if a smoker reduces their cigarette intake then dual use may help them maintain this reduction.⁸³ The 2018 NAS Review added that there is no available evidence on whether dual users have different mortality or morbidity rates than other smokers.⁸⁴

⁷⁸ Emeritus Professor Simon Chapman AO, Professor Mike Daube AO, David Bareham, and Associate Professor Matthew Peters, *Submission 313*, p. 13.

⁷⁹ Emeritus Professor Simon Chapman AO, Professor Mike Daube AO, David Bareham, and Associate Professor Matthew Peters, *Submission 313*, pp 15, 17.

⁸⁰ Australian Drug Law Reform Foundation, *Submission 317*, p. 12.

⁸¹ Associate Professor Colin Mendelsohn, *Submission 258*, p. 9.

⁸² Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 282*, pp 6-7.

⁸³ Stratton, K., Kwan, L.Y., Eaton D.L., *Exhibit 24: Public Health Consequences of E-cigarettes*, National Academy of Sciences, p. 18-25.

⁸⁴ Stratton, K., Kwan, L.Y., Eaton D.L., *Exhibit 24: Public Health Consequences of E-cigarettes*, National Academy of Sciences, p. 18-25.

Potential 'Gateway' to Smoking

- 3.53 An issue of significant debate among inquiry participants was whether there was a 'gateway effect' where young people initially experiment with E-cigarettes which then increases their likelihood of also trying traditional cigarettes. The Department of Health identified the potential gateway effect as an issue of concern and stated:

... E-cigarettes may provide a gateway to nicotine addiction or tobacco use (particularly among youth), and may renormalise smoking. Rather than encouraging smokers to quit smoking, E-cigarettes may expand the nicotine market by attracting new smokers (particularly youth) who may otherwise be unlikely to initiate smoking with conventional cigarettes.⁸⁵

- 3.54 Tobacco control policies have, over many years, sought to stop tobacco smoking being a normal, mainstream activity (for example through restricting where people can smoke). Some participants were concerned that widespread E-cigarette use could 'renormalise' smoking. For example, the Queensland Department of Health stated that 'electronic cigarettes have the potential to renormalise smoking in smoke-free environments and reverse important gains achieved in smoking reduction'.⁸⁶ Quit Victoria agreed and stated that 'E-cigarette use has the potential to re-glamorise and renormalise smoking, particularly where use occurs around children and young people.'⁸⁷

- 3.55 The National Heart Foundation of Australia (NHFA) stated that:

... it is fair to say that there is growing evidence of the gateway effect. That is of real concern to us — the number of papers being published that show an increased risk for young people if they try E-cigarettes. There is a greater risk of them then becoming smokers of traditional cigarettes.⁸⁸

- 3.56 The Queensland Department of Health advised that a randomly sampled survey of Queensland adults had found that nine per cent of E-cigarette users (representing approximately 10 000 people) reported never having smoked tobacco cigarettes. The Queensland Department of Health stated

⁸⁵ Department of Health, *Submission 297*, p. 1.

⁸⁶ Queensland Department of Health, *Submission 226*, p. 8.

⁸⁷ Quit Victoria, *Submission 328*, p. 2.

⁸⁸ Mr Maurice Gerard Swanson, National Heart Foundation of Australia (WA Division), *Official Committee Hansard*, Canberra, 8 September 2017, p. 11.

that ‘these statistics are particularly concerning, as these are the new users of devices that have the potential to be a gateway to tobacco smoking.’⁸⁹

- 3.57 Associate Professor Gartner agreed that ‘there does seem to be ... an association between experimenting with E-cigarettes amongst young people and then experimenting with tobacco cigarettes’ but suggested that many of the young people who transitioned from E-cigarettes to smoking may have tried smoking even if E-cigarettes were not available.⁹⁰ Associate Professor Mendelsohn summarised this point by saying ‘kids who try stuff try other stuff, so kids who are more rebellious, risk-taking, who have that sort of personality will try E-cigarettes and they will also smoke.’⁹¹
- 3.58 Several participants highlighted a review of longitudinal studies looking at the association between E-cigarette use and smoking by adolescents and young adults.⁹² The review found that even after adjusting for ‘demographical, psychosocial, and behavioural risk factors for cigarette smoking’, E-cigarette users were three times more likely to start smoking.⁹³
- 3.59 Associate Professor Gartner commented that some of the studies that had shown the existence of a gateway effect were conducted in locations where there were no age restrictions on the sale of E-cigarettes and this may not be the case if there were restrictions on the availability of E-cigarettes for young people.⁹⁴
- 3.60 Emeritus Professor Chapman stated that, due to their flavourings, a lack of harshness on the throat, and the ability to be used inconspicuously, E-cigarettes have more appeal to youth than smoking. Emeritus Professor Chapman also stated that after initial experimentation with E-cigarettes young people could move on to tobacco smoking, stating that:

... just as a large proportion of adults who experiment with [E-cigarettes] do not continue using them, finding them unsatisfying so too it is likely that some

⁸⁹ Queensland Department of Health, *Submission 226*, p. 4.

⁹⁰ Associate Professor Coral Gartner, Private Capacity, *Official Committee Hansard*, Canberra, 8 September 2017, p. 19.

⁹¹ Associate Professor Colin Mendelsohn, *Official Committee Hansard*, Sydney, 12 July 2017, p. 14.

⁹² TSANZ and LFA, *Submission 332*, p. 7; Professor Martin McKee, *Submission 291*, p. 3.

⁹³ Emeritus Professor Simon Chapman AO, Professor Mike Daube AO, David Bareham, and Associate Professor Matthew Peters, *Submission 313*, p. 50.

⁹⁴ Associate Professor Coral Gartner, *Official Committee Hansard*, Canberra, 8 September 2017, pp 19-20.

young people may move on to cigarettes with [E-cigarettes] abandoned as training wheels.⁹⁵

- 3.61 Dr Konstantinos Farsalinos stated regular E-cigarette use ‘is extremely rare among never-smoking adolescents’ and suggested that E-cigarettes could be preventing adolescents who had a propensity to take up smoking from initiating smoking.⁹⁶ Dr Farsalinos added that the increase in the number of adolescents who had used E-cigarettes at least once ‘has coincided with the sharpest declines in youth smoking rates for many decades.’⁹⁷
- 3.62 The All-Party Parliamentary Group for E-cigarettes in the UK Parliament (All-Party Group) suggested that, as E-cigarettes were less damaging than smoking, unless many more people were drawn into smoking than helped out of smoking by E-cigarettes there would be a net public health benefit.⁹⁸ The All-Party Group added that ‘the gateway in [to smoking] is much, much smaller than the motorway out [of smoking].’⁹⁹
- 3.63 The Royal College of Physicians of London (RCPL), in its report *Nicotine without Smoke*, 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.’¹⁰⁰
- 3.64 In contrast, the 2018 NAS Review stated that there was *substantial evidence* of an association between E-cigarette use and young people trying tobacco cigarettes.¹⁰¹ The 2018 NAS Review highlighted many methodological challenges that make analysis of the gateway effect difficult. Nevertheless, the 2018 NAS Review stated that the ‘overwhelming consistency of results’ across different studies gave it confidence in the ‘robustness, validity, and

⁹⁵ Emeritus Professor Simon Chapman AO, Professor Mike Daube AO, David Bareham, and Associate Professor Matthew Peters, *Submission 313*, p. 51.

⁹⁶ Dr Konstantinos Farsalinos, *Submission 303*, p. 9.

⁹⁷ Dr Konstantinos Farsalinos, *Submission 303*, p. 10.

⁹⁸ Viscount Matthew Ridley, Secretary, All-Party Parliamentary Group for E-cigarettes, *Official Committee Hansard*, Canberra, 18 October 2017, p. 3.

⁹⁹ Viscount Ridley, All-Party Parliamentary Group for E-cigarettes, *Official Committee Hansard*, Canberra, 18 October 2017, p. 3.

¹⁰⁰ Royal College of Physicians of London, *Submission 280*, p. 2.

¹⁰¹ Stratton, K., Kwan, L.Y., Eaton D.L., *Exhibit 24: Public Health Consequences of E-cigarettes*, National Academy of Sciences, p. 16-30.

causality of the association of E-cigarette use' and trying tobacco cigarettes.¹⁰²

3.65 The 2018 NAS Review added that among youth and young adult E-cigarette users who ever use tobacco cigarettes, there is:

- 'Moderate evidence that E-cigarette use increases the frequency and intensity of subsequent combustible tobacco cigarette smoking'; and
- 'limited evidence that E-cigarette use increases, in the near term, the duration of subsequent combustible tobacco cigarette smoking.'¹⁰³

E-cigarette and Smoking Prevalence Rates

3.66 Associate Professor Mendelsohn stated that smoking rates among under 18 year olds in the UK and USA have declined more rapidly since E-cigarettes became available. For example, in the USA since 2010, smoking rates for Year 12 students have declined three times faster than previously.¹⁰⁴

3.67 The 2018 NAS Review, however, stated that although youth smoking rates in the USA had continued to fall since the emergence of E-cigarettes, an analysis of 'trends going back a decade found that the rate of reduction of smoking in [USA] youth has remained consistent and has not accelerated in recent years when E-cigarettes have become popular.'¹⁰⁵

3.68 Public Health England stated that in 2016, 2.6 per cent of youth in the UK were using E-cigarettes at least monthly, with a further 9.3 per cent who had experimented with E-cigarettes.¹⁰⁶ E-cigarette use was most common among youth who also smoked, but rare among non-smokers with 0.4 per cent of the youth population who had never smoked using E-cigarettes at least monthly.¹⁰⁷

¹⁰² Stratton, K., Kwan, L.Y., Eaton D.L., *Exhibit 24: Public Health Consequences of E-cigarettes*, National Academy of Sciences, p. 16-31.

¹⁰³ Stratton, K., Kwan, L.Y., Eaton D.L., *Exhibit 24: Public Health Consequences of E-cigarettes*, National Academy of Sciences, p. 16-32.

¹⁰⁴ Associate Professor Colin Mendelsohn, *Official Committee Hansard*, Sydney, 12 July 2017, p. 14.

¹⁰⁵ Stratton, K., Kwan, L.Y., Eaton D.L., *Exhibit 24: Public Health Consequences of E-cigarettes*, National Academy of Sciences, p. 16-31.

¹⁰⁶ Public Health England, *Submission 336.1*, p. 14.

¹⁰⁷ Public Health England, *Submission 336.1*, p. 15; Mr Martin Dockrell, Tobacco Control Lead, Public Health England, *Official Committee Hansard*, Canberra 18 October 2017, p. 7.

- 3.69 The United Kingdom Vaping Industry Association (UKVIA) stated that E-cigarette use in the UK was growing, but that the rate of growth was decreasing. The UKVIA stated that the number of E-cigarette users increased by 86 per cent in 2013, 62 per cent in 2014, 24 per cent in 2015, and four per cent in 2016.¹⁰⁸
- 3.70 The RCPL linked the increasing use of E-cigarettes with declining rates of smoking in the UK, stating that E-cigarette use was ‘the major driver of the substantial fall in UK smoking prevalence over the past five years from 20.2 per cent in 2011 to 15.8 per cent in 2016’.¹⁰⁹
- 3.71 Counterfactual Consulting highlighted that in the UK in 2016, the number of vapers who were ex-smokers (1.5 million) exceeded the number of vapers who were current smokers (1.1 million) for the first time. In the USA in 2015, there were 8.3 million vapers, 2.5 million of whom were ex-smokers.¹¹⁰
- 3.72 Professor Sinclair Davidson highlighted a 2017 simulation study using USA data, which found that E-cigarettes resulted in a 21 per cent reduction in smoking related deaths and a 20 per cent reduction in life years lost. The study concluded that even if some non-smokers become smokers because of E-cigarette use, ‘these public health effects are more than compensated by current smokers smoking less or quitting.’¹¹¹
- 3.73 Cancer Research UK stated that despite the availability of E-cigarettes in the UK there has been ‘no increase in youth smoking of tobacco, which is another important measure in terms of establishing the gateway effect.’¹¹²

Health Considerations: E-cigarettes

E-cigarette Safety

- 3.74 Many public health agencies suggested that there is not enough evidence on the health impacts of E-cigarettes to be able to determine the safety of E-cigarette use. The Department of Health stated ‘there is currently

¹⁰⁸ Mr James Hargrave, Public Affairs Manager, UK Vaping Industry Association, *Official Committee Hansard*, Canberra, 25 October 2017, p. 4.

¹⁰⁹ Royal College of Physicians of London, *Submission 280*, p. 2.

¹¹⁰ Counterfactual Consulting, *Submission 271*, p. 4.

¹¹¹ Professor Sinclair Davidson, *Submission 164*, pp 10-11.

¹¹² Mr George Butterworth, Tobacco Policy Manager, Cancer Research UK, *Official Committee Hansard*, Canberra, 25 October 2017, p. 10.

insufficient evidence, either in Australia or internationally, to conclude whether E-cigarettes are effective in assisting people to quit smoking, or about the extent of their potential harms.’¹¹³

3.75 The NHMRC agreed and added that there:

... wasn’t enough evidence out there to actually be making definitive recommendations ... for or against electronic cigarettes ... what we are saying is that a precautionary approach must be taken, simply on the basis that there is not enough evidence to say whether they are safe or not.¹¹⁴

3.76 While there would be a risk in making E-cigarettes accessible before long term evidence of their health impacts is available, Associate Professor Mendelsohn cautioned that there is a counter risk in not allowing smokers to access a product that potentially could be beneficial, stating ‘there is a cost in waiting. People are dying every day from smoking and I think the evidence is strong enough to say we should give it a chance’.¹¹⁵

3.77 The 2018 NAS Review undertook modelling to estimate the population health impacts of E-cigarette usage. The modelling considered both the positive impact of assisting people to quit smoking and the negative impact of the increased likelihood of young people taking up smoking. The 2018 NAS Review found that in short-term projections the increased number of people quitting resulted in E-cigarettes delivering a net public benefit. Over the course of decades, however, young people who have taken up smoking begin to experience negative health impacts and this reduces the net public benefit. The 2018 NAS Review found that, under some scenarios, in the long term (for example 50 years into the future) the net public health impact of E-cigarettes becomes negative.¹¹⁶

Long-Term Studies

3.78 A limitation on the availability of evidence is that E-cigarettes are a relatively new product. Emeritus Professor Chapman highlighted that E-cigarettes have been in existence for a little over a decade and only in mass

¹¹³ Department of Health, *Submission 297*, p. 1.

¹¹⁴ Ms Samantha Robertson, Executive Director, National Health and Medical Research Council, *Official Committee Hansard*, Canberra, 8 September 2017, p. 6.

¹¹⁵ Associate Professor Colin Mendelsohn, *Official Committee Hansard*, Sydney, 12 July 2017, p. 7.

¹¹⁶ Stratton, K., Kwan, L.Y., Eaton D.L., *Exhibit 24: Public Health Consequences of E-cigarettes*, National Academy of Sciences, p. 19-16.

use for around five years and described it as ‘very, very early days’ for research into the health impacts of E-cigarettes.¹¹⁷

- 3.79 To illustrate, Emeritus Professor Chapman described the period following the first appearance of affordable cigarettes in the early twentieth century. At this time, smoking rates were rapidly increasing but for the ‘next 20 years, lung cancer remained an uncommon, even rare disease’ and it was not until the 1950s that definitive evidence was published linking smoking to lung cancer.¹¹⁸ Emeritus Professor Chapman added:

If any scientist had declared in 1920 that cigarette smoking was all but harmless, history would have judged their call as dangerously incorrect. But this is the reckless call that many [E-cigarette] advocates are making today, after just 10 years.¹¹⁹

- 3.80 The RACP stated that the long term effects of E-cigarettes are ‘currently unclear due to the limited number of studies undertaken in this area to date.’¹²⁰ The equivalent body in the UK, the RCPL agreed that the long term effects of E-cigarette use may not ‘become clear until the products had been in use for several decades.’ The RCPL added that E-cigarette use may increase the risk of smoking related diseases but that ‘the magnitude of such risks is likely to be substantially lower than those of smoking’.¹²¹
- 3.81 The TSANZ also commented on the possibility that E-cigarettes could have health impacts that are not currently apparent, stating ‘chronic respiratory conditions can take many years to become symptomatic. It is therefore important studies track health impacts over the long term, by which we mean greater than 10 years.’¹²²

¹¹⁷ Emeritus Professor Simon Chapman, Private Capacity, *Official Committee Hansard*, Canberra, 8 September 2017, p. 15.

¹¹⁸ Emeritus Professor Simon Chapman, *Official Committee Hansard*, Canberra, 8 September 2017, pp 24-25.

¹¹⁹ Emeritus Professor Simon Chapman AO, Professor Mike Daube AO, David Bareham, and Associate Professor Matthew Peters, *Submission 313*, pp 24-25.

¹²⁰ RACP, *Submission 276*, p. 3.

¹²¹ Royal College of Physicians of London, *Submission 280*, p. 3.

¹²² Professor Bruce Thompson, TSANZ, *Official Committee Hansard*, Melbourne, 5 October 2017, p. 1.

- 3.82 Some inquiry participants suggested that obtaining long term data will prove challenging because of developments in device technology and E-cigarette flavours available on the market.¹²³

Evaluating Product Safety

- 3.83 The TSANZ and Lung Foundation Australia (LFA) described the standard of evidence it considered necessary to test the safety of E-cigarettes, stating ‘until such time as long term randomised controlled studies are conducted with a homogenous product class, it is not possible to determine the safety and efficacy of E-cigarettes and personal vaporisers.’¹²⁴
- 3.84 Associate Professor Gartner and Professor Hall agreed that RCTs were suitable for testing the effectiveness of E-cigarettes as a smoking cessation aid. Associate Professor Gartner and Professor Hall also suggested that using E-cigarettes as a tobacco substitute as part of a harm reduction strategy could not be tested using RCTs. Associate Professor Gartner and Professor Hall stated that ‘there are many factors that may make vaping a successful harm reduction strategy that do not transfer effectively into a clinical trial setting’.¹²⁵
- 3.85 Associate Professor Mendelsohn also questioned whether RCTs were an appropriate standard to assess E-cigarette safety. Associate Professor Mendelsohn explained new users experiment with different brands and strengths of E-cigarettes and stated ‘you cannot test that in a standard, randomised, controlled trial but in the real world we know there are millions of people using them to quit. I think we have to look to a different standard of evidence.’¹²⁶

¹²³ Dr Sandra Costigan, Principal Toxicologist Vaping Products, British American Tobacco, *Official Committee Hansard*, Sydney, 12 July 2017, pp 8-9; Australian Drug Law Reform Foundation, *Submission 317*, p. 3.

¹²⁴ TSANZ and LFA, *Submission 332*, p. 12.

¹²⁵ Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 282.1*, p. 4.

¹²⁶ Associate Professor Colin Mendelsohn, *Official Committee Hansard*, Sydney, 12 July 2017, p. 3.

Research in Progress

- 3.86 The NHMRC advised that since 2011, it had committed nearly \$6.5 million in funding for research projects involving E-cigarettes. The eight projects currently being funded by the NHMRC are looking into:
- Using nicotine as a long-term tobacco substitute in comparison to using it as a short term smoking cessation aid (funded from 2011 to 2018).
 - Public health interventions, including less harmful nicotine products, to reduce tobacco related harm among socially disadvantaged populations and low probability quitters (2014 to 2018).
 - Using new media to translate prevention research findings in the areas of tobacco control and obesity into policy and practice (2015 to 2019).¹²⁷
 - A RCT focussed on 'enhancing pharmacological and behavioural support to reduce smoking relapse' (2015 to 2020).
 - Understanding the impacts of E-cigarettes on smoking in Australia (2016 to 2021).
 - Using E-cigarettes to help people with schizophrenia reduce their tobacco smoking (2016 to 2020).
 - A randomised trial which will assess the effectiveness of adding E-cigarettes to standard behavioural treatments for low-socioeconomic status smokers (2017 to 2021).
 - The health effects of E-cigarettes (2017 to 2019).¹²⁸

Relative Health Risk

- 3.87 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.'¹²⁹
- 3.88 The statement that E-cigarettes are 95 per cent less harmful than tobacco cigarettes has been quoted widely,¹³⁰ including by many inquiry

¹²⁷ Research Data Australia, 'Harnessing New Media to Translate Prevention Research Evidence in to Practice and Policy', <https://researchdata.ands.org.au/harnessing-new-media-practice-policy/519253>, Accessed 22 November 2017.

¹²⁸ National Health and Medical Research Council, *Submission 167*, pp 10-12.

¹²⁹ Public Health England, *Exhibit 1: E-cigarettes: An Evidence Update*, 2015, p. 5.

