Standing Committee on Health, Aged Care and Sport
Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia

July 2017

Submission from Cancer Council Australia and
the National Heart Foundation of Australia

Responsibility for content: Professor Sanchia Aranda, CEO, Cancer Council Australia, President, Union for International Cancer Control; Maurice Swanson, Tobacco Control Spokesperson, National Heart Foundation of Australia, President, Australian Council on Smoking and Health

Overview

There is insufficient evidence to support the efficacy of e-cigarette use to assist people to quit smoking.[1,2] There is growing evidence of e-cigarette use as a precursor to smoking in young people.[3,4]

A meta-analysis of nine separate studies tracking 17,389 people aged 14 to 30, published this month by the *Journal of the American Medical Association* (*Paediatrics*), reported initial e-cigarette users were more than three times more likely than non-e-cigarette users to subsequently become tobacco smokers.[5] Findings were similar across the research, including a study of 10 public high schools in Los Angeles, California, which showed 25.2% of e-cigarette users smoked tobacco compared with 9.3% of non-users.[6]

There are other examples, such as a separate cross-sectional analysis, also published in *JAMA,* which tracked circa 40,000 US school students and reported a clear association between e-cigarette use and tobacco smoking in adolescents.[7] It is a growing trend, which in our view explains why:

- the WHO recommends caution on e-cigarettes, particularly in countries with low smoking prevalence (noting Australia has 2% teenage smoking prevalence and among the world's lowest smoking rates overall);[8,9]
- Australia's independent statutory health authorities have assessed the evidence and recommended caution[10] and a continuation of current nicotine poison controls;[11] and
- the tobacco industry, which is investing heavily in the e-cigarette market, is aggressively promoting e-cigarette availability, particularly to young people – while maintaining the vast majority of its business investment in smoked tobacco.[12]

These and other evidence and observations are summarised in this submission, which we commend to the committee. Parliamentary inquiries are in our view a useful way to explore a topic in the public interest and to collect evidence and a range of perspectives; we therefore welcome the opportunity to submit.

In taking the opportunity to contribute to this inquiry, we also note that several of the issues raised have been addressed by Australia's National Health and Medical Research Council and the Therapeutic Goods Administration, which have the appropriate statutory authority, processes and frameworks to make evidence-based, scientific recommendations and contribute directly to executive government policy. We support their findings, and their

research, evaluation and advisory roles more broadly on matters of public health and medical science.

Cancer Council Australia and the National Heart Foundation of Australia are the nation's largest not-for-profit health organisations and were established to lead in the independent development and promotion of interventions for reducing the burden of cancer and cardiovascular disease. Smoking is the leading cause of preventable cancer and cardiovascular death and disease in Australia. Reducing its harms is what we do. If the balance of evidence supported e-cigarettes as an aid to quitting and a net public health benefit, we would expect Australia's statutory health authorities to facilitate their availability.

The current public health evidence, however, does not support e-cigarette use in any form.[13] We will continue to monitor the evidence with interest, while emphasising that individual opinions, personal convictions and industry lobbying are not public health evidence.

Moreover, on the matter of industry lobbying, it is in our view important to highlight to the Parliament Australia's obligations under Article 5.3 of the WHO Framework Convention on Tobacco Control[14] (signed and ratified by Australia in 2004), which states:

> "In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law."

Addressing the terms of reference

1. The use and marketing of e-cigarettes and personal vaporisers to assist people to quit smoking

Use of e-cigarettes/personal vaporisers to assist people to quit smoking

NHMRC determinations

There is no conclusive evidence to support the efficacy of e-cigarette use to assist people to quit smoking.[15,16] Australia's leading independent statutory health and medical research agencies have investigated the use of e-cigarettes as an aid to cessation and concluded that the evidence of benefit is insufficient and is outweighed by evidence of harm.