¹³⁰ Government of Western Australia, *Submission 292*, p. 4.

participants.¹³¹ This figure appears to be drawn from a 2014 article by Nutt et al. in the journal *European Addiction Research*. The Nutt study assessed 12 nicotine containing products against 14 weighted criteria, each representing a type of harm potentially caused by nicotine, to develop an overall relative harm for each product. E-cigarettes were assessed as having four per cent of the relative harm of tobacco cigarettes.¹³²

- 3.89 The Nutt assessment was undertaken by an expert panel comprised of academics, public health representatives, and a consultant.¹³³ Nutt et al. stated that the limitations of the study included that it did not include ‘formal criterion for the recruitment of the experts’ and that there was a ‘lack of hard evidence for the harms of most products on most of the criteria.’¹³⁴
- 3.90 The 95 per cent safer than tobacco cigarettes-statistic relating to E-cigarettes was criticised by a number of inquiry participants.¹³⁵ The Cancer Council Australia (CCA) and the NHFA stated that the figure was ‘unfounded and devoid of any scientific basis’.¹³⁶

¹³¹ Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 282.1*, p. 8; Associate Professor Colin Mendelsohn, *Submission 258*, p. 3; Dr Konstantinos Farsalinos, *Submission 303*, p. 2; Australian Vaping Advocacy, Trade and Research (AVATAR), *Submission 274*, p. 3; NNAA, *Submission 222*, p. 2; Professor Ricardo Polosa, *Submission 288*, p. 3; Counterfactual Consulting, *Submission 271*, p. 2; Australasian Association of Convenience Stores, *Submission 93*, p. 3; Professor Sinclair Davidson, *Submission 164*, p. 11; Australian Taxpayers’ Alliance and MyChoice, *Submission 302*, p. 6; Dr Catherine Silsbury, *Submission 159*, p. 3; Australian Drug Law Reform Foundation, *Submission 317*, p. 4; Mr Stuart Singleton, *Submission 316*, p. 7; Australian Retailers Association, *Submission 290*, p. 4.

¹³² Nutt, D.J., Phillips, L.D., Balfour, D., Curren, H.V., Dockrell, M., Foulds, J., Fagerstrom, K., Letlape, K., Milton, A., Polosa, R., Ramsey, J., Sweanor, D., ‘*Exhibit 2: Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach*’, *European Addiction Research*, 2014, 20:218-225.

¹³³ The expert panel was convened by the International Scientific Committee on Drugs, a body created in 2010 by Professor David Nutt as an ‘independent science-led drugs charity’. The expert panel was comprised of 12 representatives from the United Kingdom, Canada, the United States of America, Sweden, South Africa, and Italy. Sources: International Scientific Panel of Drugs, ‘About’, www.drugscience.org.uk/about, Accessed 14 November 2017; Nutt et al., ‘*Exhibit 2: Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach*’, *European Addiction Research*, 2014, 20:218-225.

¹³⁴ Nutt et al., *Exhibit 2: ‘Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach*, *European Addiction Research*, 2014, p. 224.

¹³⁵ Department of Health, *Submission 297*, p. 5; Western Australian Government, *Submission 292*, p. 4; National Health and Medical Research Council, *Submission 167*, p. 3.

¹³⁶ Cancer Council Australia and National Heart Foundation of Australia, *Submission 295*, p. 4.

- 3.91 Professor Martin McKee raised concerns about the lack of evidence used and the background of the expert panellists in the Nutt et al. study and stated:

... while there is acceptance that electronic cigarettes are likely to be somewhat safer than real ones by virtue of not producing tar, within Europe this 95 per cent figure has little credence beyond England.¹³⁷

- 3.92 In addition, Emeritus Professor Chapman stated that 'several of the [expert panel] had no research track record or expertise in tobacco control and some had histories of financial connections with manufacturers of [E-cigarettes] and tobacco companies'.¹³⁸

- 3.93 In contrast, Public Health England stated that claims that the authors of the Nutt et al. study or members of Public Health England were paid by tobacco companies are false and a number of media outlets had retracted or corrected claims linking the authors with tobacco companies.¹³⁹

- 3.94 Mr Steve Woodward suggested that the important point was that there were less health risks associated with E-cigarette use than with smoking; regardless of the exact degree to which E-cigarettes were safer than cigarettes. Mr Steve Woodward stated:

The contentious point appears to be by how much is E-cigarette vapour less toxic than conventional tobacco smoke – 10 per cent less, 50 per cent less, or 95 per cent less? [In any case], if fewer toxins are inhaled, less disease and premature death will result.'¹⁴⁰

- 3.95 Cancer Research UK agreed that it was 'important not to get too caught up in the 95 per cent figure' and suggested that, regardless of the exact figure, there is a series of studies that have found that vaping is 'significantly safer' than smoking.¹⁴¹

- 3.96 The TSANZ questioned whether it was appropriate to use cigarettes, which ultimately kill many smokers, as a benchmark for assessing the health impacts of E-cigarettes.¹⁴² The TSANZ added that even if not fatal, many

¹³⁷ Professor Martin McKee, *Submission 291*, p. 4.

¹³⁸ Emeritus Professor Simon Chapman AO, Professor Mike Daube AO, David Bareham, and Associate Professor Matthew Peters, *Submission 313*, p. 25.

¹³⁹ Public Health England, *Submission 336*, p. 3.

¹⁴⁰ Mr Steve Woodward, *Submission 296*, p. 11.

¹⁴¹ Mr George Butterworth, Cancer Research UK, *Official Committee Hansard*, Canberra, 25 October 2017, p. 8.

¹⁴² Professor Bruce Thompson, TSANZ, *Official Committee Hansard*, Melbourne, 5 October 2017, p. 3.

respiratory conditions ‘really disable people’ and these effects should also be considered when assessing the impacts of E-cigarettes.¹⁴³

Health Impacts of E-liquids

Nicotine

- 3.97 Dr Konstantinos Farsalinos was of the view that nicotine ‘is not classified as a carcinogen, does not cause lung disease’ and highlighted that nicotine has been approved for long term use in NRT.¹⁴⁴ Associate Professor Mendelsohn stated that the ‘long term adverse effects of nicotine are likely to be minimal except in pregnancy’ and that there ‘is no evidence that nicotine causes cancer in humans’.¹⁴⁵
- 3.98 Conversely, the Department of Health stated that nicotine is highly addictive and that it is ‘highly toxic and poses significant health risks including adverse cardiovascular, respiratory, and reproductive effects’.¹⁴⁶ The Department of Health also advised that nicotine is scheduled as a poison under the Poisons Standard.¹⁴⁷ The Department of Health added that evidence suggests that ‘nicotine is associated with DNA damage and other pathways of carcinogenesis.’¹⁴⁸
- 3.99 The 2018 NAS Review stated that while it was ‘biologically plausible’ that nicotine could promote tumours there was no evidence that nicotine was a carcinogen and that therefore ‘nicotine exposure from E-cigarette use will likely pose minimal cancer risk to users’.¹⁴⁹ The 2018 NAS Review added, however, that nicotine increased cardiovascular risks for people with pre-existing cardiovascular disease.¹⁵⁰

¹⁴³ Professor Anne Holland, Board Director, Clinical Care and Resource, TSANZ, *Official Committee Hansard*, Melbourne, 5 October 2017, p. 3.

¹⁴⁴ Dr Konstantinos Farsalinos, *Submission 303*, p. 5.

¹⁴⁵ Associate Professor Colin Mendelsohn, *Submission 258*, p. 14.

¹⁴⁶ Department of Health, *Submission 297*, p. 5.

¹⁴⁷ Department of Health, *Submission 297: Attachment A*, p. 2.

¹⁴⁸ Department of Health, *Submission 297*, p. 5.

¹⁴⁹ Stratton, K., Kwan, L.Y., Eaton D.L., *Exhibit 24: Public Health Consequences of E-cigarettes*, National Academy of Sciences, p. 4-43.

¹⁵⁰ Stratton, K., Kwan, L.Y., Eaton D.L., *Exhibit 24: Public Health Consequences of E-cigarettes*, National Academy of Sciences, p. 4-43.

- 3.100 The Centre for Adolescent Health (CAH) at the Royal Children's Hospital highlighted the health risks to adolescents from nicotine exposure. The CAH stated that adolescents may become addicted to nicotine more rapidly than adults and that nicotine exposure during adolescence 'may have a long-term negative impact on higher cognitive function.'¹⁵¹ The CAH also drew attention to the potential maternal and fetal health risks from nicotine use during pregnancy, including contributing to 'preterm delivery, still birth, neonatal apnoea, and sudden infant death syndrome'.¹⁵²
- 3.101 The CCA and NHFA stated that nicotine can contribute to the 'onset and growth of various forms of cancer' and compromise the effectiveness of cancer treatment.¹⁵³ In addition, the CCA and NHFA stated that inhaling vaporised nicotine can contribute to the following conditions:
- Acute myocardial ischemia which can contribute to Coronary Vascular Disease;
 - Respiratory disorders through effects on the lungs and central nervous system;
 - Risk of kidney disease due to loss of renoprotective mechanism; and
 - Immunosuppression including delayed wound healing and increased infection.¹⁵⁴

Flavourings and Other Chemicals

- 3.102 The liquid used to create the vapour in E-cigarettes contains chemicals which are used to flavour the vapour. The Department of Health advised that in addition to flavouring chemicals, E-cigarette vapour can include: formaldehyde, heavy metals, and particulate matter at 'levels that have the potential to cause adverse health effects.'¹⁵⁵ The Department of Health stated that E-cigarette vapour contained known carcinogens and the health impacts of exposure to E-cigarette vapour are not well understood.¹⁵⁶
- 3.103 The TSANZ and LFA commented that although some of the flavouring used in E-liquids may be approved for oral ingestion they are not approved for

¹⁵¹ Centre for Adolescent Health, *Submission 256*, p. 5.

¹⁵² Centre for Adolescent Health, *Submission 256*, p. 5.

¹⁵³ Cancer Council Australia and National Heart Foundation of Australia, *Submission 295*, p. 5.

¹⁵⁴ Cancer Council Australia and National Heart Foundation of Australia, *Submission 295*, p. 5.

¹⁵⁵ Department of Health, *Submission 297*, p. 5.

¹⁵⁶ Department of Health, *Submission 297*, p. 5.

inhalation. The TSANZ and LFA added that as the E-liquid is heated to form the vapour:

... the superheated environment alters [the flavourings into] toxins, and higher levels of toxins equal to or greater than those seen in cigarette smoking can be produced. In particular, the carcinogen formaldehyde and other aldehyde may be created in these superheated aerosols.¹⁵⁷

- 3.104 Cancer Research UK referred to a study released in February 2017 by researchers at the University College London which tracked vapers, smokers, and dual-users over a period of 18 months. The study found that vapers had levels of toxicants in their urine and saliva ‘similar to those in [users of] conventional nicotine replacement therapies’ and much lower than the levels of smokers and dual users.¹⁵⁸
- 3.105 In contrast, the CCA and NHFA highlighted a report stating that some carcinogens and other toxins present in tobacco smoke had also been detected in E-cigarette vapour, ‘which raises the possibility that long-term use might increase the risk of lung cancer, cardiovascular, [chronic obstructive pulmonary disease (COPD)] and other smoking related diseases.’¹⁵⁹
- 3.106 Associate Professor Mendelsohn stated that while potentially harmful chemicals do exist in E-cigarette vapour, research had found that they were at levels nine to 450 times lower than in cigarette smoke.¹⁶⁰ The RCPL made the similar point that while long term E-cigarette use may increase the risk of lung cancer, COPD, and cardiovascular diseases the ‘magnitude of such risks is likely to be substantially lower than those of smoking, and extremely low in absolute terms.’ The RCPL added that these risks were ‘amenable to reduction through product technological and purity improvements.’¹⁶¹
- 3.107 The 2018 NAS Review stated that there was *conclusive evidence* that E-cigarettes emit numerous potentially toxic substances and that the quantity and characteristics of these substances was highly variable between

¹⁵⁷ TSANZ and LFA, *Submission* 332, p. 9.

¹⁵⁸ Mr George Butterworth, Cancer Research UK, *Official Committee Hansard*, Canberra, 25 October 2017, p. 8.

¹⁵⁹ Cancer Council Australia and National Heart Foundation of Australia, *Submission* 295, p. 5.

¹⁶⁰ Associate Professor Colin Mendelsohn, *Submission* 258, p. 13.

¹⁶¹ Royal College of Physicians of London, *Submission* 280, p. 3.

different E-cigarette products.¹⁶² These toxic substances included: ‘formaldehyde, acetaldehyde, and acrolein, which are known cancer-producing toxicants’.¹⁶³ Despite this, the 2018 NAS Review stated that there was *substantial evidence* that E-cigarettes exposed users to significantly lower levels of potentially toxic substances than tobacco cigarettes.¹⁶⁴

- 3.108 In addition, the 2018 NAS Review also stated that there was *substantial evidence* that E-cigarette vapour contained metals and that there was *limited evidence* that (with the exception of cadmium) the quantity of these metals were higher in E-cigarette vapour than in tobacco smoke. The 2018 NAS Review stated that these metals may come from the metal coil used to heat the E-liquid. The 2018 NAS Review added, however, that there were no studies undertaken of the metals in E-cigarette vapour using the most recent third generation of E-cigarette devices.¹⁶⁵
- 3.109 The 2018 NAS Review stated that the presence of compounds such as formaldehyde and acrolein supported the biological plausibility that long-term E-cigarette use could increase the risk of cancer. Nevertheless the sparseness of evidence precluded the 2018 NAS Review from ‘making any evidence-based conclusions about the potential association between E-cigarette use and the risk of cancer in human populations’.¹⁶⁶
- 3.110 A recently published study followed nine young adult E-cigarette users, who had never smoked tobacco cigarettes, for a period of 3.5 years. The study examined whether there were any negative health impacts associated with E-cigarette use among this group, when compared to a control group of non-users. The study did not find ‘any health concerns’ related to E-cigarettes over the 3.5 year period, and concluded that:

¹⁶² Stratton, K., Kwan, L.Y., Eaton D.L., *Exhibit 24: Public Health Consequences of E-cigarettes*, National Academy of Sciences, p. 5-32.

¹⁶³ Stratton, K., Kwan, L.Y., Eaton D.L., *Exhibit 24: Public Health Consequences of E-cigarettes*, National Academy of Sciences, p. 5-31.

¹⁶⁴ Stratton, K., Kwan, L.Y., Eaton D.L., *Exhibit 24: Public Health Consequences of E-cigarettes*, National Academy of Sciences, p. 5-32.

¹⁶⁵ Stratton, K., Kwan, L.Y., Eaton D.L., *Exhibit 24: Public Health Consequences of E-cigarettes*, National Academy of Sciences, pp 5-36 – 5-37.

¹⁶⁶ Stratton, K., Kwan, L.Y., Eaton D.L., *Exhibit 24: Public Health Consequences of E-cigarettes*, National Academy of Sciences, p. 10-18.

While the sample size was small, the results of this study may provide some preliminary evidence that long-term use of [E-cigarettes] is unlikely to raise significant health concerns in relatively young users.¹⁶⁷

- 3.111 The study cautioned, however, that ‘it cannot be excluded that some harm may occur at later stages.’¹⁶⁸

Lung Health

- 3.112 The TSANZ and LFA advised that following E-cigarette use, as much as half of the thin surface fluid lining in the lungs is made up of deposits derived from vaping.¹⁶⁹ Emeritus Professor Chapman commented that the changes to the composition of the lung lining could alter the ability of the lung to absorb asthma medication, or increase the risk from cigarette smoke particles for people who both smoke and vape.¹⁷⁰
- 3.113 Emeritus Professor Chapman commented that recent research was suggesting that ‘E-cigarettes are almost certainly going to have far less carcinogenic risk than cigarettes but they may well have significant cardiovascular and respiratory risk’.¹⁷¹ The TSANZ and LFA added that the ‘early data’ from investigations into the effects of E-cigarettes on immune cells in the lungs found that E-cigarette use was making these cells less able to detect pathogenic bacteria and contributing to ‘supressed immune cell function and immune response, potentially contributing to chronic lung inflammation’.¹⁷²
- 3.114 The TSANZ and LFA also drew attention to the results from an animal study which found E-cigarette use during adolescence and early adulthood is ‘not harmless to the lungs’ as it may decrease function in the ‘areas of the lung where gas exchange occurs (parenchyma).’ A further animal study

¹⁶⁷ Polosa, R., Cibell, F., Caponnetto, P., Maglia, M., Prosperini, U., Russo, C., Tashkin, D., *Exhibit 21: ‘Health Impact of E-cigarettes: A prospective 3.5 year study of regular daily users who have never smoked’*, Scientific Reports, 17 November 2017, p. 7.

¹⁶⁸ Polosa, R., Cibell, F., Caponnetto, P., Magila, M., Prosperini, U., Russo, C., Tashkin, D., *Exhibit 21: ‘Health Impact of E-cigarettes: A prospective 3.5 year study of regular daily users who have never smoked’*, Scientific Reports, 17 November 2017, p. 1.

¹⁶⁹ TSANZ and LFA, *Submission 332*, p. 3.

¹⁷⁰ Emeritus Professor Simon Chapman AO, Professor Mike Daube AO, David Bareham, and Associate Professor Matthew Peters, *Submission 313*, p. 29.

¹⁷¹ Emeritus Professor Simon Chapman, *Official Committee Hansard*, Canberra, 8 September 2017, p. 15.

¹⁷² TSANZ and LFA, *Submission 332*, p. 9.

found that ‘maternal [E-cigarette] use enhances and worsens allergic asthma in offspring’.¹⁷³

- 3.115 In addition, the TSANZ and LFA highlighted a recent case of an individual who both smoked and vaped for a period of three months and in this time developed ‘new areas of interstitial lung damage’ which resolved following cessation of use of the E-cigarette. The TSANZ and LFA advised that this is the first case linking E-cigarette use to ‘rapid lung damage.’¹⁷⁴
- 3.116 The 2018 NAS Review found that there was no available evidence in relation to ‘whether or not E-cigarettes cause respiratory diseases’. The 2018 NAS Review found *moderate evidence* of an increase in coughing, wheezing, and asthma symptoms among adolescent E-cigarette users. For adult smokers who switch (completely or partially) to E-cigarettes, the 2018 NAS Review found that there was *limited evidence* of improvements in lung function and respiratory symptoms and a reduction in COPD exacerbations.¹⁷⁵

Other Potentially Harmful Impacts

- 3.117 The Australian Competition and Consumer Commission (ACCC) stated that it was concerned about two safety hazards from E-cigarettes: firstly, injuries resulting from fires and battery explosions; and second, ‘injuries to children from ingesting nicotine E-liquid.’¹⁷⁶

Battery Explosions

- 3.118 The ACCC explained the potential safety risks from E-cigarette batteries, stating:

E-cigarettes contain interchangeable parts, often including extra-low voltage lithium batteries. Failure of these parts has been linked to ignition of E-cigarettes, with a number of incidences of burns injuries reported overseas. Many have been linked to overcharging and overheating of batteries, causing the device to ignite or explode in close proximity to the user. The ACCC is yet to receive any reports of injuries from E-cigarettes igniting or exploding in Australia.¹⁷⁷

¹⁷³ TSANZ and LFA, *Submission 332*, p. 9.

¹⁷⁴ TSANZ and LFA, *Submission 332*, p. 9.

¹⁷⁵ Stratton, K., Kwan, L.Y., Eaton D.L., *Exhibit 24: Public Health Consequences of E-cigarettes*, National Academy of Sciences, pp 11-11 – 11-12.

¹⁷⁶ Australian Competition and Consumer Commission, *Submission 224*, p. 4.

¹⁷⁷ Australian Competition and Consumer Commission, *Submission 224*, p. 4.

- 3.119 Emeritus Professor Chapman commented that ‘there are now dozens of cases reported in medical journals of burns and other injury related to lithium-ion battery powered device malfunction.’¹⁷⁸ The AMA added that lithium batteries also ‘pose a serious health risk to small young children, who are inclined to swallow them’.¹⁷⁹
- 3.120 Emeritus Professor Chapman also stated that explosions were more common in some other lithium battery powered devices, but added that ‘when mobile phones and computers explode, we see responsible industries suspend sales or enact global recalls, until they have rendered the product safe’.¹⁸⁰
- 3.121 Associate Professor Gartner and Professor Hall stated that the number of explosions is ‘very small compared to the number of devices that are used globally’¹⁸¹ and advised that some manufacturers have issued product recalls following explosions.¹⁸² Associate Professor Gartner and Professor Hall added that:
- Some manufacturers include safety features to prevent over-heating, fire and explosions. A reasonable approach would be to require all manufacturers to implement safety features that reduce these risks and regulate them like other consumer products that contain lithium ion batteries.¹⁸³
- 3.122 The ACCC advised that it is advocating greater scrutiny of extra-low voltage lithium batteries by ‘state and territory electric safety regulators and this in time will improve battery quality and consumer safety.’¹⁸⁴
- 3.123 Associate Professor Gartner and Professor Hall also compared the risk of burns from E-cigarettes to the risk of fire caused by tobacco cigarettes, stating that in Adelaide cigarettes ‘were responsible for 47 house fires in a

¹⁷⁸ Emeritus Professor Simon Chapman AO, Professor Mike Daube AO, David Bareham, and Associate Professor Matthew Peters, *Submission 313*, p. 36.

¹⁷⁹ Dr Tony Bartone, Vice-President, Australian Medical Association, *Official Committee Hansard*, Melbourne, 5 October 2017, p. 9.

¹⁸⁰ Emeritus Professor Simon Chapman AO, Professor Mike Daube AO, David Bareham, and Associate Professor Matthew Peters, *Submission 313*, p. 38.

¹⁸¹ Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 282*, pp 5-6.

¹⁸² Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 282.1*, p. 8.

¹⁸³ Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 282*, p. 6.