In April 2017, the CEO of Australia's National Health and Medical Research Council (NHMRC) reported that "there is currently insufficient evidence to conclude whether e-cigarettes can assist smokers to quit". The conclusion drew on findings from eight prior and concurrent NHRMC research projects funded since 2011, through a total of $6.5 million in grants, to investigate the potential benefits and risks of e-cigarette use in Australia.[17]

The 2017 report from the NHMRC was a strengthening of the cautionary advice in a previous NHMRC summary statement, in 2015, at which point $1 million in NHMRC funds had been allocated to research the potential benefits and risks of e-cigarettes.

TGA determinations

The Therapeutic Goods Administration (TGA) is a statutory authority, established *inter alia* to "monitor and evaluate the safety and efficacy (performance) profile of therapeutic products and to manage any risks associated with individual products". The TGA's brief includes recommendations on the control of poisons in products that claim a health benefit.

In 2016 and 2017, the TGA undertook a review and public consultation on options for the scheduling of nicotine, following attempts to bypass existing poison controls to access liquid nicotine for vaporising. In evaluating the risks and benefits of a change in the scheduling of liquid nicotine, the TGA determined that the evidence on the risks of harms from electronic nicotine delivery system (ENDS) was significantly stronger than evidence of benefit.[18]

The TGA has not approved e-cigarettes for therapeutic use, and has since stated:

> *"*Unlike Nicotine Replacement Therapy (NRT) products, which have been rigorously assessed for efficacy and safety and, therefore, approved by the Therapeutic Goods Administration for use as aids in the withdrawal from smoking, no assessment of electronic cigarettes has been undertaken and, therefore, the quality and safety of electronic cigarettes is not known."[7]

While Cancer Council and the National Heart Foundation are non-government, not-for-profit organisations, we have long supported the independence and rigour of the NHMRC and TGA processes. We rely on their independence and defer to their systematic frameworks in areas such as the scientific merit of our own research programs and the evaluation of therapeutic goods such as sunscreens and nicotine replacement therapy.

These agencies, underpinned by independence, sound process and scientific rigour, are the benchmarks for risk-benefit analyses of health claims and pillars of Australia's health system. Their recommendations on e-cigarettes, and the evidence and processes that informed them, are publicly available.

We have nonetheless undertaken our own review of the literature on e-cigarettes (as per previously published position[19]) and have also concluded that the demonstrated (see following) and potential harms outweigh the potential benefits. As well as the evidence of vaping and subsequent tobacco use among young people,[20] there is also evidence of dual use among smokers,[21,22,23] and concerns of e-cigarette use being associated with delaying or compromising a quit attempt. Even studies that found some potential benefit of e-cigarettes also found a significant level of tandem e-cigarette and smoked tobacco use.[24,25,26]

If the balance of evidence changed and the potential benefits were subsequently shown to outweigh the demonstrated and potential harms, we would expect Australia's independent health authorities to facilitate the availability of e-cigarettes to those likely to benefit – under appropriate controls for products that claim to assist people with a chemical addiction and at risk of health harms.

Marketing of e-cigarettes and personal vaporisers

E-cigarettes are marketed with techniques designed to appeal to young people[27] and glamorise the products[28], with unfounded, misleading claims about benefits, safety of use and quitting assistance.[29,30,31] Commercial approaches to e-cigarette marketing are consistent with evidence that 1) e-cigarettes are significantly more popular among younger adults and adolescents than older age groups; and 2) e-cigarettes confer no conclusive health benefit, otherwise they could be marketed as a therapeutic good (and comply with TGA regulations in doing so) rather than as a style accessory or form of recreation. Fundamental to Australia's success in reduced cigarette use in younger people has been its de-normalisation, which, as demonstrated in Appendix 1, is under threat by the tobacco industry and other e-cigarette entrepreneurs.

Children are at particularly high risk of the harms of e-cigarettes, which are designed to be inhaled into the lung and have not been subject to appropriate safety assessments. Children are also a target market for e-cigarette entrepreneurs, including the tobacco industry. E-cigarettes come in a range of flavours including fruit, confectionary, chocolate, energy drink and other varieties that appeal to children and young adults.