¹⁸⁴ Australian Competition and Consumer Commission, *Submission 224*, p. 4.

two month period'.¹⁸⁵ Associate Professor Gartner and Professor Hall also referred to an article by the London Fire Brigade that reported that in London, smoking was responsible for 255 times more fires than vaping.¹⁸⁶

Nicotine Poisoning

- 3.124 The ACCC warned of the safety risks to children of E-liquid containing nicotine, stating:

If [E-liquid] contains high levels of nicotine and is ingested by a child, it could lead to serious illness or death. At least one death overseas has been linked to a child ingesting nicotine E-liquid. No injuries have been reported to the ACCC, but NSW Health has published anecdotal reports of harm to children.¹⁸⁷

- 3.125 The ACCC also called for import controls to limit the illicit trade in nicotine E-liquid and stated that it 'expects that a reduction in the availability of illicit nicotine E-liquids will mitigate the risk of ingestion by children.'¹⁸⁸

- 3.126 The CAH at the Royal Children's Hospital stated that nicotine is a 'highly toxic substance' and that:

In acute poisoning, death can occur within minutes due to the respiratory failure arising from paralysis of the respiratory muscles. Young children are most at risk from unintentional ingestion yet many E-cigarettes and [E-liquid] products are not manufactured with even the most basic of safety features. The risk of unintentional ingestion is further increased as the packaging is often brightly coloured and therefore appealing to young children.¹⁸⁹

- 3.127 The CAH added that in the USA between September 2010 and February 2014 reports of nicotine poisoning due to E-liquids increased from one case per month to 215 cases per month. Over half of these cases involved children under the age of five years old.¹⁹⁰

- 3.128 Public Health England stated that, in the UK, there were approximately 150 calls per year to the National Poisons Information Service regarding

¹⁸⁵ Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 282.1*, p. 9.

¹⁸⁶ Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 282.1*, p. 9.

¹⁸⁷ Australian Competition and Consumer Commission, *Submission 224*, p. 4.

¹⁸⁸ Australian Competition and Consumer Commission, *Submission 224*, p. 4.

¹⁸⁹ Centre for Adolescent Health, *Submission 256*, p. 3.

¹⁹⁰ Centre for Adolescent Health, *Submission 256*, p. 3.

children being exposed to nicotine. Less than 10 of these cases involved severe poisoning and there have been no reported cases of fatal poisoning in children. Public Health England also advised that nicotine had been used in a number of attempted suicide cases.¹⁹¹

- 3.129 The Australian Vaping Advocacy, Trade and Research (AVATAR) explained that currently over 80 per cent of vaping store customers will purchase nicotine liquid online to add to the non-nicotine E-liquid purchased in-store. The AVATAR advised that vapers ‘generally have to import pretty high strength nicotine ... a 10 per cent solution’.¹⁹² Another E-cigarette business, Bettavape, suggested that the importation of high strength nicotine ‘introduces too many unnecessary risks to the consumer and their family from the accidental ingestion or exposure to these higher concentration nicotine bases.’¹⁹³
- 3.130 The AVATAR added that high strength liquid spilt on skin can cause nausea and dizziness and it could be lethal if ingested.¹⁹⁴ The AVATAR suggested that if vaping stores were able to sell E-liquids containing nicotine it would stop vapers needing to mix liquids at home which would be a ‘far safer situation, and it would mean that the government had control over the quality of the nicotine that went in.’¹⁹⁵

Concluding Comment

- 3.131 From a public health perspective there are four main questions that must be asked in relation to the health impacts of electronic cigarettes (E-cigarettes). They are:

- Do E-cigarettes help reduce the number of people smoking tobacco cigarettes?
- What are the health effects of the long term use of E-cigarettes?
- Would the legal availability of E-cigarettes act as a gateway to nicotine use for non-smokers?

¹⁹¹ Mr Martin Dockrell, Tobacco Control Lead, Public Health England, *Official Committee Hansard*, Canberra, 18 October 2017, p. 7.

¹⁹² Mr Savvas Dimitriou, Chairperson, AVATAR, *Official Committee Hansard*, Melbourne, 5 October 2017, p. 36.

¹⁹³ Bettavape, *Submission 267*, p. 3.

¹⁹⁴ Mr Savvas Dimitriou, AVATAR, *Official Committee Hansard*, Melbourne, 5 October 2017, p. 36.

¹⁹⁵ Mr Savvas Dimitriou, AVATAR, *Official Committee Hansard*, Melbourne, 5 October 2017, p. 37.

- Is the use of E-cigarettes less harmful than the use of tobacco products?

3.132 As E-cigarettes are a relatively new product, there is very limited evidence available to answer these questions. For policy makers this poses a potential dilemma as making regulatory changes to legalise nicotine E-cigarettes comes with significant risks. Conversely, not making E-cigarettes available deprives smokers of a potentially useful tool to help them quit.

Can E-cigarettes Reduce the Number of Smokers?

E-cigarettes as a Smoking Cessation Tool

- 3.133 The view of almost all Australian public health organisations that contributed to the inquiry is that there is currently insufficient evidence to prove that E-cigarettes are an effective smoking cessation tool. In addition to public health bodies, this view was shared by the Department of Health and the State Governments of New South Wales, Queensland, South Australia, Tasmania, Victoria, and Western Australia. These organisations were generally of the view that Australia has a successful system for evaluating health claims and that the appropriate bodies to assess the research are the Therapeutic Goods Administration and the National Health and Medical Research Council.
- 3.134 Several studies, including two randomised controlled trials, found that nicotine containing E-cigarettes were effective in helping smokers quit, but other studies have found that E-cigarettes can hamper the ability of smokers to quit. The United States of America's (USA) National Academy of Sciences (NAS) concluded there was some evidence supporting the conclusion that E-cigarettes help smokers to quit but that this evidence was limited and subject to significant uncertainty.
- 3.135 Overall, while E-cigarettes may have the potential to be effective as an aid for smoking cessation there is a need for high quality research in this area, ideally including randomised controlled trials. There is also a need for more research using modern, tank-style, E-cigarettes as these deliver nicotine more efficiently to the user.
- 3.136 Another issue of concern is the dual use of E-cigarettes and tobacco. Current research suggests that using E-cigarettes to cut back on smoking without quitting entirely is likely to have little, if any, health benefit. It is not clear whether, for most smokers, dual use represents a transitional stage on the path to quitting or a permanent state that could delay attempts to completely quit smoking.

- 3.137 Smoking rates among people with mental disorders are high and are not declining. The Royal Australian and New Zealand College of Psychiatrists suggested that there could be financial and health benefits from making E-cigarettes legally available for people living with mental illness. While there are risks, such as long term dual use, the Committee considers this is worthy of further investigation.

E-cigarettes as a Gateway to Smoking for Young People

- 3.138 Many public health agencies are concerned that legalising nicotine could increase the number of young people who take up smoking. If a young person becomes addicted to nicotine through the use of E-cigarettes it seems plausible that, at some point, they may move onto smoking tobacco cigarettes.
- 3.139 The 2018 NAS Review found that there was substantial evidence that young people who used E-cigarettes were more likely to move onto tobacco smoking. This is a very concerning finding. It should be pointed out that, despite this, smoking rates in the UK and the USA have continued to decline suggesting that tobacco control policies can continue to be effective in the presence of E-cigarettes.

What are the Health Effects of E-cigarette Use?

- 3.140 E-cigarette vapour has been found to contain dangerous substances such as heavy metals and formaldehyde. E-cigarette use also appears to have negative impacts on lung health, and potentially contribute to respiratory and cardiovascular conditions. In addition, some inquiry participants were concerned that long term nicotine use could have a negative health effect on adolescent health and maternal and fetal health during pregnancy. In contrast, other participants considered the health effects of nicotine negligible and comparable to those of caffeine.
- 3.141 Overall knowledge about the long term health impacts of E-cigarette use is limited. There are many thousands of E-cigarette flavours and there is little known about the long term effects of inhaling the chemicals used in these flavours. The possibility that some of these chemicals could have serious adverse health impacts is a cause for concern.
- 3.142 Consideration must be given to whether the health impacts of E-cigarettes should be primarily assessed in their own right or relative to the known impacts of tobacco smoking. Given cigarettes kill almost two-thirds of their long term users, they appear far from a suitable benchmark for assessing

safety. Nevertheless, if E-cigarettes prove to be able to help reduce the overall number of smokers it will become necessary to weigh the potential risks of vaping against the known impacts of smoking.

- 3.143 Widespread attention has been given to the figure reported by Public Health England that E-cigarettes are 95 per cent safer than tobacco cigarettes. Public Health England indicated that this figure was only an estimate and many inquiry participants disputed its accuracy. There does appear to be agreement that E-cigarettes are probably safer than tobacco but the magnitude of the difference is still under debate.

Weighing the Potential Risks and Benefits

- 3.144 Some of the long term health impacts of nicotine E-cigarettes may not be known for a decade or more but their impact on smoking rates should become clear much sooner. If E-cigarettes can be shown to reduce the number of smokers, then the potential benefits this may bring could strengthen the case for the legalisation of E-cigarettes.

Recommendation 1

- 3.145 **The Committee recommends that the National Health and Medical Research Council fund an independent and comprehensive review of the evidence relating to the health impacts of electronic cigarettes (E-cigarettes). This review should be updated every two years to take into account the findings of new research into E-cigarettes. Topics covered by the review should include:**
- **The effectiveness of E-cigarettes as an aid to help people quit smoking tobacco cigarettes;**
 - **The health effects of ingredients commonly used in E-cigarette liquids. Following the review, any ingredients found to have significant negative impacts on human health should be prohibited from use in E-cigarette liquids;**
 - **The likelihood that E-cigarettes will increase the number of young people using nicotine and the number of young people smoking;**
 - **The health impacts of long term E-cigarette use;**

- **The relative health impacts of E-cigarettes as compared to tobacco products.**

Recommendation 2

- 3.146 The Committee recommends that the Department of Health convenes an international meeting of health experts from similar economic jurisdictions to discuss different policy and legislative approaches to electronic cigarettes.**

4. Personal Accounts

Overview

- 4.1 As outlined in Chapter 1, the Committee received a large number of submissions from individuals detailing their personal experiences of using electronic cigarettes (E-cigarettes), both with and without nicotine.
- 4.2 In general, most submissions outlined the perceived positive health impact individuals experienced when they switched from smoking traditional tobacco cigarettes to vaping. Many individuals provided similar accounts of how they had attempted to quit tobacco smoking using available methods (such as nicotine replacement therapies (NRTs) or medication) and then they turned to E-cigarettes.
- 4.3 Another common theme in evidence to the Committee was a sense of frustration at Australia's regulatory framework for E-cigarettes, particularly regarding access to nicotine. A number of individuals highlighted the regulatory frameworks of countries where nicotine E-cigarettes are available and suggested Australia should adopt a similar approach.

Methods for Quitting Smoking

Quitting Smoking

- 4.4 Many individuals who provided evidence to the Committee relayed that they had been smoking since an early age, sometimes for decades. Some individuals described a feeling of hopelessness regarding the prospect of quitting smoking. Comments included:

- 'As a former committed smoker for over 15 years on and off, I knew I would continue to smoke until it took my life away.'¹
- 'I started smoking cigarettes back in 1975 and continued to do so for the next 35 years. I was a very heavy smoker ... and ultimately ended up smoking in excess of 40 per day, unfiltered rollies ... I believed that I would die as a smoker and had virtually given up all hope of quitting cigarettes.'²
- 'I am a 57 year old male living in Victoria who smoked tobacco for 37 years. I resigned myself to the fact that I would smoke for the rest of my life.'³

4.5 A number of individuals outlined how they had attempted to quit smoking cigarettes using NRTs, such as nicotine gum, patches or inhalers.⁴ Other common quit attempt methods mentioned included using medication⁵ or going 'cold turkey.'⁶

Use of E-cigarettes

4.6 A number of inquiry participants explained how they began using E-cigarettes. Mr Adam Bentley stated that 'a friend suggested trying E-cigarettes as a method to quit smoking.'⁷ Mr Richard Yeadon stated that he 'found information on the internet about vaping', and 'after several weeks of investigating and researching vaping, [he] ordered a vaporiser kit and nicotine E-juice from overseas.'⁸ Mr Patrick Slack first tried an E-cigarette 'while on an overseas trip'.⁹

¹ Name Withheld, *Submission 243*, p. 2.

² Mr Robert Kennedy, *Submission 235*, p. 1.

³ Mr Andrew Wall, *Submission 151*, p. 1.

⁴ Mr Liam McCreavy, *Submission 107*, p. 1; Mr Destry Hart, *Submission 7*, p. 1; Name Withheld, *Submission 13*, p. 1; Name Withheld, *Submission 14*, p. 1; Mr Andrew Kiddle, *Submission 16*, p. 1; Mr Colin Whisson, *Submission 23*, p. 1; and Mr John Richardson, *Submission 31*, p. 1.

⁵ Mr Dan Jackson, *Submission 4*, p. 2; Mr Lee Brown, *Submission 18*, p. 1; Name Withheld, *Submission 27*, p. 1; Mr Robert Bertram, *Submission 32*, p. 1; and Ms Jennifer Stone, *Submission 264*, p. 1.

⁶ Mr Steve Douglas, *Submission 318*, p. 1; Mrs Sarah Fulton McIsaac, *Submission 6*, p. 1; Mr Andrew Ziser, *Submission 39*, p. 2; and Miss Philippa Wilson, *Submission 40*, p. 1.

⁷ Mr Adam Bentley, *Submission 140*, p. 1.

⁸ Mr Richard Yeadon, *Submission 144*, p. 1.

⁹ Mr Patrick Slack, *Submission 148*, p. 1.

- 4.7 A large number of individuals described how they had been able to successfully quit tobacco smoking by switching to vaping E-cigarettes. Examples of this included:
- 'With the help of E-cigarettes I have managed to stay off smoking with ease.'¹⁰
 - 'Giving up with an electronic cigarette was so easy. A lot easier than any other method that I have tried. My need for hand to mouth action was satisfied, my need for inhalation was satisfied, and with the small amount of nicotine in my E-cigarette juice, my want for nicotine was also satisfied.'¹¹
 - 'I have been vaping for over twelve months and not touched a cigarette in this time.'¹²
- 4.8 A number of individuals described how they began vaping using high concentrations of nicotine, and then reduced the concentration over time.¹³ Mr Tarrant stated that he had reduced his nicotine levels from 12 milligrams (mg) to zero and was now 'completely free' from his addiction.¹⁴ Mr Brendan Cilla described his personal experience and stated that 'I started using nicotine E-liquid at 24 mg strength and over approximately a 12 month period I have reduced my nicotine intake to just 5 mg strength.'¹⁵
- 4.9 Dual use of E-cigarettes and tobacco cigarettes was also raised. A number of individuals explained that they had used both E-cigarettes and tobacco cigarettes at first and had managed to cut down their tobacco cigarette use,¹⁶ while others had managed to quit smoking completely.¹⁷ One inquiry participant described their experience and stated:

'For a month I used a combination of cigarette smoking and vaping and finally on the 11th November 2016, I woke up one morning, and made the decision to

¹⁰ Mr Matt Thomas, *Submission 36*, p. 1.

¹¹ Mr Shane Presser, *Submission 41*, p. 1.

¹² Ms Anne Hamilton, *Submission 46*, p. 1.

¹³ Name Withheld, *Submission 56*, p. 1; Miss Shannon Janiszewski, *Submission 66*, p. 1; Mr Destry Hart, *Submission 7*, p. 1; and Ms Dianne Gorman, *Submission 101*, p. 3.

¹⁴ Mr Tyrone Tarrant, *Submission 37*, p. 1.

¹⁵ Mr Brendan Cilla, *Submission 70*, p. 1.

¹⁶ Mr Shane Charlton, *Submission 323*, p. 1.

¹⁷ Name Withheld, *Submission 57*, pp 1-2; Name Withheld, *Submission 228*, pp 1-2; and Ms Colleen Wright, *Submission 200*, p. 1.

not go and buy another packet of cigarettes. Since then, I have been able to maintain that decision.’¹⁸

Switching from Smoking to Vaping

- 4.10 A number of individuals described how, once they had switched from smoking to vaping, they experienced improvements in their health. Experienced health benefits ranged from finding it easier to breathe,¹⁹ being able to exercise more²⁰ and for longer,²¹ less coughing,²² more energy,²³ improved taste and smell,²⁴ lower blood pressure,²⁵ and less frequent colds²⁶ and chest infections.²⁷
- 4.11 A number of individuals described the benefits that switching from smoking to vaping had on their social life, work, and family. Mr Phil Perry described how he switched from smoking to vaping and is ‘once again able to play football with [his] children.’²⁸ Miss Michelle Sawyers similarly stated that switching from tobacco cigarettes to E-cigarettes has enabled her to set a ‘positive example’ for her sons.²⁹ Another individual explained that they ‘no longer have to worry about the stench of cigarettes’ on them in the workplace.³⁰ Mr Robert Cox outlined the benefits that flowed to his family after he switched to vaping, including no second hand smoke, smell, or need for ashtrays.³¹

¹⁸ Name Withheld, *Submission 45*, p. 1.

¹⁹ Name Withheld, *Submission 60*, p. 1.

²⁰ Mr Shane Presser, *Submission 41*, p. 1.

²¹ Name Withheld, *Submission 45*, p. 1.

²² Mr Brooke Wilson, *Submission 68*, p. 1.

²³ Name Withheld, *Submission 124*, p. 1.

²⁴ Mr David Graham, *Submission 52*, p. 1.

²⁵ Mr Nathan Barr, *Submission 8*, p. 1.

²⁶ Name Withheld, *Submission 9*, p. 1.

²⁷ Mr Matthew Muscat, *Submission 161*, p. 1.

²⁸ Mr Phil Perry, *Submission 89*, p. 1.

²⁹ Miss Michelle Sawyers, *Submission 174*, p. 1.

³⁰ Name Withheld, *Submission 80*, p. 1.

³¹ Mr Robert Cox, *Submission 187*, p. 1.

- 4.12 A number of individuals described a monetary benefit from switching from smoking to vaping, finding that vaping was more affordable than smoking cigarettes.³² One individual stated that they had been ‘spending around \$600 per month on cigarettes’ and that when they switched to vaping their expenditure on E-cigarettes was ‘below \$50 per month.’³³

Box 4.1 Individual Experiences

- 4.13 Many individuals described how their health and lifestyle had improved after switching from smoking tobacco cigarettes to vaping. Personal comments include:

- ‘I feel amazing! My taste is back. I don’t snore anymore. I wake up feeling refreshed after I sleep. I don’t smell. I used to cough up the most awful stuff in the mornings, that’s stopped. My mouth ulcers, which I’d suffered for years with, have disappeared. I have more energy. I don’t feel like I’m trying to catch my breath all the time. I don’t get breathless when I walk or climb stairs.’³⁴
- ‘I am able to run around with my incredibly active and sports talented son, I am able to get back into the ocean and enjoy surfing again. I can ride my bicycle for 20+kms without hesitation.’³⁵
- ‘I was overweight and depressed at the time [of switching] and thanks to giving up smoking and switching to vaping eventually I could breathe better enough to start going to the gym. I started looking after my health better and now 15 months on I have lost 35kgs and feel better both physically and mentally.’³⁶
- ‘I no longer cough up phlegm or feel short of breath after physical exercise, no chest infections with a common flu that I always would get and my smell and taste now is amazing. I free dive also and find my lung capacity has improved greatly.’³⁷
- ‘I no longer have disgusting breath and a constant stench on my skin and clothes. I no longer get chest infections and haven’t had antibiotics every other week like I used to. I am fit and healthy now due to the simple fact that

³² Name Withheld, *Submission 71*, p. 1; Name Withheld, *Submission 75*, p. 1; and Name Withheld, *Submission 78*, p. 2.

³³ Name Withheld, *Submission 47*, p. 1.

³⁴ Mr Matthew Pike, *Submission 1*, p. 2.

³⁵ Mr Adam Gray, *Submission 2*, p. 2.

³⁶ Name Withheld, *Submission 307*, p. 1.

³⁷ Mr Matthew Muscat, *Submission 161*, p. 1.

I can run a mile and not feel like my lungs are collapsing. My skin is clear and radiant.’³⁸

- ‘Since switching ... I no longer have coughing fits, trouble breathing, my blood pressure has decreased dramatically and I no longer have sleepless nights worrying about not living to see my daughters grow up.’³⁹
- ‘I can now do all of the things that I had to give up [when smoking cigarettes]. I can breathe better, I smell better, I feel better, life is simply better now, not to mention how much money I have saved since giving up. The colour of the walls in my house have also halted their growing shade of yellow.’⁴⁰
- ‘Not only has my blood pressure and heart function improved dramatically, but my much better ability to do sustained exercise is bringing other health benefits as well as weight control and better all-round fitness ... Additional benefits I am experiencing include the ability to taste and smell much better, better dental health, lower cholesterol, and better general fitness.’⁴¹

Access to E-cigarettes and E-liquids

4.14 A number of individuals commented that they ordered nicotine online from overseas suppliers, despite knowing it is unlawful to do so.⁴² Some individuals who did not wish to be named expressed frustration at being seen as a ‘criminal’ for using nicotine E-cigarettes to help them quit tobacco smoking.⁴³ Ms Angela Gordon described this as being ‘forced ... to choose between the law and our own life.’⁴⁴

4.15 Others described the issues involved in purchasing an overseas E-liquid product online without having expert product advice.⁴⁵ Mr Teskey described his experience and stated:

³⁸ Mrs Hikmet Yondemli, *Submission 17*, p. 1.

³⁹ Mr Brad Ringersma, *Submission 19*, p. 1.

⁴⁰ Miss Nicole Daws, *Submission 232*, p. 1.

⁴¹ Mr Chris Robinson, *Submission 268*, p. 3.

⁴² Mr David Jenkins, *Submission 214*, p. 2; Name Withheld, *Submission 229*, p. 2; and Ms Janet Stockley, *Submission 150*, p. 1.