These approaches to e-cigarette marketing and the targeted market segment of young people is out of step with (unsubstantiated) claims that e-cigarettes are a cessation aid or harm-minimisation alternative for heavily addicted, long-term smokers – most of whom are in significantly older age groups.[32]

A 2014 *Eurobarometer for Tobacco* survey reported that people aged 15-24 were more receptive to design and packaging features when choosing an e-cigarette brand, further indicating the effects of e-cigarette advertising on attracting younger users.[33]

In our view, 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.

2. The health impacts of the use of e-cigarettes and personal vaporisers

Catalyst for smoking

In April 2017, Australia's NHMRC stated that there "is some evidence from longitudinal studies to suggest that e-cigarette use in non-smokers is associated with future uptake of tobacco cigarette smoking".[34]

In the two months since this statement, a meta-analysis published by the *Journal of the American Medical Association* (*Paediatrics*) reported that people aged 14 to 30 who had initiated e-cigarette use were more than three times as likely as non e-cigarette users to become tobacco smokers.[35] The systematic review, of nine separate studies published in the US and the UK, was based on a sample size of 17,389 adolescents and young adults. There are other examples.[36] It is part of a continuing trend corroborating our initial concerns about the risks of e-cigarette exposure and subsequent tobacco use in younger people and reinforcing the need for caution in the regulation of e-cigarettes.

The association between e-cigarette use and subsequent tobacco smoking would, in our view, also in part explain the aggressive promotion of e-cigarettes by tobacco companies and the marketing techniques designed to appeal to younger people.

Therefore, considerations of the health impacts of e-cigarettes should factor in the associated long-term harms of increased tobacco smoking in younger people. This risk is particularly relevant to Australia, given only 2% of Australian teenagers are current smokers,[37] a record low rate which should be protected and improved. While the demonstrated harms of e-cigarettes in isolation (see following), it is critical to also note the growing evidence of e-cigarettes as a precursor to smoking in young people.

Comparisons with smoked tobacco

In April 2017, the NHMRC advised 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".[38]

Our analysis is consistent with the NHMRC's advice, noting that it is too early for conclusive evidence on the harms of e-cigarettes compared with tobacco smoking. Claims that e-cigarettes are "95% safer" than tobacco smoke, however, are unfounded and devoid of any scientific basis. Their propagation is redolent of the misleading claims of harm-reduction made about tobacco products over many years – claims that would be unlawful if e-cigarettes were approved for use in Australia as a therapeutic good.

These comparisons are in any case of limited scientific value in a public health context, in the absence of conclusive evidence to show e-cigarettes are an aid to quitting tobacco use.

E-cigarette health effects in isolation

The NHMRC further advises that "e-cigarettes may expose users to chemicals and toxins such as formaldehyde, heavy metals, particulate matter and flavouring chemicals, at levels that have the potential to cause adverse health effects". Propylene glycol and glycerin are often added to e-liquids as humectants. Both substances when overheated can produce dangerous levels of the carcinogens formaldehyde and acetaldehyde.[39,40] Health harms associated with inhaling vaporised nicotine, and nicotine exposure generally, include:

- 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.[41]

Studies have also shown that nicotine can directly contribute to both the onset and growth of various forms of cancer[42,43] and can compromise the effectiveness of cancer treatments such as chemotherapy and radiotherapy.[44]

The UK Royal College of Physicians has noted that some of the carcinogens and other toxins present in tobacco smoke have also been detected in e-cigarette vapour, which raises the possibility that long-term use might increase the risk of lung cancer, cardiovascular, chronic pulmonary obstructive disorders and other smoking-related diseases.[45]

There are also practical risks in the widespread availability of liquid nicotine. For example, a retrospective analysis in the US journal Paediatrics found that "frequency of exposures to e-cigarettes and nicotine liquid among young children is increasing rapidly and severe outcomes are being reported".[46]

The random mixing of nicotine and direct inhalation with multiple other substances could pose a number of unknown health risks. It is difficult to imagine Australian parents of adolescents and young adults being comfortable with their children, few of whom are at risk of being long-term smokers on a population level, being lured into nicotine addiction and vaping. Yet the marketing of e-cigarettes[47] (see Appendix 1) clearly targets younger people.