⁴³ Name Withheld, *Submission 74*, p. 3; Name Withheld, *Submission 13*, p. 1; Name Withheld, *Submission 99*, p. 2.

⁴⁴ Ms Angela Gordon, *Submission 206*, p. 3.

⁴⁵ Name Withheld, *Submission 306*, p. 2; Mr Paul Marshall, *Submission 145*, p. 1; and Ms Annie Hastings, *Submission 157*, pp 1-2.

‘The first problem I had was to find a liquid that suited me. Because I couldn’t go into a shop and try liquids with nicotine I had to order from overseas and I wasted a few hundred dollars on flavours I didn’t like. This was a major hurdle because I came very close to just giving up on quitting but luckily my persistence paid off and I found some flavours I liked and since that day ... I have not had a single cigarette.’⁴⁶

- 4.16 Another individual similarly stated that ‘it can take several weeks of trial and error through ordering products from different online websites’ before finding a device and E-liquid that suits. This ‘long and tiresome’ process can see some people ‘admit defeat and return to cigarettes.’⁴⁷
- 4.17 As nicotine for E-cigarettes is not readily available, some vapers import nicotine and mix it into the E-liquid themselves.⁴⁸ Miss Nicole Daws stated that this process can be ‘harmful’ if is not mixed correctly, and ‘if people had access to liquids already containing nicotine we would not need to do this.’⁴⁹ Mr Damian Dwyer agreed and stated that ‘dealing with concentrated nicotine can be dangerous.’⁵⁰
- 4.18 The fact that tobacco cigarettes can be purchased easily throughout Australia, while sourcing E-cigarettes is difficult and in some cases unlawful, was a source of frustration for many inquiry participants.⁵¹ Mr Van Horick stated:

‘You can legally buy cigarettes without prescription which contain nicotine and numerous cancer causing chemicals, yet in Australia you cannot buy liquid used in electronic cigarettes that contains nicotine. So, on the one hand you have a government which allows the sale of cigarettes which contains all these chemicals but won’t allow people who want to quit smoking cigarettes to have nicotine in their E-liquid.’⁵²

⁴⁶ Mr Peter Teskey, *Submission 38*, p. 1.

⁴⁷ Name Withheld, *Submission 97*, p. 1.

⁴⁸ Name Withheld, *Submission 229*, p. 3; Name Withheld, *Submission 191*, p. 1; and Mr Dave Chatterton, *Submission 102*, p. 1.

⁴⁹ Miss Nicole Daws, *Submission 232*, p. 2.

⁵⁰ Mr Damian Dwyer, *Submission 211*, p. 1.

⁵¹ Mr Tony Atkinson, *Submission 246*, p. 1; Name Withheld, *Submission 238*, p. 2; Name Withheld, *Submission 236*, p. 2; Ms Stacey O’Brien, *Submission 202*, p. 1; and Miss Michelle Sawyers, *Submission 174*, p. 1.

⁵² Mr John Van Horick, *Submission 248*, p. 1.

Suggested Reforms

- 4.19 A number of inquiry participants highlighted the regulatory approaches of the United Kingdom of Great Britain, the United States of America, Canada and New Zealand, to suggest that Australia's regulation of E-cigarettes is not in line with international best practice.⁵³ International research findings estimating that E-cigarettes were 95 per cent safer than tobacco cigarettes were also frequently raised.⁵⁴
- 4.20 A number of individuals considered that New Zealand's proposed legislation for E-cigarettes could be a suitable regulatory model for Australia.⁵⁵ Mr Richard Yeadon stated that he is:
- '... encouraged by the fact that the New Zealand government has decided to introduce level-headed legislation that will prohibit the sale of devices and E-juice to under 18 year olds, but allows the free sale of devices and E-juice, including nicotine, at the retail level.'⁵⁶
- 4.21 Overwhelmingly, individual participants called for the legalisation of nicotine E-cigarettes, to enable smokers to switch:
- 'E-cigarettes and E-nicotine should be legal as they are less harmful by far than actual cigarettes and smoking tobacco.'⁵⁷
 - 'New Zealand has legalised the sale of nicotine for E-cigarettes and has made them marketable for the public and I feel Australia needs to follow in their footsteps and do the same thing.'⁵⁸
 - 'I hope the inquiry into the use and availability of E-cigarette products and juice (with nicotine) will look at the positives for allowing purchase of a safer alternative to smoking in Australia.'⁵⁹

⁵³ Name Withheld, *Submission 306*, p. 3; Name Withheld, *Submission 237*, p. 1; Ms Catherine Lambert, *Submission 209*, p. 2; and Name Withheld, *Submission 309*, p. 1.

⁵⁴ Mr Ian Strickland, *Submission 62*, p. 1; Mrs Christine May, *Submission 100*, p. 3; Mr Matthew Pike, *Submission 1*, p. 1; Name Withheld, *Submission 11*, p. 1; Brad Ringersma, *Submission 19*, p. 1; and Miss Phillipa Wilson, *Submission 40*, p. 2.

⁵⁵ Name Withheld, *Submission 9*, p. 2; Mr Emile Fadel, *Submission 149*, p. 1; and Mrs Nancy Suttoff, *Submission 172*, p. 1.

⁵⁶ Mr Richard Yeadon, *Submission 144*, p. 1.

⁵⁷ Ms Cat Wright, *Submission 22*, p. 1.

⁵⁸ Mr Joshua Waters, *Submission 29*, p. 1.

⁵⁹ Mrs Fiona Young, *Submission 84*, p. 1.

4.22 A number of individuals further stated that they would prefer to be able to buy nicotine E-liquid in Australia, instead of purchasing it online from overseas retailers.⁶⁰ One participant explained that they would:

... like to see legislation that allows Australians to buy all their E-cigarette supplies here in Australia, and to have access to local retailers and shop fronts where staff can educate and inform consumers on how best to safely move to using E-cigarettes and give up smoking for good.⁶¹

4.23 A number of individuals called for regulation which enabled the use of E-cigarettes by smokers, while minimising any potential risks to the rest of the public.⁶² Ms Margaretha Joyce considered that:

Sensible regulation should make vaping readily available as a less harmful alternative to smoking for adult smokers while minimising any risk to other members of the community, such as by banning sales to children and mandating childproof nicotine containers.⁶³

4.24 Regulations suggested included limits on sales to minors,⁶⁴ safety standards⁶⁵ and labelling requirements.⁶⁶ A number of inquiry participants recommended nicotine be available at a range of concentration levels to encourage heavy smokers to switch and then reduce their nicotine intake

⁶⁰ Name Withheld, *Submission 307*, p. 1; Mr Dean Burgess, *Submission 254*, pp 1-2; Name Withheld, *Submission 237*, p. 2; Name Withheld, *Submission 228*, p. 2; and Name Withheld, *Submission 9*, p. 1.

⁶¹ Name Withheld, *Submission 238*, p. 2.

⁶² Ms Louise Ross, *Submission 72*, p. 1; Ms Cat Wright, *Submission 22*, p. 1; Name Withheld, *Submission 59*, p. 1; Mr Laurie Flanders, *Submission 165*, p. 1, 4-6; and Mr Cameron Fortune, *Submission 160*, p. 1.

⁶³ Ms Margaretha Joyce, *Submission 44*, p. 2.

⁶⁴ Mr Bryce Cummings, *Submission 3*, p. 1; Mr James West, *Submission 5*, p. 2; Name Withheld, *Submission 59*, p. 1; and Mrs Sarah Fulton McIsaac, *Submission 6*, p. 2.

⁶⁵ Mr Colin Mannings, *Submission 34*, p. 3; Name Withheld, *Submission 233*, p. 5; and Name Withheld, *Submission 122*, p. 2.

⁶⁶ Name Withheld, *Submission 54*, pp 1-2; Ms Diane Gorman, *Submission 101*, p. 3; and Name Withheld, *Submission 53*, p. 2.

over time.⁶⁷ The importance of having a wide availability of flavours was also raised.⁶⁸

- 4.25 In addition, the taxation of E-cigarettes was raised by a number of individuals.⁶⁹ Mr Cameron Salway recommended E-cigarettes be taxed at a lower rate to cigarettes, to encourage smokers to switch.⁷⁰ Other inquiry participants stated that the revenue the government receives from high taxes on cigarettes may be contributing to its reluctance to make E-cigarettes widely available.⁷¹

Concluding Comment

- 4.26 The Committee is grateful to the individuals who relayed their experiences using electronic cigarettes (E-cigarettes). A number of these individuals explained how they had been unable to quit smoking cigarettes using available methods, such as nicotine patches, gums and inhalers, or medication.
- 4.27 Many individuals then described how they were able to successfully quit smoking traditional tobacco cigarettes once they had switched to vaping E-cigarettes. These individuals also highlighted positive health impacts they believe they experienced after switching from smoking traditional cigarettes to vaping.
- 4.28 A number of individuals also put forward regulatory options for E-cigarettes. In particular, many of these individuals considered that liquid nicotine should be made available for use in E-cigarettes. Additional regulatory suggestions included taxing E-cigarettes at a lower rate to traditional tobacco cigarettes, age restrictions for the sale of E-cigarettes and safety and packaging requirements. Overseas jurisdictions including the United Kingdom of Great Britain, the United States of America, Canada and

⁶⁷ Name Withheld, *Submission 98*, p. 4; Name Withheld, *Submission 233*, p. 4; and Mr Paul Marshall, *Submission 145*, p. 2.

⁶⁸ Ms Bronwyn Cook, *Submission 105*, p. 1; Mr Laurie Flanders, *Submission 165*, p. 5; and Mr Matthew Sallur, *Submission 51*, p. 4.

⁶⁹ Mr Robert Adams, *Submission 24*, p. 1; and Mr Jarryd Wilson, *Submission 67*, p. 4.

⁷⁰ Mr Cameron Salway, *Submission 43*, p. 2.

⁷¹ Name Withheld, *Submission 54*, pp 2-3; Mr James West, *Submission 5*, p. 3; Mr Lee Brown, *Submission 18*, p. 1; Name Withheld, *Submission 47*, p. 2; Mr Scott Wright, *Submission 50*, p. 2; Name Withheld, *Submission 71*, p. 1; and Ms Stacey O'Brien, *Submission 202*, p. 1.

New Zealand were also highlighted as potential regulatory models for Australia.

- 4.29 These experiences, observations and recommendations provided the Committee with a valuable insight into how E-cigarettes are impacting the lives of Australians.

5. Regulatory Approaches

Overview

- 5.1 A variety of approaches have been used to regulate electronic cigarettes (E-cigarettes) internationally. These include regulating E-cigarettes as: tobacco products, a unique product type, consumer goods, therapeutic goods, or using a combination of these approaches. Nicotine availability also varies between countries. In some countries, nicotine in E-cigarettes is widely available, while other countries have classified it as a dangerous poison.
- 5.2 This chapter outlines international approaches to regulation; guidance provided by the World Health Organization (WHO); and examines the regulatory frameworks of the European Union (EU), the United Kingdom of Great Britain (UK), the United States of America (USA), Canada, and New Zealand.
- 5.3 The current regulatory framework for E-cigarettes in Australia is also discussed, as well as potential areas of regulatory reform.

International Approaches to E-cigarette Regulation

World Health Organization

- 5.4 The WHO Framework Convention on Tobacco Control (FCTC) is a global public health treaty which entered into force on 27 February 2005,¹ to which Australia is a Party.²
- 5.5 The Department of Health described the aim of the FCTC as:
- ... to advance international cooperation to protect present and future generations from the preventable and devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke.³
- 5.6 In 2014, a decision was adopted by Parties to the FCTC regarding E-cigarettes. The decision was described by the WHO as one that:
- ... acknowledges the need for regulations along the lines of policies concerning other tobacco products, including banning or restricting promotion, advertising and sponsorship of [E-cigarettes].⁴
- 5.7 The WHO's advice was described by the Australian Self Medication Industry as having:
- ... encouraged a precautionary approach to E-cigarettes in response to the lack of evidence of safety, the potential risks to users and non-users, the lack of evidence of effectiveness in smoking cessation, the concerns about use by children and non-smokers and the potential for undermining of tobacco control efforts.⁵
- 5.8 The Government of Western Australia and the Cancer Council Australia and the National Heart Foundation of Australia (CCA and NHFA) referenced a section of the WHO's guidance on E-cigarettes which cautioned against the

¹ World Health Organization (WHO), 'The WHO Framework Convention on Tobacco Control: an Overview', www.who.int/fctc/WHO_FCTC_summary_January2015_EN.pdf?ua=1, Accessed 14 November 2017.

² Department of Health, *Submission 297*, p. 9.

³ Department of Health, *Submission 297*, p. 9.

⁴ WHO, 'Outcome of the Sixth Session of the Conference of the Parties', www.who.int/fctc/cop/sessions/COP6factsheet.pdf?ua=1, Accessed 14 November 2017.

⁵ Australian Self Medication Industry, *Submission 251*, p. 4.

introduction of E-cigarettes in countries with low smoking rates.⁶ The passage states:

Governments should consider that if their country has already achieved a very low prevalence of smoking and that prevalence continues to decrease steadily, use of [E-cigarettes] will not significantly decrease smoking-attributable disease and mortality even if the full theoretical risk reduction potential of [E-cigarettes] were to be realised.⁷

- 5.9 The Government of Western Australia highlighted the relevance of this section in relation to Australia 'having among the lowest smoking rates in the world.'⁸ Further, the Department of Health advised that 'the Conference of the Parties to the WHO FCTC has repeatedly invited Parties to the Convention to consider regulating and/or prohibiting [nicotine and non-nicotine E-cigarettes].'⁹
- 5.10 Associate Professor Colin Mendelsohn stated that the WHO's report on E-cigarettes¹⁰ had been 'harshly critiqued by the UK Centre for Tobacco and Alcohol Studies', particularly for disregarding the 'potential [for E-cigarettes] to reduce consumption of smoked tobacco', as well as 'factual errors and misinterpretations' and a lack of transparency.¹¹
- 5.11 British American Tobacco Australia quoted a section of the WHO's advice which highlighted the potential for E-cigarettes to help some people quit smoking.¹² This section of the WHO's advice stated:

If the great majority of tobacco smokers who are unable or unwilling to quit would switch without delay to using an alternative source of nicotine with

⁶ Government of Western Australia, *Submission 292*, p. 4; Cancer Council Australia and the National Heart Foundation of Australia, *Submission 295*, p. 6.

⁷ WHO, 'Electronic Nicotine Delivery Systems', July 2014, p. 11, http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10-en.pdf, Accessed 13 November 2017.

⁸ Government of Western Australia, *Submission 292*, p. 4.

⁹ Department of Health, *Submission 297*, p. 9.

¹⁰ WHO, 'Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS)', August 2016, www.who.int/fctc/cop7/FCTC_COP_7_11_EN.pdf, Accessed 24 November 2017.

¹¹ Associate Professor Colin Mendelsohn, *Submission 258.1*, p. 4.

¹² British American Tobacco Australia, *Submission 326*, p. 10.

lower health risks, and eventually stop using it, this would represent a significant contemporary public health achievement.¹³

National and Regional Approaches

5.12 Associate Professor Mendelsohn advised that countries have classified E-cigarettes in different ways in order to regulate them. These include:

- Creating a new regulatory classification for E-cigarettes (55 countries);
- Classification as a tobacco product (42 countries);
- Classification as a medicinal product (22 countries);
- Classification as a poison (4 countries); and
- Using multiple classification systems (16 countries).¹⁴

5.13 Associate Professor Mendelsohn stated that the sale of all types of E-cigarettes is banned in 27 countries.¹⁵ The Department of Health advised that this includes: Brazil, Singapore, Uruguay, Jordan, Oman and Qatar.¹⁶ The CCA and NHFA stated that the sale of nicotine E-cigarettes is banned in nine countries: Australia, Canada, Costa Rica, Jamaica, Japan, Malaysia, Mexico, New Zealand and Switzerland.¹⁷ Associate Professor Coral Gartner and Professor Wayne Hall advised, however, that Canada is in the process of implementing regulatory changes.¹⁸

European Union and the United Kingdom

5.14 In the EU, E-cigarettes are regulated as consumer products under the Tobacco Products Directive (TPD).¹⁹ Public Health England outlined requirements regarding E-cigarettes under the TPD and stated:

All [E-cigarette consumer] products must be notified to a common notification system, with a maximum nicotine concentration, leak proof/tamper proof containers, on-pack health warnings, quality standards for ingredients and the

¹³ WHO, 'Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS)', August 2016, p. 2, www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf, Accessed 24 November 2017.

¹⁴ Associate Professor Colin Mendelsohn, *Submission 258*, p. 16.

¹⁵ Associate Professor Colin Mendelsohn, *Submission 258*, p. 16.

¹⁶ Department of Health, *Submission 297*, p. 7.

¹⁷ Cancer Council Australia and the National Heart Foundation of Australia, *Submission 295*, p. 13.

¹⁸ Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 282.1*, p. 6.

¹⁹ Philip Morris Limited, *Submission 321*, p. 11.

removal of products that do not comply ... Each Member State is required to nominate a “competent authority” to oversee the national notification process.²⁰

- 5.15 The TPD also prohibits most forms of advertising for E-cigarettes.²¹ Counterfactual Consulting stated that the TPD ‘has been extensively criticised for its arbitrary standards, bureaucratic burdens for which no clear purpose exists, and excessive restrictions on advertising and trade.’²²
- 5.16 The All-Party Parliamentary Group for E-cigarettes in the UK Parliament (All-Party Group) explained that the maximum nicotine concentration level for E-liquid introduced under the TPD may be ‘insufficient to satisfy the cravings of nicotine from somebody using a high-tar cigarette.’ The All-Party Group further stated that this limit may encourage people who ‘want something stronger’ to purchase it from an unregulated supplier.²³
- 5.17 The UK adheres to the TPD through its *Tobacco Related Products Regulations 2016*. Under the UK’s system, nicotine and non-nicotine E-cigarettes can legally be bought and sold.²⁴ E-cigarettes can be classified as either consumer goods or therapeutic goods,²⁵ although no E-cigarette has been approved as a therapeutic good to date.²⁶
- 5.18 The UK Vaping Industry Association stated that the Westminster Government has also started to ‘actively promote vaping as a tool to stop smoking.’²⁷ The UK Department of Health’s ‘Tobacco Control Plan for England’ stated that:

The best thing a smoker can do for their health is to quit smoking. However, the evidence is increasingly clear that E-cigarettes are significantly less harmful to health than smoking tobacco. The government will seek to support

²⁰ Public Health England, *Submission 336*, p. 1.

²¹ Royal College of Physicians of London, *Submission 280*, p. 4.

²² Counterfactual Consulting, *Submission 271*, p. 14.

²³ Mr Mark Pawsey, Chairman, All-Party Parliamentary Group for E-cigarettes, United Kingdom Parliament, *Official Committee Hansard*, Canberra, 18 October 2017, p. 2.

²⁴ British American Tobacco Australia, *Submission 326*, p. 12.

²⁵ Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 282*, pp 10-11.

²⁶ Royal College of Physicians of London, *Submission 280*, pp 3-4.

²⁷ Mr James Hargrave, Public Affairs Manager, UK Vaping Industry Association, *Official Committee Hansard*, Canberra, 25 October 2017, p. 1.

consumers in stopping smoking and adopting the use of less harmful nicotine products.²⁸

- 5.19 Public Health England advised that it had recently highlighted E-cigarettes as smoking cessation devices for the ‘Stoptober’ campaign, which encourages smokers to quit smoking in the month of October.²⁹

North America

- 5.20 In Canada, nicotine E-cigarettes are regulated as medicines, while non-nicotine E-cigarettes that do not make health claims are unregulated.³⁰ The Government of Canada has introduced legislative amendments that will regulate the sale of E-cigarettes as consumer goods, and classify them as separate from tobacco products.³¹ Regulations under this proposal include prohibiting the sale of E-cigarettes to minors and in vending machines, restrictions on advertising, and quality standards for products. Any E-cigarette product that makes a therapeutic claim would continue to be regulated separately as a medicine.³²
- 5.21 In the USA, the Food and Drug Administration (FDA) regulates E-cigarettes as tobacco products. The Royal Australasian College of Physicians (RACP) summarised the regulatory arrangements in the USA by stating:
- ... E-cigarettes with nicotine are regulated in the same way as traditional tobacco products, including their manufacture, import, packaging, labelling, advertising, promotion, sale, and supply. All [E-cigarettes with nicotine] have to undergo the FDA’s review and evaluation, including their ingredients, product features, health risks and their attractiveness to minors and non-users. The regulations also prohibit the sale of nicotine containing E-cigarettes to minors in person or online, require health warnings on product packages and in advertisements, and ban their sale in vending machines.³³

²⁸ UK Department of Health, *Exhibit 14: Towards a Smokefree Generation: a Tobacco Control Plan for England*, p. 15.

²⁹ Professor John Newton, Director of Health Improvement, Public Health England, *Official Committee Hansard*, Canberra, 18 October 2017, p. 11.

³⁰ Royal Australasian College of Physicians, *Submission 276*, p. 5.

³¹ Associate Professor Colin Mendelsohn, *Submission 258*, p. 18.

³² Associate Professor Colin Mendelsohn, *Submission 258*, p. 18.

³³ Royal Australasian College of Physicians, *Submission 276*, pp 4-5.

- 5.22 Philip Morris advised that the FDA application process for E-cigarette liquids and devices can range from over \$100 000 to over \$2 million. Philip Morris stated that ‘such an approach tends to favour products currently on the market - notably, combustible tobacco products - over disruptive technologies.’³⁴

New Zealand

- 5.23 From 18 to 20 December 2017, the Committee undertook a delegation to inquire into the development of E-cigarette policy in New Zealand. The delegation met with representatives of the New Zealand Government, the New Zealand Parliament, public health bodies, and academics.
- 5.24 New Zealand currently has regulatory arrangements in place which are similar to that of Australia, with nicotine E-cigarettes unable to be legally sold.³⁵ New Zealand’s current legislation, however, is considered to have loopholes that make enforcement of this prohibition difficult.
- 5.25 In 2017, the New Zealand Government announced a decision to amend the *Smoke-free Environments Act 1990* in order to legalise the sale of nicotine E-cigarettes and E-liquids as consumer products.³⁶
- 5.26 The proposed changes would prohibit the sale of E-cigarettes to people under 18 years of age and prohibit sale via vending machines. Retailers would be permitted to have marketing displays at point-of-sale locations with more extensive marketing permitted in shops restricted to people over the age of 18 years. Broader advertising in the media, on billboards, and on the internet would, however, be prohibited. Vaping would also be prohibited in all smoke-free areas.³⁷
- 5.27 New Zealand’s proposed regulatory framework would be likely to operate using a notification system where E-cigarette importers inform the government of the products and ingredients imported. New Zealand’s framework would also be designed to be flexible enough so that particular ingredients could be banned if they were found to have negative health impacts.

³⁴ Philip Morris Limited, *Submission 321*, p. 11.

³⁵ Department of Health, *Submission 297*, p. 7.

³⁶ Royal Australasian College of Physicians, *Submission 276*, p. 4.

³⁷ New Zealand Ministry of Health, ‘Vaping (E-cigarettes)’, <https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/e-cigarettes>, Accessed 11 January 2018.

- 5.28 Following the New Zealand election on 23 September 2017 there was a change of government in New Zealand. The new government is yet to announce its position on the proposal to legalise the sale of E-cigarettes in New Zealand.

Populations with High Smoking Rates

- 5.29 While the smoking rate across the total New Zealand population is relatively low at 15.7 per cent, there are particularly high levels of smoking within particular demographics. Specifically, 35 per cent of Māori adults and 24 per cent of Pacific adults smoke, while adults living in socio-economically deprived areas are three times more likely to smoke than other New Zealanders.³⁸
- 5.30 In New Zealand, traditional tobacco control approaches no longer appear to be reducing smoking rates among the above mentioned demographics and there is a hope that E-cigarettes may offer a new tool to encourage these smokers to quit.
- 5.31 One group of particular concern is young Māori women. Currently 42.7 per cent of Māori women aged 18 to 24 smoke daily.³⁹ Stakeholders suggested that many of these women valued the time spent smoking as a moment of respite from the daily pressures of life or as an opportunity to talk and bond with other women. Further, these stakeholders suggested that E-cigarettes could offer an alternative to tobacco that allows these women to retain the psychological and social benefits they gain from the time spent smoking.
- 5.32 In addition, there was a perception that many quit smoking options used a medical approach that treated smokers as patients and that this was not appealing to some members of the Māori population. E-cigarettes may offer a more self-directed treatment option that could be more suitable.

³⁸ New Zealand Ministry of Health, 'Annual Update of Key Results 2016/17: New Zealand Health Survey', <https://www.health.govt.nz/publication/annual-update-key-results-2016-17-new-zealand-health-survey>, Accessed 11 January 2018.

³⁹ New Zealand Ministry of Health, *Young Māori Women who Smoke: Technical Report*, June 2017, p. 10.

Attitudes to E-cigarettes in the Public Health Community

- 5.33 In comparison with Australia, the approach to tobacco control in New Zealand has focussed less on mass media campaigns and more heavily emphasised the use of pharmaceutical aids for smoking cessation. This may have resulted in public health groups in New Zealand being more receptive (than their Australian counterparts) to the potential use of E-cigarettes as a smoking cessation aid or tobacco substitute.
- 5.34 When the proposal to legalise the sale of nicotine E-cigarettes was first announced in New Zealand, it was broadly, but not universally, supported by the public health community. In the last few years many public health bodies and tobacco control researchers have moved from initial scepticism to a growing acceptance that there could be a role for E-cigarettes within a tobacco control framework.
- 5.35 Nevertheless, many of New Zealand's public health groups and tobacco control researchers remain cautious regarding how E-cigarettes should be used within tobacco control. In New Zealand, E-cigarettes are considered to offer potential benefits only for smokers who have unsuccessfully tried to quit using other methods and within populations with high smoking rates. One view was that, from an ethical perspective, health professionals should at least be able to offer E-cigarettes as a potential cessation aid to those smokers who had been unable to quit using traditional methods.
- 5.36 There remains, in New Zealand, a concern about the potential for E-cigarettes to appeal to young people. New Zealand's public health professionals believe that if E-cigarettes are legalised, this should be accompanied by strong messages emphasising that, while safer than tobacco smoking, E-cigarettes are still not safe.
- 5.37 Another key concern for the public health community was the potential presence of the tobacco industry within a legal E-cigarette industry. Currently, the tobacco industry is not involved in the E-cigarette industry in New Zealand but this would most likely change if nicotine E-cigarettes became legal. There was a concern that E-cigarettes could be being used by the tobacco industry as a 'stalking horse' to make the introduction of Heat-not-Burn cigarettes more politically acceptable.
- 5.38 There is also debate in New Zealand about where E-cigarettes should be sold. Many stakeholders were supportive of vaping stores being the primary sales outlet, as staff in these stores had the knowledge to assist customers to choose a product that would suit their needs. Concerns were raised,

however, that vaping stores often sold other drug paraphernalia and that they did not have a good compliance record in regard to the sale of these products. An alternative view was that E-cigarettes could be sold at pharmacies but there was a concern that staff would lack the necessary working knowledge to assist customers. In addition, having pharmacists selling E-cigarettes could create the impression that E-cigarettes are a health enhancing product. This could contradict the message that, while safer than smoking, E-cigarettes are still not safe.

International Comparisons with Australia

- 5.39 The Australian Drug Law Reform Foundation (ADLRF) considered that Australia's regulation of E-cigarettes is out of step with many international approaches. The ADLRF stated that:

... Australia does have a much more unfriendly environment for people who want to switch to vaping than all of the countries that we like to compare ourselves with. So that is UK, New Zealand, Canada and the [USA]. More countries are moving in that direction ... I think Australia is going to be more and more isolated.⁴⁰

- 5.40 The Department of Health considered that decisions of other countries do not necessarily mean Australia should go down the same path, and stated that:

While it is true that nicotine is available for use in E-cigarettes in a number of overseas jurisdictions, the department is of the view that this alone does not justify widespread access to nicotine for use in E-cigarettes in Australia, nor should this situation be seen to inhibit further substantial progress in tobacco control in Australia.⁴¹

Regulatory Approaches in Australia

Current Regulatory Arrangements in Australia

- 5.41 In Australia, the regulation of E-cigarettes and nicotine is a shared responsibility between the Federal Government and the states and

⁴⁰ Dr Alexander (Alex) David Wodak, President, Australian Drug Law Reform Foundation, *Official Committee Hansard*, Sydney, 12 July 2017, p. 24.

⁴¹ Dr Lisa Studdert, Acting Deputy Secretary, Department of Health, *Official Committee Hansard*, Canberra, 8 September 2017, p. 4.

territories.⁴² The Department of Health described the current regulatory arrangements in Australia and stated:

In Australia, the current regulatory framework draws on existing regulation of tobacco products, poisons, therapeutic goods and consumer goods, however there remains significant variation between states and territories in their regulatory approaches to E-cigarettes.⁴³

- 5.42 Nicotine is classified as a dangerous poison under Schedule 7 of the Poisons Standard. Schedule 7 provides an exemption for the use of nicotine in nicotine replacement therapies, tobacco smoking and for veterinary purposes.⁴⁴ All Australian jurisdictions have implemented legislation consistent with Schedule 7, and as such the commercial supply of nicotine for use in E-cigarettes is currently prohibited.⁴⁵ Current regulatory state and territory frameworks for the use of E-cigarettes and the sale and marketing of non-nicotine E-cigarettes appear in Table 5.1.
- 5.43 The Department of Health advised that, while states and territories ‘have the legislative ability to make individual variations’, it is rare for them to depart from the TGA’s federal scheduling system — although Victoria has done this in relation to medicinal cannabis.⁴⁶ The Department of Health also advised that variations to the national scheduling would be contrary to the Council of Australian Governments agreement to adopt all scheduling decisions.⁴⁷

Table 5.1 State and Territory Regulation of E-cigarettes

All states and territories	The commercial supply of nicotine for use in E-cigarettes is prohibited by legislation in all states and territories. ⁴⁸
Qld, Vic,	E-cigarettes are subject to similar restrictions as

⁴² Tasmanian Government, *Submission 182*, p. 1.

⁴³ Department of Health, *Submission 297*, p. 1.

⁴⁴ Therapeutic Goods Administration (TGA), ‘Scheduling Delegate’s Final Decisions, March 2017’, www.tga.gov.au/book-page/21-nicotine-0, Accessed 7 November 2017.

⁴⁵ Department of Health, *Submission 297: Attachment A*, p. 2.

⁴⁶ Department of Health, *Submission 297.1*, p. 1.

⁴⁷ Department of Health, *Submission 297.1*, pp 1-2.

⁴⁸ Department of Health, *Submission 297: Attachment A*, p. 2.

the ACT and Tas	conventional tobacco cigarettes, including: restrictions on sales to minors, use in smoke-free areas, advertising, and sales. ⁴⁹
NSW	Regulations regarding E-cigarettes include: restrictions on sales to minors, advertising and sales. ⁵⁰ E-cigarettes can be used in smoke free areas, including indoors, unless an individual establishment or workplace chooses to ban it. ⁵¹ The NSW Government has introduced a Bill to prohibit the use of E-cigarettes in areas which are smoke-free areas for tobacco products. ⁵²
SA	Currently, the sale of products that resemble tobacco products is prohibited. ⁵³ The South Australian Parliament is currently considering legislation that proposes to treat E-cigarettes in a similar way to conventional tobacco cigarettes, including: prohibiting sale to minors and use in smoke-free areas, advertising and sales restrictions. ⁵⁴
WA	The sale of products that resemble tobacco products, including E-cigarettes, is an offence. ⁵⁵

⁴⁹ Department of Health, *Submission 297: Attachment A*, p. 3; Queensland Department of Health, *Submission 226*, p. 6; Victorian Department of Health and Human Services, 'E-cigarette reforms: factsheet', www2.health.vic.gov.au/about/publications/factsheets/e-cigarette-reforms-factsheet, Accessed 7 December 2017; ACT Health, 'Electronic Cigarettes', www.health.act.gov.au/public-information/public-health/tobacco-and-smoke-free/electronic-cigarettes, Accessed 7 December 2017; Parliament of Tasmania, 'Fact Sheet: Public Health Amendment (Healthy Tasmania) Bill 2017', www.parliament.tas.gov.au/bills/Bills2017/pdf/notes/35_of_2017-Fact%20Sheet.pdf, Accessed 14 March 2018.

⁵⁰ NSW Health, *Submission 333*, p. 2.

⁵¹ NSW Government, 'Are Electronic Cigarettes Legal in NSW?' www.health.nsw.gov.au/tobacco/Factsheets/e-cigs-are-they-legal.pdf
Accessed 7 November 2017.

⁵² Parliament of New South Wales, 'Smoke-free Environment Amendment Bill 2018,' www.parliament.nsw.gov.au/bills/Pages/bill-details.aspx?pk=3498, Accessed 14 March 2018.

⁵³ Cancer Council SA 'E-cigarette Fact Sheet', www.cancersa.org.au/assets/E-cigarette%20brochure%20December%202013%202015%20branding.pdf, Accessed 27 November 2017.

⁵⁴ South Australian Government, *Submission 230*, p. 1.

⁵⁵ Department of Health, *Submission 297: Attachment A*, p. 3.

NT	E-cigarettes can be used anywhere in the NT, unless there are signs prohibiting their use. ⁵⁶ The NT Government is considering regulations about E-cigarettes. ⁵⁷
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5.44 The Thoracic Society of Australia and New Zealand and the Lung Foundation Australia (TSANZ and LFA) described the existing federal, state and territory regulatory arrangements as ‘confusing’ and ‘complex.’⁵⁸ The Australian Competition and Consumer Commission (ACCC) highlighted the risks associated with current regulatory arrangements and stated:

Cumulatively, the [E-cigarette regulatory] framework is not consistent nationally and nor is it uniformly enforced. As a result, a number of emerging safety hazards associated with E-cigarettes and nicotine E-liquid may need to be addressed.⁵⁹

5.45 The RACP advised that a nationally consistent framework for E-cigarettes is needed:

The RACP is of the view that developing a national E-cigarette policy framework is crucial. It will not only allow for a clear set of shared objectives to be set, but also support consistency and coherence in implementing effective policy measures across Australia for the benefits of all Australians regardless of where they live and how they travel across state borders.⁶⁰

5.46 The Tasmanian Government recommended the development of agreed principles to guide discussion around a national regulatory framework. The Tasmanian Government recommended the consideration of issues including: the need for evidence based policy, use of the precautionary principle, the need to protect public health gains, legal clarity for the public, and that any changes complement state laws.⁶¹ The Department of Health expressed similar sentiments, and stated that any national regulatory policy for E-cigarettes should:

⁵⁶ Northern Territory Government, ‘Electronic Cigarettes’, <https://nt.gov.au/wellbeing/healthy-living/smoking/electronic-cigarettes>, Accessed 7 November 2017.

⁵⁷ Department of Health, *Submission 297: Attachment A*, p. 3.

⁵⁸ Thoracic Society of Australia and New Zealand (TSANZ) and the Lung Foundation Australia (LFA), *Submission 332*, p. 13.

⁵⁹ Australian Competition and Consumer Commission (ACCC), *Submission 224*, p. 4.

⁶⁰ Royal Australasian College of Physicians, *Submission 276*, p. 5.

⁶¹ Tasmanian Government, *Submission 182*, pp 1-2.

- be precautionary in nature, as well as flexible and responsive to change in light of new evidence in relation to the potential short and long term harms associated with E-cigarettes;
- be proportionate to the level of risks and potential benefits that E-cigarettes may pose to population health;
- protect the Australian community from any potential health risks associated with the short and long term use of E-cigarettes; and
- not undermine Australia's efforts to reduce smoking prevalence or impede the de-normalisation of smoking in Australia.⁶²

'Black Market'

- 5.47 Many E-cigarette users order nicotine online and import it unlawfully.⁶³ In addition, it was suggested that some vaping stores in Australia sell under the counter liquid nicotine.⁶⁴ One participant described these methods of obtaining liquid nicotine for personal use as an 'open secret' and that the lack of regulation of ingredients in E-liquids was potentially dangerous.⁶⁵
- 5.48 The Peregrine Corporation called on the government to enforce existing regulations to combat the 'illicit trade' of nicotine for E-cigarettes.⁶⁶ The ACCC expressed similar sentiments and recommended that states and territories consistently enforce poisons laws, and the federal government consider any import controls that could 'assist in the reduction of the illicit trade of nicotine E-liquids.'⁶⁷

Regulating E-Cigarettes as a Therapeutic Good

- 5.49 In Australia, all therapeutic goods must be approved by the TGA before they can be sold. This includes products that claim to help people to quit

⁶² Department of Health, *Submission 297*, p. 8.

⁶³ Associate Professor Colin Mendelsohn, Private Capacity, *Official Committee Hansard*, Sydney, 12 July 2017, p. 22.

⁶⁴ Peregrine Corporation, *Submission 110*, p. 5.

⁶⁵ Dr Muhammad Aziz Rahman, *Submission 112*, p. 2.

⁶⁶ Peregrine Corporation, *Submission 110*, p. 4.

⁶⁷ ACCC, *Submission 224*, p. 4.

smoking.⁶⁸ Currently, no E-cigarette has been approved as a therapeutic good by the TGA.⁶⁹

- 5.50 Emeritus Professor Simon Chapman, Professor Mike Daube, David Bareham, and Associate Professor Matthew Peters (Emeritus Professor Chapman) recommended that E-cigarettes remain under the remit of the TGA because ‘a core part of the case being put forward for the benefits of [E-cigarettes] is based on a therapeutic claim (efficacy in smoking cessation)’. Emeritus Professor Chapman stated that the TGA is ‘vastly experienced in assessing therapeutic product safety.’⁷⁰
- 5.51 The TSANZ similarly stated that ‘the only potential benefit [of an E-cigarette] in the literature, although unproven, is as a smoking cessation device, which makes it a therapeutic good.’⁷¹

TGA Application Process

- 5.52 Counterfactual Consulting advised that the regulation of E-cigarettes as a therapeutic good ‘functions as a de facto ban,’ as ‘no vaping products have been approved by a medicines regulator and brought to market in any country.’⁷² Associate Professor Mendelsohn agreed and added that the TGA application process for products is ‘onerous and expensive’, which could ‘delay innovation’ and ‘be a huge barrier to entry’ for new products.⁷³ Associate Professor Mendelsohn also stated that the cost associated with the therapeutic model could make E-cigarettes more expensive for consumers.⁷⁴
- 5.53 The TSANZ agreed that the TGA process is an ‘expensive undertaking’, but that this was necessary ‘to ensure the equipment and ingredients are manufactured and sold to the standard required to protect the lungs of Australians using them.’⁷⁵

⁶⁸ Department of Health, *Submission 297: Attachment A*, p. 1.

⁶⁹ Department of Health, *Submission 297: Attachment A*, p. 1.

⁷⁰ Emeritus Professor Simon Chapman AO, Professor Mike Daube AO, David Bareham, and Associate Professor Matthew Peters, *Submission 313*, p. 3.

⁷¹ Professor Anne Holland, Board Director, Clinical Care and Resources, TSANZ, *Official Committee Hansard*, Melbourne, 5 October 2017, p. 5.

⁷² Counterfactual Consulting, *Submission 271.1*, p. 4.

⁷³ Associate Professor Colin Mendelsohn, *Official Committee Hansard*, Sydney, 12 July 2017, p. 13.

⁷⁴ Associate Professor Colin Mendelsohn, *Official Committee Hansard*, Sydney, 12 July 2017, p. 28.

⁷⁵ TSANZ and LFA, *Submission 332*, p. 12.

5.54 In contrast, the Department of Health suggested that the costs were not overly prohibitive for manufacturers. The Department of Health stated:

... a smoking cessation product could be available over the counter or ... [as] a prescription medicine. If it is an over-the-counter medicine, for example, the maximum application registration fee is \$27 000; the annual one is \$1430 a year ... it is difficult to see how that would be a major impost on some of the significant multinational companies involved in this area. Even as a prescription medicine ... it's a one-off cost of about \$240 000 and then I think it is \$3230 [annually] — again, hardly onerous for a company that is expecting to have a major market presence.⁷⁶

5.55 Associate Professor Coral Gartner and Professor Wayne Hall explained that there are additional costs of a therapeutic good application and stated:

... the TGA application fee is only a small proportion of the total costs of making an application. Other costs include running clinical trials to provide data on efficacy, certification of manufacturing at [Good Manufacturing Practice] standards, pharmacovigilance monitoring and regulatory consultant fees in preparing an application. These are not costs required to market tobacco cigarettes in Australia.⁷⁷

Personal Importation Scheme

5.56 In some cases, nicotine for E-cigarettes can be legally imported under the TGA's Personal Importation Scheme.⁷⁸ A person may be able to import nicotine for E-cigarettes under the Personal Importation Scheme if:

- they have a valid prescription from a general practitioner (GP);
- no more than three months' supply for personal use is imported at one time; and
- they do not import more than 15 months' supply within 12 months.⁷⁹

5.57 The Department of Health advised that states and territories may have additional requirements that prohibit the use of nicotine E-cigarettes even with a prescription.⁸⁰ The Queensland Department of Health stated that:

⁷⁶ Dr John Skerritt, Deputy Secretary, Department of Health, *Official Committee Hansard*, Canberra, 8 September 2017, pp 4-5.

⁷⁷ Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 282.1*, pp 2-3.

⁷⁸ Department of Health, *Submission 297: Attachment A*, p. 2.

⁷⁹ Dr John Skerritt, Department of Health, *Official Committee Hansard*, Canberra, 8 September 2017, p. 9.

Specifically, it is an offence for a person to manufacture, obtain, possess, prescribe, dispense, sell, advertise, use or destroy nicotine, unless the person is specifically authorised or holds an approval under the *Health (Drugs and Poisons) Regulation 1996*. This includes importing electronic cigarettes containing nicotine for personal or therapeutic use even with a prescription from a medical practitioner.⁸¹

- 5.58 Associate Professor Mendelsohn stated that as the TGA and the National Health and Medical Research Council have not endorsed the use of E-cigarettes for quitting smoking, GPs generally do not provide prescriptions. As such, it was estimated that the vast majority of people using liquid nicotine for E-cigarettes do not have prescriptions and are importing it illegally.⁸²
- 5.59 The Royal Australian College of General Practitioners (RACGP) also commented that the paperwork GPs need to fill out to provide a prescription for nicotine is 'quite onerous'. The RACGP further stated that this process may 'make it extremely difficult for people who want to get access to some form of nicotine.'⁸³
- 5.60 The New Nicotine Alliance Australia (NNAA) stated that E-cigarettes should be 'at least as available or more available than cigarettes.' The NNAA therefore did not support making it necessary to have a prescription to access E-cigarettes.⁸⁴ The Australian Taxpayers' Alliance (ATA) agreed, and outlined the following scenario:

... [smokers] can go to their local servo and buy a packet of cigarettes. If they're trying to quit [using E-cigarettes on prescription], they think: 'Oh, I've run out! I need to schedule an [appointment] with my doctor, go to visit the doctor, see the doctor, pay for the doctor if they're not bulk billing, then go to the pharmacy and hope the pharmacy is ... open, because it might be out of

⁸⁰ Dr John Skerritt, Department of Health, *Official Committee Hansard*, Canberra, 8 September 2017, p. 9.