3. International approaches to legislating and regulating the use of e-cigarettes

WHO advice

In 2014, the WHO published a comprehensive international analysis of e-cigarette use, evidence on risks and benefits, and specific country approaches to legislation/regulation, advising that:

> "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 ENDS [electronic nicotine delivery system] will not significantly decrease smoking-attributable disease and mortality even if the full theoretical risk reduction potential of ENDS were to be realized".[48]

Australia's extraordinarily low smoking prevalence, particularly among younger people, adds significant weight to the WHO advice in a domestic context.

The WHO report pre-dates trend data showing an increased association between e-cigarette initiation in young people and subsequent tobacco use. It also pre-dates last month's Australian Institute of Health and Welfare data reporting that: only 2% of Australian teenagers are smokers; and younger people are trying electronic cigarettes at double the rate of older age groups.[49]

These findings in the context of WHO international data and advice are in our view further vindication of the cautionary approach recommended by Australia's independent statutory health and medical authorities.[50]

The report also advises that there is wide variation in legislative and regulatory approaches to e-cigarettes (with and without nicotine) worldwide, with "ENDS with nicotine banned in 13 of the 59 countries that regulate them. However, the majority of these 13 countries report that ENDS are available to the public, probably through illicit trade and cross-border Internet sales".[51]

There have been further developments since the 2014 WHO report; Appendix 2 is a summary of international arrangements.

Importance of protecting Australian achievements

In our view, consideration of international approaches to e-cigarette controls is of limited benefit, given:

- Australia's extraordinarily low smoking rates, particularly among young people (who are most aggressively targeted by the tobacco industry and other e-cigarette entrepreneurs);[52]
- Australia's global standing as a leader in tobacco control policy (the reason for the outstanding successes in reduced prevalence); and
- The integrity and effectiveness of Australia's world-leading statutory authorities on medical research and therapeutic goods, which have already provided precautionary advice on e-cigarette use and availability, specific to Australia.

Countries with comparable economies, political systems and demographics, such as New Zealand [53] and the UK,[54] have higher smoking prevalence than Australia.[55]

In our view, most Australians if informed of the evidence on e-cigarette use and risks, Australia's record on smoking prevalence and the integrity of our statutory authorities, would question the logic of seeking to learn from countries that have inferior outcomes to ours.

4. The appropriate regulatory framework for e-cigarettes and personal vaporisers in Australia

Nicotine is a highly addictive chemical. Tobacco cigarettes, the most prevalent delivery device for nicotine, are the leading cause of preventable disease in Australia.[56]

E-cigarette proponents (advocates and/or entrepreneurs) claim that e-cigarettes are a safe (or less harmful) delivery system for nicotine.[57] The appropriate regulatory framework for controlling their availability is therefore the TGA, whose remit includes to "monitor and evaluate the safety and efficacy (performance) profile of therapeutic products and to manage any risks associated with individual products".

In the absence of effectiveness of e-cigarettes as an aid to quitting, rhetoric from e-cigarette proponents has shifted from cessation to "harm minimisation". Evidence shows there are only two effective ways to minimise the long-term harms of smoking – to quit or to avoid take-up.[58,59,60] E-cigarettes are unproven as an aid to quitting but increasingly shown as a lure to take-up – hence the tobacco industry and other commercial interests seeking to subvert the TGA.

Products that claim to minimise substance use harms are invariably assessed for risk, benefit and appropriate controls by the TGA. This has already occurred in respect of liquid nicotine for vaporising.[61] Attempts to bypass this process, and in the absence of any new evidence of benefit, would in our view be a "shifting of the goalposts" to accommodate commercial interests and individual advocates.

If e-cigarettes are not a therapeutic good – and some proponents clearly believe they are not, hence the push to bypass TGA – they are in our view either a device promoted to minimise harm without the evidence, or they are a style accessory. A snapshot of how they are currently promoted, at Appendix 1, suggests they are the seen as the latter by entrepreneurs and other lobbyists.

If the weight of evidence shifts and the vaporising of liquid nicotine and its delivery are assessed by the TGA as beneficial to public health, such substances and devices would not be marketed as they currently are – any more than naltrexone, methadone or other scheduled narcotics and poisons aimed at minimising the harms of chemical addiction.

The TGA is the appropriate regulatory framework for e-cigarettes. The appropriate framework for monitoring the ongoing health and medical research evidence on risks and benefits more broadly is the NHMRC.

These exercises have been undertaken; the NHMRC is continuing its investigation, a process we support. Any attempt to bypass these processes would, in our view, be 1) an unprecedented circumventing of Australia's independent health and medical authorities; 2) a concession that lobbying and opinion are more important than process and evidence; and 3) if driven by tobacco industry interests, a breach of Australia's obligations under Article 5.3 of the WHO Framework Convention of Tobacco Control.[62]

5. Any other related matter

We are aware of the rhetoric from lobbyists for e-cigarettes to be exempted from legislative and regulatory instruments, and international conventions, relating to tobacco control. This in our view is patently absurd, as e-cigarettes are promoted (without evidence) as a way to minimise tobacco harms and are being aggressively promoted by the tobacco industry lobby and its agents. As well as a delivery device for nicotine (the chemical driver of tobacco

addiction) they are, as the evidence increasingly shows, a lure to increase tobacco use. Therefore, separating e-cigarettes from mechanisms relating to tobacco is illogical and will only play into the hands of vested interests whose objective is to get more people using e-cigarettes and nicotine, for commercial gain irrespective of public health risks.

The notion that tobacco companies, which continue to expand their tobacco smoking markets wherever possible (thankfully not in Australia), are promoting e-cigarettes at the risk of compromising their main profit-making business would be laughable. It is, however, no laughing matter that these companies are notorious for subverting attempts to reduce their profiteering worldwide, at the cost of millions of lives.

The tobacco industry has a long history of lies and deceit, as well as intentionally designing cigarettes to make them more addictive, and misleading the public about harms from products such as lower tar cigarettes. Tobacco companies active in Australia have a long history of opposing and undermining the work of governments and non-government health authorities to reduce smoking and its harms. This includes litigation in national and international courts and tribunals to oppose the Australian government's policies. It is for these reasons that 168 countries worldwide, as signatories on the WHO Framework for Convention on Tobacco Control, have supported the convention's Article 5.3 to develop and promote public health policies without the malign interference of the tobacco industry.

Any information provided by tobacco companies should in our view be seen in this light.

Our organisations have been at the forefront of advocacy for all interventions in Australia shown to reduce smoking prevalence and its harms – dating back to the introduction of text warnings on packets in the 1960s. Tobacco control is core business for us, and every effective intervention we have recommended has been opposed by the tobacco industry and its agents. If governments in Australia continue to do more of what works (including mass-media campaigns, which have waned in recent years) to reduce the harms of smoking, we could reach a point within the next generation when smoking and nicotine addiction are a marginal activity in young adults.

In the meantime, if the balance of evidence on health impacts of e-cigarettes were to indicate a public health benefit, we would be advocates for their availability, under appropriate controls. But it does not. Conversely, evidence on the association between e-cigarette use and smoking in young people is growing, along with evidence of the harms of e-cigarette use in isolation.

References

1 NHMRC CEO Statement: Electronic Cigarettes (e-cigarettes). Australian Government National Health and Medical Research Council; 2017 [Accessed 29 June 2017] Available from https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/ds13_nhmrc_ceo_statement_ecigarettes.pdf

2 Malas M, van der Tempel J, Schwartz R, Minichiello A, Lightfoot C, Noormohamed A, et al. Electronic cigarettes for smoking cessation: a systematic review. Nicotine & Tobacco Research. 2016;18(10):1926-36.