⁸¹ Queensland Department of Health, *Submission 226*, p. 6.

⁸² Associate Professor Colin Mendelsohn, *Official Committee Hansard*, Sydney, 12 July 2017, p. 18.

⁸³ Associate Professor John Litt, Deputy Chair, Expert Committee on Quality Care, Royal Australian College of General Practitioners (RACGP), *Official Committee Hansard*, Melbourne, 5 October 2017, p. 20.

⁸⁴ Dr Attila Danko, President, New Nicotine Alliance Australia, *Official Committee Hansard*, Sydney, 12 July 2017, p. 22.

hours.' If we are trying to stop people from smoking, giving them so many hoops to go through just to buy something doesn't really work.⁸⁵

- 5.61 In addition to the Personal Importation Scheme, other avenues to access unapproved therapeutic goods include the Special Access Scheme and Authorised Prescriber Scheme. The Department of Health stated that:

Under these Schemes, medical practitioners are required to apply to access the unapproved therapeutic good on behalf of their patient(s), and they are required to formally prescribe them to the patient/s. While these schemes may be used to import unapproved therapeutic goods into Australia, they are intended ... to enable access to products only in cases when suitable TGA-approved alternatives that achieve the same therapeutic purpose are not available on the Australian market.⁸⁶

Other Considerations

- 5.62 Counterfactual Consulting considered E-cigarettes to be 'unsuited' to a therapeutic regulatory model, as they are 'designed to replace an existing but much more harmful consumer nicotine product, combustible cigarettes, and fit in the same place in the market and consumer psychology.' Using the analogy of diet cola to illustrate this point, Counterfactual Consulting advised that 'if it was only possible to place diet cola on the market if it was approved as an anti-obesity drug, then there would be few if any diet cola options.'⁸⁷
- 5.63 Associate Professor Coral Gartner and Professor Wayne Hall highlighted the potential consequences of regulating E-cigarettes as a therapeutic good while 'a much more harmful consumer product — tobacco cigarettes — continues to be sold without similar restrictions.'⁸⁸
- 5.64 In contrast, the Department of Health stated that 'the current availability of conventional tobacco products, which we all know is an anomaly of history, does not provide a reasonable basis to expose the public to other harmful substances and products.'⁸⁹

⁸⁵ Mr Tim Andrews, Executive Director, Australian Taxpayers' Alliance (ATA), *Official Committee Hansard*, Melbourne, 5 October 2017, p. 31.

⁸⁶ Department of Health, *Submission 297: Attachment A*, p. 2.

⁸⁷ Counterfactual Consulting, *Submission 271.1*, p. 5.

⁸⁸ Associate Professor Coral Gartner and Professor Wayne Hall, *Submission 282.1*, p. 2.

⁸⁹ Dr Lisa Studdert, Department of Health, *Official Committee Hansard*, Canberra, 8 September 2017, p. 4.

- 5.65 Associate Professor Mendelsohn suggested that E-cigarettes could be regulated as both consumer and therapeutic goods, which is currently the system in the UK. Professor Mendelsohn stated:

... there is the option of allowing a therapeutic pathway as well [as a consumer pathway] ... some countries like New Zealand and the UK mostly allocate products as consumer products, if they do not make a therapeutic claim, but they also have a therapeutic pathway. If a company like [British American Tobacco] wants to promote a product as a cessation aid, then they can go down that pathway.⁹⁰

Regulating E-cigarettes as Consumer Goods

- 5.66 Another option for the regulation of E-cigarettes is to classify them as consumer goods. Associate Professor Mendelsohn explained that 'the first essential step' in developing an appropriate regulatory framework is 'to exempt low-concentrations of nicotine from Schedule 7 [of the Poisons Standard] ... so that it may be available for use with an E-cigarette for tobacco harm reduction.'⁹¹ British American Tobacco Australia explained that amending the Poisons Standard in this way will mean that nicotine for E-cigarettes will no longer be overseen by the TGA but by the ACCC under Australian Consumer Law.⁹²
- 5.67 In 2016, the TGA received an application from a member of the public⁹³ to exempt nicotine from Schedule 7 for use in low concentrations in E-cigarettes 'for the purpose of tobacco harm reduction.'⁹⁴ In March 2017, the TGA decided that 'the current scheduling of nicotine remains appropriate.'⁹⁵
- 5.68 The Australian Retailers Association recommended E-cigarettes be regulated as consumer goods,⁹⁶ and stated that the legalisation of nicotine E-cigarettes

⁹⁰ Associate Professor Colin Mendelsohn, *Official Committee Hansard*, Sydney, 12 July 2017, p. 28.

⁹¹ Associate Professor Colin Mendelsohn, *Submission 258*, p. 20.

⁹² British American Tobacco Australia, *Submission 326*, pp 16-17.

⁹³ TGA, 'General Process for Amending the Poisons Standard: Nicotine,' <https://www.tga.gov.au/media-release/general-process-amending-poisons-standard-nicotine>, Accessed 1 December 2017.

⁹⁴ TGA, Scheduling Delegate's Final Decisions, March 2017,' www.tga.gov.au/book-page/21-nicotine-0, Accessed 7 November 2017.

⁹⁵ TGA, Scheduling Delegate's Final Decisions, March 2017,' www.tga.gov.au/book-page/21-nicotine-0, Accessed 7 November 2017.

⁹⁶ Australian Retailers Association, *Submission 290*, p. 4.

provides 'greater choice to consumers and allows retailers to sell a harm reduction product whilst also replacing revenue from the traditional [tobacco cigarette] product.'⁹⁷ The ADLRF also stated that regulating E-cigarettes as consumer goods may encourage competition and drive innovation, as a greater diversity of products will be able to come into the market.⁹⁸

- 5.69 Counterfactual Consulting supported a consumer good framework, stating that 'vapour technologies are consumer products rather than medicines.'⁹⁹ The NNAA expressed similar sentiments, stating that using a therapeutic model of regulation 'medicalises' E-cigarettes, and that 'most smokers switching to vaping do not see themselves as sick'.¹⁰⁰
- 5.70 Dr Neil McKeganey from the Centre for Substance Use Research agreed and stated a consumer model could be used to provide access to E-cigarettes for smokers, while also deterring young people:
- ... [A] regulatory model which would provide smokers with much easier access to these devices would be to regulate them as consumer products — though subjecting them to appropriate consumer regulatory requirements in terms of manufacturing standards, chemical constituents, age verification, etc. Through existing and if necessary enhanced consumer regulation ... it would be possible to maximise adult's access to this technology whilst reducing young peoples' access to the technology.¹⁰¹
- 5.71 Conversely, the TSANZ and LFA cautioned against the regulation of E-cigarettes as consumer products. They instead recommended E-cigarettes be prohibited altogether, unless they are found to have therapeutic benefits and would consequently be classified as a therapeutic good.¹⁰²
- 5.72 VicHealth also advised against the regulation of E-cigarettes as anything other than therapeutic goods (and only to be sold as therapeutic goods following TGA approval). VicHealth explained:

⁹⁷ Australian Retailers Association, *Submission 290*, p. 3.

⁹⁸ Dr Alexander (Alex) David Wodak, Australian Drug Law Reform Foundation, *Official Committee Hansard*, Sydney, 12 July 2017, p. 24.

⁹⁹ Counterfactual Consulting, *Submission 271.1*, p. 5.

¹⁰⁰ New Nicotine Alliance Australia, *Submission 222*, p. 3.

¹⁰¹ Dr Neil McKeganey, *Submission 210*, p. 2.

¹⁰² TSANZ and LFA, *Submission 332*, p. 2.

There are no health benefits to promoting nicotine products, including [E-cigarettes], to non-smokers and ex-smokers. Indeed, there is potential for harm to non-smokers and ex-smokers by indirectly encouraging uptake of nicotine products and/or smoking.¹⁰³

5.73 The CCA and NHFA similarly stated:

... the lobbying from commercial interests, including tobacco companies, for mass-market E-cigarette availability in Australia and a sidestepping of established poison controls, medical research and therapeutic goods authorities, is itself another example of aggressive E-cigarette marketing to drive take-up rather than confer a health benefit.¹⁰⁴

Other Regulatory Issues

5.74 Regulatory requirements for E-cigarettes that have been used in Australia and/or overseas include:

- Restrictions on sale, such as prohibitions on the use of nicotine;
- Minimum age restrictions for use;
- Restrictions or prohibition of advertising, promotion and sponsorship;
- Packaging requirements, such as health warnings, child safety packaging and lists of ingredients, emissions and concentration levels;
- Product standards for liquid and devices, such as prohibition of certain ingredients or limits on nicotine concentration;
- Reporting requirements, such as requiring e-cigarette manufacturers to notify health authorities of their intention to bring a product to market;
- Taxation; and
- Restrictions on places of use, such as in public places or in a vehicle with a minor present.¹⁰⁵

5.75 The Public Health Association of Australia (PHAA) considered that the restrictions that apply to conventional cigarettes, such as plain packaging and a ban on smoking in public places such as restaurants and pubs, should apply to E-cigarettes. The PHAA stated that these restrictions would guard against the renormalisation of smoking.¹⁰⁶

¹⁰³ VicHealth, *Submission 327*, p. 2.

¹⁰⁴ Cancer Council Australia and the National Heart Foundation of Australia, *Submission 295*, p. 4.

¹⁰⁵ Associate Professor Colin Mendelsohn, *Submission 258*, pp 16-17.

¹⁰⁶ Mr Michael Moore, Chief Executive Officer, Public Health Association of Australia, *Official Committee Hansard*, Melbourne, 5 October 2017, p. 16.

- 5.76 In contrast, Philip Morris and British American Tobacco Australia stated that E-cigarettes should have different rules to tobacco cigarettes to encourage people to switch.¹⁰⁷ Philip Morris stated:

Non-combustible alternatives to cigarettes should be treated differently from combustible products, favouring the former and disfavouring the latter: different health warnings and packaging requirements; different rules for displaying the products and communicating about them with adult smokers; and different rules for where they can be used should apply to clearly distinguish them from cigarettes and encourage adult smokers to switch to them.¹⁰⁸

- 5.77 Japan Tobacco International advised that ‘governments and regulators should avoid excessive regulation that prevents adult consumers from choosing these products.’¹⁰⁹
- 5.78 The RACP recommended that ‘all states and territories that haven’t introduced laws specifically governing E-cigarettes should be encouraged to impose some regulation to control their sale, display, advertising and promotion.’¹¹⁰

Vaping in Public Places

- 5.79 Inquiry participants including VicHealth, the RACP and Emeritus Professor Chapman recommended that the use of E-cigarettes be prohibited in smoke-free areas. The RACP stated that the prohibition of E-cigarette use in smoke-free areas would protect non-users from exposure to second-hand vapour.¹¹¹ VicHealth added that it would also prevent the renormalisation of smoking.¹¹² Emeritus Professor Chapman agreed and stated that the restriction would help prevent former smokers from being triggered into relapsing, and also protect bystanders from a potential explosion of an E-cigarette device.¹¹³ The TSANZ and LFA recommended restrictions be put

¹⁰⁷ Philip Morris Limited, *Submission 321*, p. 13; British American Tobacco Australia, *Submission 326*, p. 16.

¹⁰⁸ Philip Morris Limited, *Submission 321*, p. 13.

¹⁰⁹ Japan Tobacco International, *Submission 265*, p. 6.

¹¹⁰ Royal Australasian College of Physicians, *Submission 276*, p. 5.

¹¹¹ Royal Australasian College of Physicians, *Submission 276*, p. 5.

¹¹² VicHealth, *Submission 327*, pp 2-3.

¹¹³ Emeritus Professor Simon Chapman AO, Professor Mike Daube AO, David Bareham, and Associate Professor Matthew Peters, *Submission 313*, p. 52.

in place to discourage use among young people, such as banning the use of E-cigarettes in cars with minors present, indoors, and places where children are likely to be (such as playgrounds).¹¹⁴

- 5.80 Counterfactual Consulting stated that ‘the evidence suggests that E-cigarettes cause no material risk to bystanders.’¹¹⁵ As such, Counterfactual Consulting recommended that:

... the appropriate policy is to allow owners and operators to decide their policy and make informed judgements, including the welfare value to vapers and smokers and make clear whether vaping is permitted or not. The role of the government should be limited to providing guidance to assist in making such decisions, an approach that has been adopted in England.¹¹⁶

- 5.81 The Royal Australian and New Zealand College of Psychiatrists (RANZCP) commented that there may be some benefits of using E-cigarettes in some smoke-free places, such as mental health facilities. The RANZCP explained that:

... many mental health facilities are now smoke-free and there may be benefits in allowing the use of E-cigarettes and vaporisers in these settings. This may encourage patients to switch to these less harmful alternatives while reducing the conflicts which smoking bans can sometimes cause.¹¹⁷

- 5.82 Philip Morris considered that people using E-cigarettes should not be forced to use the same space as smokers. Instead, it recommended that ‘new spaces can be carved out for exclusive use of smoke-free products.’¹¹⁸

Labelling and Packaging

- 5.83 The TSANZ and LFA recommended that, if E-cigarettes are approved as therapeutic products, product labels should include detailed information about the E-liquid content. The TSANZ and LFA recommended this information include:

- Nicotine content;

¹¹⁴ TSANZ and LFA, *Submission 332*, p. 2.

¹¹⁵ Counterfactual Consulting, *Submission 271*, p. 22.

¹¹⁶ Counterfactual Consulting, *Submission 271*, p. 22.

¹¹⁷ Royal Australian and New Zealand College of Psychiatrists, *Submission 294*, p. 3.

¹¹⁸ Philip Morris Limited, *Submission 321.1*, p. 6.

- All ingredients and concentrations ... including specifying compounds used for flavouring, not just the common name of the flavour, (e.g. 'apple flavouring'); and
- A warning statement about the impact on health.¹¹⁹

5.84 The TSANZ and LFA also recommended the use of 'tamper-proof and kid-safe packaging.'¹²⁰

5.85 Japan Tobacco International recommended that E-cigarette packaging include a leaflet with instructions for use, a statement as to whether the product contains nicotine, and contact details of the manufacturer or importer.¹²¹ Japan Tobacco International also listed elements that should not be included in the leaflet, including misleading statements about health effects and risks.¹²² Japan Tobacco International further recommended that the packaging include a list of ingredients and a warning to keep out of reach of children.¹²³

5.86 The Australian Self Medication Industry recommended the use of plain packaging (along with other restrictions) to 'prevent the (re)glamorisation of smoking, especially among children.'¹²⁴ The Australian Vaping Advocacy, Trade and Research (AVATAR), in contrast, cautioned that plain packaging could lead to a 'race to the bottom in terms of pricing' of E-liquid, and 'you would just have incredibly cheap E-liquid sold for \$1.'¹²⁵

Regulating Marketing

5.87 Dr Becky Freeman advised that E-cigarette advertising is currently found in Australian print media, retail outlets and online.¹²⁶ The Australian Medical Association (AMA) observed that online marketing in particular is

¹¹⁹ TSANZ and LFA, *Submission* 332, p. 12.

¹²⁰ TSANZ and LFA, *Submission* 332, p. 13.

¹²¹ Japan Tobacco International, *Submission* 265, p. 5.

¹²² Japan Tobacco International, *Submission* 265, p. 6.

¹²³ Japan Tobacco International, *Submission* 265, pp 5-6.

¹²⁴ Australian Self Medication Industry, *Submission* 251, p. 1.

¹²⁵ Mr Savvas Dimitriou, Chairperson, Australian Vaping Advocacy, Trade and Research Inc, *Official Committee Hansard*, Melbourne, 5 October 2017, p. 38.

¹²⁶ Dr Becky Freeman, *Submission*, 249, p. 1.

‘sophisticated’ and ‘designed to entice young consumers.’¹²⁷ Dr Freeman added that ‘E-cigarette ads often contain misleading information about health benefits and safety’.¹²⁸ The AMA agreed and stated that it would ‘welcome moves to address the inappropriate advertising of E-cigarettes as cessation aids.’¹²⁹

5.88 The ACCC advised that it had taken enforcement action against three E-cigarette retailers ‘for making false and misleading representations that their products did not contain toxins and carcinogens contained in cigarettes when this was not the case.’¹³⁰ The ACCC further stated that these representations ‘had the potential to mislead consumers about the health effects of non-nicotine electronic cigarettes.’¹³¹

5.89 The ACCC also advised that it had ‘identified low levels of compliance with the Australian Consumer Law (ACL)’ from the Australian online E-cigarette industry. Reflecting this finding, the ACCC wrote to over 30 Australian E-cigarette suppliers ‘reminding them of their obligations under the ACL.’¹³² The TSANZ and LFA also expressed concern that ‘the wide and poorly regulated marketing of E-cigarettes will make smoking socially acceptable again and will undermine the smoke free legislation.’¹³³

5.90 The AMA explained how the advertising of E-cigarettes differs from advertising for nicotine replacement therapies, such as nicotine gums, patches and inhalers:

The marketing of products such as nicotine replacement therapy is in stark contrast [to the marketing of E-cigarettes]. These are not desirable consumer products. We do not see young people being compelled to improve their image by using nicotine replacement products.¹³⁴

5.91 Dr Freeman explained that research has shown that E-cigarette advertisements may increase a person’s desire to try the products, and if

¹²⁷ Dr Tony Bartone, Vice President, Australian Medical Association (AMA), *Official Committee Hansard*, Melbourne, 5 October 2017, p. 9.

¹²⁸ Dr Becky Freeman, *Submission 249*, p. 1.

¹²⁹ AMA, *Submission 289*, p. 4.

¹³⁰ ACCC, *Submission 224*, p. 2.

¹³¹ ACCC, *Submission 224*, p. 2.

¹³² ACCC, *Submission 224*, p. 3.

¹³³ TSANZ and LFA, *Submission 332*, p. 4.

¹³⁴ Dr Tony Bartone, AMA, *Official Committee Hansard*, Melbourne, 5 October 2017, p. 9.

advertisements show people vaping, they may also increase the urge to smoke tobacco cigarettes.¹³⁵ The AMA and Dr Freeman both considered that advertising of E-cigarettes should be subject to the same restrictions applied to tobacco cigarettes.¹³⁶

5.92 The Australasian Association of Convenience Stores (AACS) explained that currently, E-cigarettes are ‘hidden behind a cupboard door’ in shops, ‘so people do not know they are available to be sold.’¹³⁷ The AACS considered that E-cigarette devices should be more easily accessible, and that information should be available in store about the positives and negatives of E-cigarette use.¹³⁸ The ATA agreed and stated that consumers need to be educated about the potential benefits of E-cigarettes through advertising and other means, to encourage smokers to switch to vaping.¹³⁹ The ATA concluded that therefore ‘advertising restrictions, hiding them with display bans and all those other things will be very counterproductive.’¹⁴⁰

5.93 In contrast, the CCA and NHFA stated that:

Arguments that vaping and its promotion should be exempted from advertising restrictions related to smoking are in our view fallacious, in light of the relationship between vaping and smoking, the involvement of the tobacco industry in seeking to maximise profits from both, and vaping as a precursor to smoking in young people.¹⁴¹

5.94 VicHealth cautioned that E-cigarettes should not be marketed in any way except as a therapeutic good (if approved). VicHealth stated:

There are no health benefits to promoting nicotine products, including [E-cigarettes], to non-smokers and ex-smokers. Indeed, there is potential for harm to non-smokers and ex-smokers by indirectly encouraging uptake of nicotine products and/or smoking. If [E-cigarettes] are approved for use as a

¹³⁵ Dr Becky Freeman, *Submission 249*, p. 1.

¹³⁶ Dr Tony Bartone, AMA, *Official Committee Hansard*, Melbourne, 5 October 2017, p. 9; and Dr Becky Freeman, *Submission 249*, p. 2.

¹³⁷ Mr Jeff Rogut, Chief Executive Officer, Australasian Association of Convenience Stores (AACS), *Official Committee Hansard*, Melbourne, 5 October 2017, p. 24.

¹³⁸ Mr Jeff Rogut, AACS, *Official Committee Hansard*, Melbourne, 5 October 2017, p. 25.

¹³⁹ Mr Tim Andrews, ATA, *Official Committee Hansard*, Melbourne, 5 October 2017, p. 32.

¹⁴⁰ Mr Tim Andrews, ATA, *Official Committee Hansard*, Melbourne, 5 October 2017, p. 32.