3 Soneji S, Barrington-Trimis JL, Wills TA, Leventhal AM, Unger JB, Gibson LA, et al. Association Between Initial Use of e-Cigarettes and Subsequent Cigarette Smoking Among Adolescents and Young Adults, A Systematic Review and Meta-analysis. JAMA Pediatrics. Published online June 26, 2017.

4 NHMRC CEO Statement: Electronic Cigarettes (e-cigarettes). Australian Government National Health and Medical Research Council; 2017 [Accessed 29 June 2017] Available from https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/ds13_nhmrc_ceo_statement_ecigarettes.pdf

5 Soneji S, Barrington-Trimis JL, Wills TA, Leventhal AM, Unger JB, Gibson LA, et al. Association Between Initial Use of e-Cigarettes and Subsequent Cigarette Smoking Among Adolescents and Young Adults, A Systematic Review and Meta-analysis. JAMA Pediatrics. Published online June 26, 2017.

6 Leventhal AM, Strong DR, Kirkpatrick MG, Unger JB, Sussman S, Riggs NR, et al. Association of electronic cigarette use with initiation of combustible tobacco product smoking in early adolescence. Jama. 2015;314(7):700-7.

7 Dutra LM, Glantz SA. Electronic cigarettes and conventional cigarette use among US adolescents: a cross-sectional study. JAMA pediatrics. 2014;168(7):610-7.

8 WHO Framework Convention on Tobacco Control Conference of the Parties, 'Electronic nicotine delivery systems and electronic non-nicotine delivery systems', FCTC/COP6(9)(18 October 2014).

9 Australian Institute of Health and Welfare. 2016 National Drug Strategy Household Survey. 2017 [Accessed 29 June 2017] Available from: http://www.aihw.gov.au/alcohol-and-other-drugs/data-sources/ndshs-2016/data/

10 NHMRC CEO Statement: Electronic Cigarettes (e-cigarettes). Australian Government National Health and Medical Research Council; 2017 [Accessed 29 June 2017] Available from https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/ds13_nhmrc_ceo_statement_ecigarettes.pdf

11 Therapeutic Goods Administration. Electronic cigarettes. Australian Government Department of Health; 2015 [Accessed 29 June 2017] Available from: http://www.tga.gov.au/consumers/ecigarettes.htm

12 E-Cigarette Market In The U.K. Part 2: Big Tobacco Enters The Fray, Forbes Business News, 2016, Available: https://www.forbes.com/sites/greatspeculations/2016/02/02/e-cigarette-market-in-the-u-k-part-2-big-tobacco-enters-the-fray/#70e5be4632f1

13 Ibid.

14 World Health Organization, Framework Convention on Tobacco Control. Article 5.3. Available: http://www.who.int/tobacco/wntd/2012/article_5_3_fctc/en/

15 NHMRC CEO Statement: Electronic Cigarettes (e-cigarettes). Australian Government National Health and Medical Research Council; 2017 [Accessed 29 June 2017] Available from https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/ds13_nhmrc_ceo_statement_ecigarettes.pdf

16 https://www.tga.gov.au/book-page/21-nicotine

17 Ibid.

18 https://www.tga.gov.au/book-page/21-nicotine

19 http://www.cancer.org.au/policy-and-advocacy/position-statements/smoking-and-tobacco-control/#jump_8

20 Ibid.

21 Chaloupka FJ. Tobacco Control Policy and Electronic Cigarettes. JAMA Pediatr. 2014.

22 US Centers for Disease Control summary. Available at: https://www.cdc.gov/tobacco/campaign/tips/diseases/dual-tobacco-use.html

23 Manzoli et al, Cohort study of electronic cigarette use: effectiveness and safety at 24 months, British Medical Journal 2016. http://tobaccocontrol.bmj.com/content/early/2016/06/06/tobaccocontrol-2015-052822.

24 Schneider et al, Vaping as a Catalyst for Smoking? An Initial Model on the Initiation of Electronic Cigarette Use and the Transition to Tobacco Smoking Among Adolescents, Nicotine & Tobacco Research, 2015.

25 Hitchman et al, Associations Between E-Cigarette Type, Frequency of Use, and Quitting Smoking: Findings From a Longitudinal Online Panel Survey in Great Britain, Nicotine & Tobacco Research, 2015.

26 Brose et al, Is the use of electronic cigarettes while smoking associated with smoking cessation attempts, cessation and reduced cigarette consumption? A survey with a 1-year follow-up, Addiction Journal, 2015.

27 Editorial. Time for e-cigarette regulation. The Lancet Oncology. 2013;14(11):1027.

28 Grana RA, Glantz SA, Ling PM. Electronic nicotine delivery systems in the hands of Hollywood. Tobacco Control. 2011;20(6):425–6.

29 World Health Organization Study Group on Tobacco Product Regulation. Report on the scientific basis of tobacco product regulation: third report of a WHO study group. Geneva, Switzerland: 2009 WHO Technical Report Series 955.

30 Cobb NK, Brookover J, Cobb CO. Forensic analysis of online marketing for electronic nicotine delivery systems. Tobacco Control. 2013. Epub 17 September 2013.

31 Australian Competition and Consumer Commission. 'E-cigarette companies to pay penalties.' (Media release, MR 61/17, 8 May 2017). [Accessed 29 June 2017]. Available from: www.accc.gov.au/media-release/e-cigarette-companies-to-pay-penalties.

32 Ibid

33 Laverty AA, Vardavas CI, Filippidis FT. Design and marketing features influencing choice of e-cigarettes and tobacco in the EU. The European Journal of Public Health. 2016;26(5):838-41.

34 NHMRC CEO Statement: Electronic Cigarettes (e-cigarettes). Australian Government National Health and Medical Research Council; 2017 [Accessed 29 June 2017] Available from https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/ds13_nhmrc_ceo_statement_ecigarettes.pdf

35 Soneji S, Barrington-Trimis JL, Wills TA, Leventhal AM, Unger JB, Gibson LA, et al. Association Between Initial Use of e-Cigarettes and Subsequent Cigarette Smoking Among Adolescents and Young AdultsA Systematic Review and Meta-analysis. JAMA Pediatrics. Published online June 26, 2017.

36 Ibid.

37 Australian Institute of Health and Welfare. 2016 National Drug Strategy Household Survey. 2017 [Accessed 29 June 2017] Available from: http://www.aihw.gov.au/alcohol-and-other-drugs/data-sources/ndshs-2016/data/

38 NHMRC CEO Statement: Electronic Cigarettes (e-cigarettes). Australian Government National Health and Medical Research Council; 2017 [Accessed 29 June 2017] Available from https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/ds13_nhmrc_ceo_statement_ecigarettes.pdf

39 Kosmider L, Sobczak A, Fik M, Knysak J, Zaciera M, Kurek J, et al. Carbonyl compounds in electronic cigarette vapors: effects of nicotine solvent and battery output voltage. Nicotine & Tobacco Research. 2014;16(10):1319-26.

40 Jensen RP, Luo W, Pankow JF, Strongin RM, Peyton DH. Hidden formaldehyde in e-cigarette aerosols. New England Journal of Medicine. 2015;372(4):392-4.

41 Mishra A, Chaturvedi P, Datta S, Sinukumar S, Joshi P, Garg A. Harmful effects of nicotine. Indian journal of medical and paediatric oncology: official journal of Indian Society of Medical & Paediatric Oncology. 2015;36(1):24.

42 Grando SA. Connections of nicotine to cancer. Nature Reviews Cancer. 2014;14(6):419-29.

43 Bavarva JH, Tae H, Settlage RE, Garner HR. Characterizing the genetic basis for nicotine induced cancer development: a transcriptome sequencing study. PloS one. 2013;8(6):e67252.