¹⁴¹ Cancer Council Australia and the National Heart Foundation of Australia, *Submission 295*, p. 12.

smoking cessation aid, VicHealth strongly recommends that marketing is restricted for that purpose only.¹⁴²

- 5.95 Counterfactual Consulting advised that ‘the approach used to regulate the advertising of alcohol [in Australia] would provide a reasonable starting place’ for the regulation of E-cigarette advertising.¹⁴³
- 5.96 Japan Tobacco International recommended Australia look to the UK Committee of Advertising Practice’s (CAP) guidance regarding the advertising of E-cigarettes.¹⁴⁴ Japan Tobacco International advised that this approach in the UK strikes ‘the right balance between allowing a responsible advertising of electronic cigarettes while preventing the targeting of minors and non-smokers’.¹⁴⁵
- 5.97 The UK CAP guidance included an emphasis on socially responsible marketing; avoiding any association with tobacco; only using approved health claims; prohibition on the use of health professionals to advertise E-cigarettes; factual information about nicotine and other ingredients; and prohibition of marketing to non-smokers and young people.¹⁴⁶

Taxation

- 5.98 The RACP recommended E-cigarettes be ‘subject to Australia’s excise tax, at a lower rate than that of tobacco cigarettes to discourage any E-cigarette users switching to tobacco cigarettes.’¹⁴⁷ Philip Morris agreed and added that taxation should also ‘encourage manufacturers to invest in research and development of smoke-free alternatives to cigarettes.’¹⁴⁸
- 5.99 The RANZCP considered that any tax on E-cigarettes should be minimal to ensure socioeconomically disadvantaged individuals, who are more likely to have a mental illness and more likely to smoke, can access E-cigarette devices.¹⁴⁹

¹⁴² VicHealth, *Submission 327*, p. 2.

¹⁴³ Counterfactual Consulting, *Submission 271*, p. 19.

¹⁴⁴ Japan Tobacco International, *Submission 265*, p. 7.

¹⁴⁵ Japan Tobacco International, *Submission 265*, p. 8.

¹⁴⁶ Japan Tobacco International, *Submission 265*, pp 7-8.

¹⁴⁷ Royal Australasian College of Physicians, *Submission 276*, p. 6.

¹⁴⁸ Philip Morris Limited, *Submission 321.1*, p. 6.

¹⁴⁹ Royal Australian and New Zealand College of Psychiatrists, *Submission 294*, p. 4.

Sales and Product Safety

- 5.100 A number of inquiry participants discussed ways to enhance the safety of E-cigarette liquids and devices. The RANZCP advised that E-cigarette products should be subject to ‘strict regulations’ including:
- Legislated maximum nicotine concentrations for E-liquids; and
 - Requirements for the disclosure, testing and monitoring of E-liquid composition.¹⁵⁰
- 5.101 Japan Tobacco International recommended that E-cigarette manufacturers be required to report to authorities prior to bringing a new product to market. The reporting would include details of the manufacturer, a list of ingredients and their quantities, a list of the main constituents present in emissions, toxicological data, information on nicotine dosage and a description of product components and production processes.¹⁵¹
- 5.102 Philip Morris made a similar point, and added that ‘an abbreviated process should be used where a product has already been approved by a trusted overseas regulator, an approach which has been adopted in New Zealand.’¹⁵²
- 5.103 The appropriate age limit for accessing E-cigarettes was also discussed. Philip Morris and British American Tobacco Australia recommended that sales of E-cigarettes be restricted to persons over 18 years of age.¹⁵³ Associate Professor Mendelsohn stated that while this age limit was the most ‘politically acceptable’ option, two USA studies found that bans on E-cigarette sales to adolescents in some states had led to ‘significantly increased adolescent smoking rates’. As such, Associate Professor Mendelsohn put forward the alternative of allowing ‘youth to purchase E-cigarettes with the explicit permission of a parent, guardian or doctor.’¹⁵⁴

Concluding Comment

- 5.104 The Committee understands that Australia is a world leader on tobacco control and acknowledges the achievements that have been made in halving

¹⁵⁰ Royal Australian and New Zealand College of Psychiatrists, *Submission 294*, pp 2-3.

¹⁵¹ Japan Tobacco International, *Submission 265*, pp 3-4.

¹⁵² Philip Morris Limited, *Submission 321.1*, pp 3, 4-5.

¹⁵³ Philip Morris Limited, *Submission 321*, p. 13; British American Tobacco Australia, *Submission 326*, p. 1.

¹⁵⁴ Associate Professor Colin Mendelsohn, *Submission 258*, p. 21.

the rate of daily smokers over the last 25 years. Care should be taken to ensure this progress is not undermined.

International Regulatory Approaches

- 5.105 Countries around the world have taken a variety of approaches to regulating electronic cigarettes (E-cigarettes). Many of the countries Australia has close links with, such as Canada, the United Kingdom of Great Britain and the United States of America, have, or are in the process of implementing, a liberalised regulatory system for E-cigarettes.
- 5.106 New Zealand, like many countries, is currently in the process of developing its policy response to E-cigarettes. Many public health groups in New Zealand have adopted a different position on E-cigarettes than their Australian counterparts. These New Zealand groups support E-cigarettes having a role in tobacco control, especially as a cessation aid for people who have been unable to quit using other methods and among particular demographics with high smoking rates.
- 5.107 Nevertheless, the Committee agrees with the Department of Health that the actions of other countries are not a sufficient justification for Australia to legalise nicotine E-cigarettes. The Committee also acknowledges that the World Health Organization has encouraged caution in relation to E-cigarettes, particularly for countries like Australia, which already have low smoking rates.

Regulation of E-cigarettes in Australia

- 5.108 The Committee notes there is an existing process for the consideration of nicotine replacement therapies through the Therapeutic Goods Administration (TGA). The Committee believes that this process is adequate for assessing any application for the sale of nicotine E-cigarettes, and the Committee does not recommend changes be made to the existing process.
- 5.109 State and territory regulation of non-nicotine E-cigarettes, and enforcement of these regulations, varies across Australia. The Committee heard from individuals who found it difficult to understand whether they could use E-cigarettes in their state or territory, and what rules applied. The Committee considers that there is a need to ensure that these regulations are applied consistently across Australia.
- 5.110 The Committee heard evidence that the TGA's *Personal Importation Scheme* enables some smokers to access nicotine E-cigarettes using a doctor's prescription and that this could assist long term, heavy smokers to quit

tobacco smoking. Despite this being an existing pathway for smokers to access nicotine E-cigarettes, it is not widely used. The Committee heard evidence that the regulatory paperwork that doctors must fill out so a patient can access this Scheme may be overly burdensome, and that rules regarding the application of this Scheme differ across states and territories.

- 5.111 In Chapter 3, the Committee outlined its concern that the ingredients and flavourings used in non-nicotine E-cigarettes may have negative health impacts, and that further research in this area is needed. The Committee further considers that any regulatory framework for non-nicotine E-cigarettes should assess the ingredients used in E-cigarette liquid and their potential to cause harm.
- 5.112 The Committee received a large amount of evidence from a range of stakeholders as part of this inquiry. While the evidence presented was often conflicting, it was provided in good faith by people wanting to reduce the health burden created by tobacco cigarettes. Having considered this evidence, the Committee is of the view that the current regulatory arrangements for nicotine E-cigarettes remain appropriate. The Committee also considers that further research into the health impacts of E-cigarettes is needed.

Recommendation 3

- 5.113 The Committee recommends a national approach be taken to the regulation of non-nicotine electronic cigarettes.**

Recommendation 4

- 5.114 The Committee recommends that the Therapeutic Goods Administration continues to oversee the classification of nicotine and relevant exemptions, and the assessment of any electronic cigarette product as a therapeutic good.**

Recommendation 5

- 5.115 The Committee recommends that the Australian Government establish a regulatory process for assessing and, if necessary, restricting colourings and flavourings used in electronic cigarettes.**

Mr Trent Zimmerman MP
Chair
15 March 2018

Additional Comments – Mr Steve Georganas MP

As Deputy Chair of the Committee, I believe that nicotine e-cigarettes should be evaluated by independent health experts – not politicians.

I note that the Therapeutic Goods Administration (TGA) rejected an application to allow nicotine use in e-cigarettes in March 2017 (paragraphs 1.35-1.36 refer). Committee Members also note that the National Health and Medical Research Council (NHMRC) concluded in April 2017 that policy makers should act to minimise the harm of nicotine e-cigarettes until ‘evidence of safety, quality and efficacy can be produced’ (1.40-1.41).

The referral also gave Big Tobacco an appalling opportunity to influence tobacco policy in Australia. This appears to have violated the World Health Organization Framework Convention on Tobacco Control by inviting the tobacco industry to submit and testify to the Committee (1.19-1.23). This alarmed some of the Committee Members and experts such as the Australian Medical Association who also testified, and should alarm the Government.

Governments should continue to follow the advice of the independent experts on nicotine e-cigarettes.

Mr Steve Georganas MP
Deputy Chair

Dissenting Report – Mr Trent Zimmerman MP and Mr Tim Wilson MP

The Standing Committee on Health, Aged Care and Sport has undertaken a year-long inquiry into E-cigarettes. The level of interest in this issue from health experts and the broader Australian community is reflected in the large number of submissions and letters received by the Committee with 352 submissions lodged and over 1700 standard letters received from individual Australians.

The issue of whether there should be a change in the current regulation and effective prohibition of E-cigarettes containing nicotine is one that has provoked claim and counter claim. The Committee has received submissions and heard evidence from some of Australia's leading health experts (and many from overseas) on both sides of the debate. Invariably, the contentions made by those participating in the inquiry have been supported by conflicting medical and statistical evidence.

In some respects, this reflects the fact that E-cigarettes have only been readily available in relatively recent times. During that period the technology involved in E-cigarettes has changed significantly and the range of products is considerable (represented by both the E-cigarette device and the liquids used in them).

Attitudes towards E-cigarettes are also influenced by, at times, competing approaches to the management of nicotine addiction and smoking. Some submissions placed greater emphasis on a precautionary approach and tended to oppose change to the current regulatory settings. Others came to the inquiry arguing for a harm minimisation approach leading to the conclusion that

E-cigarettes containing nicotine should be available in Australia to assist people who have unsuccessfully tried other ways to quit smoking.

The Committee also heard evidence that Australia's approach was significantly different to that adopted in other nations with similar cultures and health care systems. Specifically, the United Kingdom (UK), the European Union (EU), the United States of America (US) and New Zealand were frequently cited as jurisdictions in which (while not universal) there was far greater acknowledgement (from regulators and health experts) that E-cigarettes could play a legitimate and valuable role in reducing the negative consequences of smoking. E-cigarettes used with nicotine are legal in the UK, the EU and the US. New Zealand health authorities are advocating a similar approach and, at the time of writing, awaiting a decision from the new national government (the previous government had announced its intention to 'legalise' E-cigarettes with nicotine). While Australia should not automatically follow the lead of other nations, the difference in approaches of other health systems we respect, is striking.

Australia's approach to E-cigarettes is complex and marked by contradictions:

- The use of tobacco-based products for smoking is legal, yet a less harmful nicotine product is effectively prohibited;
- While E-cigarettes containing nicotine cannot be legally bought in Australia, consumers are legally permitted to import nicotine for E-cigarettes through the Therapeutic Goods Administration's (TGA) Personal Importation Scheme if they have a valid prescription from a general practitioner; and
- E-cigarettes which do not contain nicotine can be legally bought and sold in most Australian states and territories, despite much of the concern about the health impact of E-cigarettes presented to this inquiry emanating from the non-nicotine elements of E-cigarette liquids (for example, colour and flavouring).

In the face of often contradictory evidence, this has been a difficult inquiry for the Committee. Having considered the evidence presented to the Committee, however, we have formed a very different view to that reflected in the majority report.

Considerations

In considering the issues presented to the Committee, we believe there are two fundamental questions relevant to the future regulation of E-cigarettes:

- Are E-cigarettes less harmful than smoking and could their use by smokers reduce the health impacts of tobacco and help people quit smoking?
- Would the legal availability of E-cigarettes containing nicotine act as a 'gateway' to smoking and increase the number of smokers, particularly in younger age groups?

The Committee heard considerable evidence about the health impacts of E-cigarettes, with many witnesses arguing that the long-term impacts of E-cigarettes are unknown. Disputed claims which emerged from the UK were that E-cigarettes are 95 per cent less harmful than smoking cigarettes, and pointed to the possible health impacts of additives used to colour and flavour E-cigarette liquids.

The Committee heard evidence that was, at times, contradictory. In particular, some witnesses argued that E-cigarettes were too harmful to be legally available, while concurrently arguing that there was insufficient research into their long-term health impacts.

We accept E-cigarettes have not been the subject of the several-decade longitudinal studies which are often required to determine the health impacts of products such as these. As many witnesses reminded the Committee, it took many years for the full consequences of smoking to become known and agreed.

This is made more challenging by the evolving nature of E-cigarette technology which makes having a single point of reference for assessing the impact of E-cigarettes challenging.

We have, however, formed the view that there is enough evidence to determine that it is highly improbable E-cigarettes will have the health consequences of smoking tobacco cigarettes, which will kill the majority of their long-term users. This is supported by the well-known carcinogenic consequences of burning tobacco, which does not occur in E-cigarettes.

It is worth noting that, to the best of our recollection, no witnesses argued E-cigarettes would have a greater health impact than smoking. The key question is whether E-cigarettes are less harmful to a significant degree. From the evidence presented four conclusions can be drawn:

- The health impacts of E-cigarettes cannot be quantified with precision, however, based on the pharmacology of E-cigarette products and studies conducted to date, their health impacts are likely to be substantially less than those generated by smoking tobacco products. The January 2018 National Academy of Sciences (US) review found that

there was conclusive evidence that the complete substitution of tobacco products with E-cigarettes reduced users' exposure to toxicants and carcinogens.

- While nicotine is highly addictive and there is some conjecture about its long-term health impacts, it is not of itself the principal health risk from either smoking or using E-cigarettes. In E-cigarettes the primary concern relates to the impact of additives, including colouring and flavouring.
- The dual use of tobacco cigarettes and E-cigarettes is unlikely to deliver better health outcomes.
- For nicotine addicts, however, who make the complete switch from smoking to E-cigarettes, it is likely that significant health benefits will be realised.

We accept that E-cigarettes are a valid mechanism for harm reduction for those addicted to nicotine. Harm minimisation is a well-established concept in Australia and other examples in the health sphere include the use of methadone for heroin addicts, needle and syringe exchange programs, and the safe sex messaging used to prevent the transmission of Human Immunodeficiency Virus (HIV) and other sexually transmitted infections.

The Royal College of Physicians of London highlighted, in their submission to the Committee, the role of another form of tobacco in reducing harm in Sweden. *Snus*, an oral form of tobacco, is widely accepted in Sweden and has resulted in that nation having the lowest smoking rates in Europe (7 per cent of the adult population).

In summary, E-cigarettes are not a safe product but they will cause considerably less harm than smoking. Their use by smokers who have tried and failed other ways of quitting could save their lives.

There are legitimate concerns about the health impacts of colour and flavouring used in E-cigarette liquids. In circumstances where E-cigarettes are widely available (legally in most states if they do not contain nicotine), the 'legalisation' of E-cigarettes with a notification system and disclosures in relation to content could assist regulators in improving the safety of E-cigarette products.

The Committee also heard differing opinions about whether E-cigarettes had therapeutic application as a means of allowing smokers to quit.

Goods that promote therapeutic outcomes are required to gain the approval of the TGA before they can be sold in Australia.

The TGA was unable to advise whether it had or had not received any applications for E-cigarette products to be made available for this purpose due to commercial-in-confidence provisions. A number of submitters, however, indicated the cost of bringing a product to market through TGA processes was a very expensive one in circumstances where E-cigarette products are changing as technology evolves.

While we support the TGA's ongoing role in determining whether a product can be sold based on its therapeutic attributes, we note that:

- A large number of individual Australians provided the Committee with details of their own experience in successfully using E-cigarettes as a means of quitting smoking. While the Committee submission process is not a scientific study, it would be wrong to simply dismiss the testimony of many people who have successfully used E-cigarettes in this way.
- Evidence presented from the UK points to the possible benefits of E-cigarettes as a means of quitting. Approximately 1.5 million E-cigarette users in the UK are former smokers. Submitters pointed to other jurisdictions where similar results had been recorded.
- Quitting smoking is hard. Many smokers will try multiple times to quit smoking and fail using existing nicotine replacement therapies, medication or other mechanisms. E-cigarettes provide an additional option for smokers.
- Countries that have made E-cigarettes available have seen a decrease in smoking rates even without many of the complimentary regulations on combustible tobacco that exist in Australia, while consumption of tobacco in Australia has stabilised.

In summary, our view is that E-cigarettes have assisted many people to quit smoking and may have benefits at a population level as a cessation device. We accept, however, that the TGA should continue its role to assess individual products sold for therapeutic purposes.

A frequent concern about E-cigarettes was the possibility that their availability may serve as a 'gateway' into smoking, particularly for young people. Specifically, the Committee was presented with arguments that E-cigarettes could renormalise smoking and could lead to new nicotine addictions and a pathway to tobacco cigarettes.

Again, the Committee heard conflicting evidence from experts in the field.

Our view is that, while this risk needs further investigation and careful monitoring, international examples indicate that smoking rates among younger cohorts continue to fall in many countries where E-cigarettes are widely available.

For example, Cancer Research UK stated that despite the availability of E-cigarettes in the UK there has been ‘no increase in youth smoking of tobacco, which is another important measure in terms of establishing the gateway effect.’

Restrictions on the sale and marketing of E-cigarettes to younger people can help to alleviate this risk.

The risk of a ‘gateway’ effect needs to be weighed against the benefits of people quitting smoking via E-cigarettes. As one UK witness succinctly put it: ‘the gateway in is much, much smaller than the motorway out [of smoking].’

Conclusions

We have considered the possibility of the long-term, negative health impacts of E-cigarettes that could emerge over the coming years or decades. We have also had regard to, on balance, the weight of evidence indicating that using E-cigarettes is less harmful, potentially significantly so, than smoking tobacco cigarettes. As such, while E-cigarettes could be harmful, they are a better option than smoking and their use could save many thousands of lives.

We are also concerned that there is limited regulation of nicotine E-cigarettes, which are already available in Australia via online overseas retailers and the ‘black market’. Nicotine E-cigarettes are widely available, used, but unregulated. A regulated market would help improve product safety and provide more effective controls over E-cigarette marketing and promotion, particularly to young people.

We have therefore formed the conclusion that nicotine E-cigarettes should be available as a consumer good to Australians, subject to regulations which will limit their appeal to non-smokers and young people.

We recommend that:

- Nicotine in E-cigarettes be made exempt from Schedule 7 of the Poisons Standard.
- Legislation be passed to permit the sale, purchase and possession of E-cigarettes with restrictions based on those in place in the EU which include prohibitions on the sale of E-cigarettes to people under 18 years of age, restrictions on advertising and marketing, child proof and tamper proof packaging, a limit on the concentration of nicotine, safety features to reduce the harm of battery explosions, labelling which provides for the listing of ingredients contained in E-cigarette liquids and health warnings about the potential health consequences of using E-cigarettes.

- The Australian government establish a notification system for E-cigarette products entering the market and a regulatory process for assessing and, if necessary, restricting colouring and flavouring used in E-cigarettes.

Mr Trent Zimmerman MP
Chair

Mr Tim Wilson MP
Committee Member

Dissenting Report – Mr Andrew Laming MP

Life is short and shorter for smokers. Just legalise vaping.

Mr Andrew Laming MP
Committee Member

A. Submissions and Form Letters

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- 6 Mrs Sarah Fulton McIsaac
- 7 Mr Destry Hart
- 8 Mr Nathan Barr
- 9 *Name Withheld*
- 10 *Name Withheld*
- 11 *Name Withheld*
- 12 *Name Withheld*
- 13 *Name Withheld*
- 14 *Name Withheld*
- 15 *Confidential*
- 16 Mr Andrew Kiddle
- 17 Mrs Hikmet Yondemli
- 18 Mr Lee Brown
- 19 Mr Brad Ringersma

- 20 Dr Tim Stockwell
- 21 Mr Darren Goring
- 22 Ms Cat Wright
- 23 Mr Colin Whisson
- 24 Mr Robert Adams
- 25 *Name Withheld*
- 26 *Name Withheld*
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- 28 Mr Paul Stevens
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- 41 Mr Shane Presser
- 42 *Name Withheld*
- 43 Mr Cameron Salway
- 44 Ms Margaretha Joyce
- 45 *Name Withheld*
- 46 Ms Anne Hamilton

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- 47 *Name Withheld*
- 48 Mr Harry Vilskersts
- 49 *Name Withheld*
- 50 Mr Scott Wright
- 51 Mr Mathew Sallur
- 52 Mr David Graham
- 53 *Name Withheld*
- 54 *Name Withheld*
- 55 Mr Prakash Balia
- 56 *Name Withheld*
- 57 *Name Withheld*
- 58 *Name Withheld*
- 59 *Name Withheld*
- 60 *Name Withheld*
- 61 *Confidential*
- 62 Mr Ian Strickland
- 63 Mr Paul Adams
- 64 Mr Greg Miller
- 65 Emeritus Professor Ian Webster
- 66 Miss Shannon Janiszewski
- 67 Mr Jarryd Wilson
- 68 Mr Brooke Wilson
- 69 Professor Peter Hajek
- 70 Mr Brendan Cilia
- 71 *Name Withheld*
- 72 Ms Louise Ross
- 73 Mr Dwayne Groom
- 74 *Name Withheld*
- 75 *Name Withheld*

- 76 *Name Withheld*
- 77 *Name Withheld*
- 78 *Name Withheld*
- 79 *Name Withheld*
- 80 *Name Withheld*
- 81 Mr Michael Gorman
- 82 Mr Simon Loxton
- 83 Mr Mark Whitham
- 84 Mrs Fiona Young
- 85 Mr Greg Dare
- 86 Professor Richard Day
- 87 Mr Rodney Bambridge
- 88 Ms Alison Paul
- 89 Mr Phil Perry
- 90 Dr Joe Kosterich
- 91 Mr Ben Grotegoed
- 92 Mr Andrew Ziser
- 93 Australasian Association of Convenience Stores Limited
- 94 Mr Mark Halvorsen
- 95 Mr Keith David Hopper
- 96 Mr Sam Parsons
- 97 *Name Withheld*
- 98 *Name Withheld*
- 99 *Name Withheld*
- 100 Mrs Christine May
- 101 Ms Dianne Gorman
- 102 Mr Dave Chatterton
- 103 Mr Beau Blackley
- 104 Mr Dwayne Archer

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- 105 Ms Bronwyn Cook
- 106 Thibault Dubreuil
- 107 Mr Liam McGreavy
- 108 Mr Anthony Alms
- 109 United Convenience Buyers
- 110 Peregrine Corporation
- 111 Ms Dee White
- 112 Dr Aziz Rahman
- 113 *Name Withheld*
- 114 Mr Gordon Beard
- 115 Mr Daniel Kirton
- 116 *Name Withheld*
- 117 *Name Withheld*
- 118 *Name Withheld*
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- 134 *Name Withheld*
- 135 *Name Withheld*
- 136 *Name Withheld*
- 137 *Name Withheld*
- 138 *Confidential*
- 139 Mr Brendon Douglas
- 140 Mr Adam Bentley
- 141 Mrs Margaret Boyd
- 142 Mr Federico Rebechi
- 143 Mr Drew Harris
- 144 Mr Richard Yeadon
- 145 Mr Paul Marshall
- 146 Mr Jay Cottrell
- 147 Mr Michael Wright
- 148 Mr Patrick Slack
- 149 Mr Emile Fadel
- 150 Mrs Janet Stockley
- 151 Mr Andrew Wall
- 152 Mr Charles Tinch
- 153 Mr Josef Rayment
- 154 Mr Paul Kirkwood
- 155 Mrs Leanne Wall
- 156 Mr Lance Ross
- 157 Ms Annie Hastings
- 158 Dr Michael Baigent
- 159 Dr Catherine Silsbury
- 160 Mr Cameron Fortune
- 161 Mr Matthew Muscat
- 162 Ms Christine Solazzo

- 163 Mr Timothy May
- 164 Professor Sinclair Davidson
- 165 Mr Laurie Flanders
- 166 Professor Paul Haber
- 167 National Health and Medical Research Council
- 168 Mr Ben Rommell
- 169 Mr Alan Ballantyne
- 170 Mr Alex Williams
- 171 Rev Kerry Buckley
- 172 Mrs Nancy Sutthoff
- 173 Dr Richard Hallinan
- 174 Miss Michelle Sawyers
- 175 Dr Stephen Elsom
- 176 Miss Ami Tarasinski
- 177 Mr Joshua Berry-Porter
- 178 *Name Withheld*
- 179 *Name Withheld*
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- 184 Ritchy Group Limited
- 185 Ms Annette Huppatz
- 186 Mr Steven Smith
- 187 Mr Robert Cox
- 188 Ms Rita Danko
- 189 Mr Wayne Guthberlet
- 190 Ms Rebecca Ruwhiu-Collins

- 191 *Name Withheld*
- 192 *Name Withheld*
- 193 *Name Withheld*
- 194 *Name Withheld*
- 195 *Name Withheld*
- 196 Ms Anne Radford
- 197 Mr Gus Meredith
- 198 Mr Mark Dodd
- 199 Mr Jason White
- 200 Ms Colleen Wright
- 201 *Confidential*
- 202 Ms Stacey O'Brien
- 203 *Confidential*
- 204 Mr George Lowe
- 205 Ms Leslie Anderson
- 206 Ms Angela Gordon
- 207 Aotearoa Vaper's Community Advocacy (AVCA)
- 208 Ms Vicki Ryan
- 209 Ms Catherine Lambert
- 210 Dr Neil McKeganey
- 211 Mr Damian Dwyer
- 212 New Nicotine Alliance (UK)
- 213 Mr Terry Brophy
- 214 Mr David Jenkins
- 215 Dr Gary Johns
- 216 Professor Ron Borland
- 217 Dr Benny Monheit
- 218 Mr Jason Santa
- 219 Mr Charles Yates

- 220 Dr Richard Watkins
- 221 Mr David Newell
- 222 New Nicotine Alliance, Australia
- 223 *Confidential*
- 224 Australian Competition and Consumer Commission
- 225 *Name Withheld*
- 226 Department of Health, Queensland Government
- 227 *Name Withheld*
- 228 *Name Withheld*
- 229 *Name Withheld*
- 230 South Australian Government
- 231 TSG ST Helena
- 232 Miss Nicole Daws
- 233 *Name Withheld*
- 234 *Name Withheld*
- 235 Mr Robert Kennedy
- 236 *Name Withheld*
- 237 *Name Withheld*
- 238 *Name Withheld*
- 239 *Name Withheld*
- 240 *Name Withheld*
- 241 *Name Withheld*
- 242 *Name Withheld*
- 243 *Name Withheld*
- 244 *Name Withheld*
- 245 *Confidential*
- 246 Mr Tony Atkinson
- 247 Mr Michael Parker
- 248 Mr John Van Horick

- 249 Dr Becky Freeman
- 250 Mr George Xanthopoulos
- 251 Australian Self-Medication Industry
- 252 Mr Paul McNamara
- 253 Fact Asia Consultants Ltd
- 254 Mr Dean Burgess
- 255 Fontem Ventures
- 256 Centre for Adolescent Health, Royal Children's Hospital
- 257 Vapora Pty Ltd
- 258 Associate Professor Colin Mendelsohn
 - 258.1 Supplementary to submission 258
- 259 Mr Wojtek Stec
- 260 Mr Mike Bailey
- 261 Mr Andrew McKellar
- 262 Mr Brendan Albury
- 263 Mr Charles McCracken
- 264 Ms Jennifer Stone
- 265 Japan Tobacco International
- 266 TSG Franchise Management P/L
- 267 Bettavape
- 268 Mr Chris Robinson
- 269 Associate Professor Renee Bittoun
- 270 Professor Chris Bullen
- 271 Counterfactual Consulting
 - 271.1 Supplementary to submission 271
- 272 Ms Cathy Watson
- 273 Australian Lottery & Newsagents Association
- 274 Australian Vaping Advocacy Trade and Research
- 275 Ms Jeannie Cameron

- 276 Royal Australasian College of Physicians
- 277 End Smoking NZ
- 278 Ms Carmel James
- 279 Mr Chris Baxter
- 280 Royal College of Physicians UK
- 281 Mr Chris Snowdon
- 282 Associate Professor Coral Gartner and Professor Wayne Hall
- 282.1 Supplementary to submission 282
- 283 Dr David Outridge
- 284 Electronic Cigarettes Australia Pty Ltd
- 285 Australian Council on Smoking and Health
- 285.1 Supplementary to submission 285
- 286 Adjunct Professor David T. Sweanor
- 287 Professor Gerry Stimson
- 288 Professor Riccardo Polosa
- 289 Australian Medical Association
- 290 Australian Retailers Association
- 291 Professor Martin McKee
- 292 Western Australian Government
- 293 Pfizer Australia
- 294 The Royal Australian and New Zealand College of Psychiatrists
- 295 Cancer Council Australia and the National Heart Foundation of Australia
- 296 Mr Steve Woodward
- 297 Department of Health
- 297.1 Supplementary to submission 297
- 298 Australian Dental Association
- 299 Broome Regional Aboriginal Medical Service
- 300 National Heart Foundation of Australia, WA Division
- 301 Public Health Association of Australia

- 301.1 Supplementary to submission 301
- 302 Australian Taxpayers' Alliance and MyChoice Australia
- 303 Dr Konstantinos Farsalinos M.D.
- 304 Professor Ann McNeill
- 305 *Name Withheld*
- 306 *Name Withheld*
- 307 *Name Withheld*
- 308 *Name Withheld*
- 309 *Name Withheld*
- 310 *Name Withheld*
- 311 *Name Withheld*
- 312 Mr Paul Blamire
- 313 Emeritus Professor Simon Chapman AO, Professor Mike Daube AO, David Bareham, Associate Professor Matthew Peters
 - 313.1 Supplementary to submission 313
 - 313.2 Supplementary to submission 313
- 314 Master Grocers Australia
- 315 Mister Ecigs
- 316 Mr Stuart Singleton
- 317 Australian Drug Law Reform Foundation
- 318 Mr Steve Douglas
- 319 Vape4life
- 320 Advertising Standards Bureau
- 321 Philip Morris Limited
 - 321.1 Supplementary to submission 321
 - 321.2 Supplementary to submission 321
- 322 Mr Andrew Bryce
- 323 Mr Shane Charlton
- 324 Professor Con Stough
- 325 Mrs Judith Wolters

- 326 British American Tobacco Australia
- 327 VicHealth
- 328 Quit Victoria
- 329 Royal Australasian College of Surgeons
- 330 Mr Terry Barnes
- 331 Mr Daniel Wolters
- 332 Thoracic Society of Australia and New Zealand and Lung Foundation Australia
- 333 NSW Health
- 334 Cignall Tobacconists
- 335 Mr Clive Bates and Associate Professor Colin Mendelsohn
 - 335.1 Supplementary to submission 335
- 336 Public Health England
 - 336.1 Supplementary to submission 336

Form Letters

Form Letter 1 was received from 2 individuals

Form Letter 2 was received from 1695 individuals

Form Letter 3 was received from 7 individuals

B. Exhibits

1. QA Vaping
E-cigarettes: an evidence update, a report commissioned by Public Health England, August 2015.
2. Mr David Nutt
Nutt, D., Phillips, L.D., Balfour, D., Curran, H.V., Dockrell, M., Foulds, J., Fagerstrom, K., Letlape, K., Milton, A., Polosa, R., Ramsey, J., Sweanor, D., *Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach*, European Addiction Research, 2014.
3. Professor Stanton Glantz and David Bareham
David W. Bareham and Stanton A. Glantz, *E-Cigarettes: Use, Effects on Smoking, Risks, and Policy Implications*, Annual Review of Public Health, scheduled for publication March 2018.
4. Peregrine Corporation
Statement from specialists in nicotine science and public health policy, 26 May 2014.
a) Letter to Director General, World Health Organization, 16 June 2014.
5. National Health and Medical Research Council
NHMRC CEO Statement: Electronic Cigarettes (E-Cigarettes), 3 April 2017.
6. Fact Asia
David Sweanor, *Comment: Pragmatism on nicotine could save lives*, Financial Times, 22 February 2017.
a) Vaporised Nicotine Products Bill 2017, Parliament of the Commonwealth of Australia.

b) Public Health England, *E-cigarettes: a developing public health consensus*, July 2016.

7. Mr Chris Snowdon

Christopher Snowdon, *Free Market Solutions in Health – the Case of Nicotine*, Current Controversies Paper No. 45, Institute of Economic Affairs, July 2013.

8. Adjunct Professor David T Sweanor

The Canadian Institutes of Health Research in collaboration with the Tobacco Control Directorate, Health Canada, *Best Brains Exchange Report: Measuring and Managing the Risks and Benefits of Vaping Products in Canada*, 20 March 2017.

9. Dr Karen Counter

Martinne Geller, *Tobacco Group Philip Morris Sees IQOS as Key to Smokeless Future in UK*, Medscape, 3 July 2017.

a) Jonas Z Hines, MD et al, *Electronic Cigarettes as an Introductory Tobacco Product Among Eighth and 11th Grade Tobacco Users – Oregon, 2015*, Morbidity and Mortality Weekly Report, 2017.

b) Claudio Tanner, *E-cigarettes are NOT harmless – chemicals in vaping trigger bladder cancer, study reveals*, 17 May 2017.

10. Emeritus Professor Simon Chapman

Tobacco Control, *Teenagers, Smoking and Transnational Tobacco Corporations: Evidence from Tobacco Industry Documents*, online presentation.

a) Simon Chapman, Mike Daube and Wasim Maziak, *Should e-cigarette use be permitted in smoke free public places? – No*, Tobacco Control.

11. Philip Morris Limited

Philip Morris, *Designing a Smoke-Free Future*.

a) PMI Research and Development, *Executive Summary*, PMI application to the US Federal Food, Drug and Cosmetic Act.

b) PMI Science, *Reduced-Risk Product Scientific Update*, Issue 1, September 2016.

c) PMI Science, *Scientific Update for Smoke-Free Products*, Issue 2, May 2017.

12. Quit Victoria
Copy of Submission from the Cancer Council Australia and the National Heart Foundation Australia.
13. Cormorant Policy Advice
Cormorant Submission to the TGA on an Application to Amend Schedule 7 of the Poisons Standard in Relation to Nicotine, 1 September 2016.
14. Associate Professor Colin Mendelsohn, Dr Alex Wodak and Dr Catherine Silsbury
UK Department of Health; *Towards a Smokefree Generation: A Tobacco Control Plan for England*, July 2017.
15. Associate Professor Colin Mendelsohn
BMJ Article: *Rise in E-cigarette use linked to increase in smoking cessation rates*, Christopher Bullen, 26 July 2017.
a) BMJ Article: *E-cigarette use and associated changes in population smoking cessation: evidence from US current population surveys*, 4 July 2017.
16. National Heart Foundation of Australia
Images used in advertisements in the USA for the marketing of electronic cigarettes.
17. Australian Taxpayers' Alliance
Drug and Alcohol Nurses of Australasia Position Statement #3: *Electronic Cigarettes for Tobacco Harm Reduction*, September 2017.
a) Letter from 69 signatories to the National Health and Medical Research Council seeking a review of the harm minimisation impact of smoking electronic cigarettes, 5 October 2017.
b) Queensland Government, Gold Coast Hospital and Health Service, Correspondence notifying seizure of presumed illegal substances: Vegasm Vape Juice 100 ml and Still Hangin Vape Juice 100ml and Notice of forfeiture of seized thing completed form: Vegasm Vape Juice 100 ml (2100mg/kg Nicotine) and Still Hangin Vape Juice 100 ml (2100 mg/kg Nicotine).
c) Government of Western Australia, Regulatory Support and Training Unit, Correspondence to Australian importer of Nicotine from the United States of America, notifying possible breach of Poisons Act 1964, 20 March 2015.

d) Australian Taxpayers' Alliance, Summary of Australian State and Territory Penalties for the possession, use or obtaining of nicotine for use in personal vaporisers, 5 October 2017.

18. Philip Morris (Australia) Ltd.

Philip Morris Australia New Zealand and the Pacific, and PMI Science, Slides accompanying opening statement, 5 October 2017.

a) Philip Morris International, Sustainability Report, *Communication on Progress, United Nations Global Compact*, 2016.

b) Brochure - Philip Morris International, *Product Acceptance and Usage of IQOS*, July 2017.

19. Cancer Research UK

Cancer Research UK: *List of Funded E-Cigarette Research*.

a) *Young People's Use of E-Cigarettes across the United Kingdom: Findings from Five Surveys 2015–2017*, Linda Bauld et al. August 2017.

20. Philip Morris Australia

Philip Morris International, *Scientific Update for Smoke-Free Products*, November 2017.

21. Professor Riccardo Polosa

Polosa, R., Cibella, F., Caponnetto, P., Maglia, M., Prosperini, U., Russo, C., Tashkin, D., *Health Impact of E cigarettes: A Prospective 3.5 year study of regular daily users who have never smoked*, Scientific Reports, 17 November 2017.

22. Professor Natalie Walker

Bullen, C., Howe, C., Laugesen, M., McRobbie, H., Parag, V., Williman, J., Walker, N., *Electronic cigarettes for smoking cessation: a randomised controlled trial*, The Lancet, 7 September 2013.

a) O'Brien, B., Knight-West, O., Walker, N., Parag, V., Bullen, C., *E cigarettes versus NRT for smoking reduction or cessation in people with mental illness: secondary analysis of data from the ASCEND trial*, Tobacco Induced Diseases, 2015.

b) Walker, N., Laugesen, M., Parag, V., Laking, G., Verbiest, M., Bullen, C., *ASCEND II: A trial to evaluate the effectiveness and safety of combining nicotine patches with E cigarettes (with and without nicotine) plus behavioural support, on smoking abstinence*.

23. New Zealand Parliament Select Committee on Health
Ministry of Health, *Exploring why young Maori women smoke*, July 2017.
24. National Heart Foundation of Australia
Stratton, K., Kwan, K.Y., Eaton, D.L., *Public Health Consequences of E-Cigarettes*, Committee on the Review of the Health Effects of Electronic Nicotine Delivery Systems, the National Academies Press, Washington.
a) National Academies of Sciences, Engineering and Medicine, *Public Health Consequences of E-Cigarettes: Conclusions by Level of Evidence*.
25. Professor Mike Daube AO
Media Release, 27 November 2017.

C. Hearings and Witnesses

Wednesday, 12 July 2017 - Sydney

British American Tobacco Australia

- Dr Sandra Costigan, Principal Toxicologist Vaping Products

New Nicotine Alliance Australia

- Dr Attila Danko, President

Associate Professor Colin Mendelsohn, Private capacity

Australian Drug Law Reform Foundation

- Dr Alex Wodak, President

Friday, 8 September 2017 - Canberra

Department of Health

- Dr Lisa Studdert, Acting Deputy Secretary
- Mr George Masri, Assistant Secretary
- Adjunct Professor John Skerritt, Deputy Secretary

National Health and Medical Research Council

- Professor Anne Kelso, Chief Executive Officer
- Ms Samantha Robertson, Executive Director

Australian Competition and Consumer Commission

- Mr Richard Fleming, General Manager – Enforcement ACT

National Heart Foundation of Australia

- Mr Maurice Swanson, Chief Executive (WA Division)

Cancer Council Australia

- Mr Paul Grogan, Director of Public Policy, Acting Chair, Tobacco Issues Committee

The Royal Australian and New Zealand College of Psychiatrists

- Dr Shalini Arunogiri, Chair, Faculty of Addiction Psychiatry

Emeritus Professor Simon Chapman, Private capacity

Professor Wayne Hall, Private capacity

Associate Professor Coral Gartner, Private capacity

Dr Becky Freeman, Private capacity

Thursday, 5 October 2017 - Melbourne

Thoracic Society of Australia and New Zealand

- Professor Anne Holland, Board Director, Clinical Care and Resources
- Professor Bruce Thompson, Treasurer and Board Director, Finance, Risk and Audit Compliance

Australian Medical Association

- Dr Tony Bartone, Vice-President

Public Health Association of Australia

- Professor Michael Moore, Chief Executive Officer
- Ms Danielle Dalla, Policy and Communications Manager

Royal Australian College of General Practitioners

- Associate Professor John Litt, Deputy Chair, RACGP Expert Committee – Quality Care

Australasian Association of Convenience Stores Limited

- Mr Jeff Rogut, Chief Executive Officer

Australian Retailers Association

- Mr Heath Michael, Director, Policy, Government and Corporate Affairs

Australian Taxpayers' Alliance

- Mr Tim Andrews, Executive Director

Australian Vaping Advocacy, Trade and Research

- Mr Savvas Dimitriou, Chairperson

Philip Morris Limited

- Mr Mark Powell, Manager, Public Policy
- Dr Maurice Smith, Scientific Affairs Fellow

Wednesday, 18 October 2017 – Canberra

All-Party Parliamentary Group for E-cigarettes, United Kingdom Parliament

- Mr Mark Pawsey MP, Chairman
- Mr Glyn Davies MP, Secretary
- Viscount Matthew Ridley, Vice Chair

Public Health England

- Professor John Newton, Director of Health Improvement
- Rosanna O'Connor, Director, Alcohol, Drugs and Tobacco
- Martin Dockrell, Tobacco Control Lead

Thursday, 19 October 2017 – Canberra

- Mr Clive Bates, Director, Counterfactual Consulting
- Mr Stephen Woodward, Private capacity

Wednesday, 25 October 2017 – Canberra

UK Vaping Industry Association

- Mr Doug Mutter, Board Member
- Mr John Dunne, Board Member
- Mr James Hargrave, Public Affairs Manager

Cancer Research UK

- Mr George Butterworth, Tobacco Policy Manager
- Ms Alyssa Best, Tobacco Control Policy Advisor

D. Meetings in New Zealand

Monday, 18 December 2017 — Auckland

Action on Smoking and Health (ASH)

- Mr Ben Broughton, Programme Manager
- Mr Ben Youdon

Professor Hayden McRobbie, Chair, Technical Experts Advisory Group

National Institute for Health Innovation, Auckland University

- Dr Natalie Walker, Honorary Associate Professor in Population Health
- Dr Marjolein Verbiest, Research Fellow

Tuesday, 19 December 2017 — Wellington

Australian High Commission to New Zealand

- Mr Andrew Cumpston, Chargé d'affaires
- Ms Alana Mackay, First Secretary

Ministry of Health, New Zealand

- Dr Stewart Jessamine, Director Protection, Regulation and Assurance
- Ms Sally Stewart, Senior Advisor Tobacco Control Program
- Ms Haley Ataera, Manager, Regulatory Practice and Analysis, Ministry of Health

Australian-NZ Parliamentary Friendship Group

- Mr Chris Bishop MP, Co-Convenor

New Zealand Select Committee on Health

- Ms Louisa Wall MP, Chair
- Dr Liz Craig MP, Member
- Hon Nicky Wagner MP, Member
- Ms Angie Warren-Clark MP, Member

Wednesday, 20 December 2017— Wellington*Hon Jenny Salesa, Associate Minister of Health**New Zealand Cancer Society*

- Mr Mike Kernaghan, Manager and National Strategic Advisor
- Mr Shayne Nahu, Health Promotion and Campaigns Manager
- Dr Rachel Nicholls, Health Promotion Advisor