44 Sanner T, Grimsrud T, Nicotine: Carcinogenicity and Effects on Response to Cancer Treatment – A Review, Frontiers in Oncology, 2015.

45 Physicians TAGotRCo, editor. Nicotine without smoke-tobacco harm reduction. Royal College of Physicians; 2016.

46 Kamboj et al, Pediatric Exposure to E-Cigarettes, Nicotine, and Tobacco Products in the United States, journal of Paediatrics, 2016.

47 Ibid.

48 WHO Framework Convention on Tobacco Control Conference of the Parties, 'Electronic nicotine delivery systems and electronic non-nicotine delivery systems', FCTC/COP6(9)(18 October 2014).

49 Australian Institute of Health and Welfare. 2016 National Drug Strategy Household Survey. 2017 [Accessed 29 June 2017] Available from: http://www.aihw.gov.au/alcohol-and-other-drugs/data-sources/ndshs-2016/data/

50 Ibid.

51 WHO Framework Convention on Tobacco Control Conference of the Parties, 'Electronic nicotine delivery systems and electronic non-nicotine delivery systems', FCTC/COP6(9)(18 October 2014).

52 Ibid.

53 http://www.smokefree.org.nz/smoking-its-effects/facts-figures

54https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandlifeexpectancies/bulletins/adultsmokinghabitsingreatbritain/2016

55 Australian Institute of Health and Welfare. 2016 National Drug Strategy Household Survey. 2017 [Accessed 29 June 2017] Available from: http://www.aihw.gov.au/alcohol-and-other-drugs/data-sources/ndshs-2016/data/

56 AIHW Burden of Disease in Australia 2016, http://www.aihw.gov.au/publication-detail/?id=60129555173.

57 Individual comments tendered to this inquiry.

58 NHMRC CEO Statement: Electronic Cigarettes (e-cigarettes). Australian Government National Health and Medical Research Council; 2017 [Accessed 29 June 2017] Available from https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/ds13_nhmrc_ceo_statement_ecigarettes.pdf

59 Malas M, van der Tempel J, Schwartz R, Minichiello A, Lightfoot C, Noormohamed A, et al. Electronic cigarettes for smoking cessation: a systematic review. Nicotine & Tobacco Research. 2016;18(10):1926-36.

60 Therapeutic Goods Administration. Electronic cigarettes. Australian Government Department of Health; 2015 [Accessed 29 June 2017] Available from: http://www.tga.gov.au/consumers/ecigarettes.htm

61 Ibid.

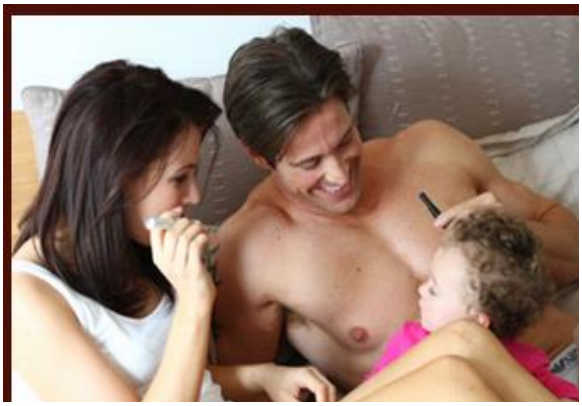
62 Ibid.

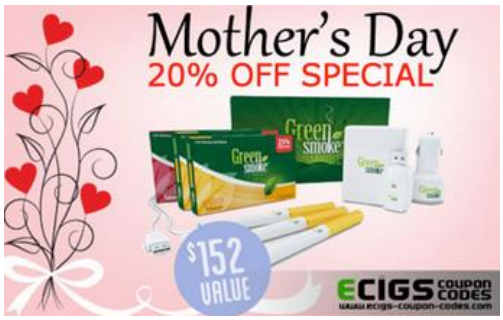
Appendix 1 – flavours and advertising techniques

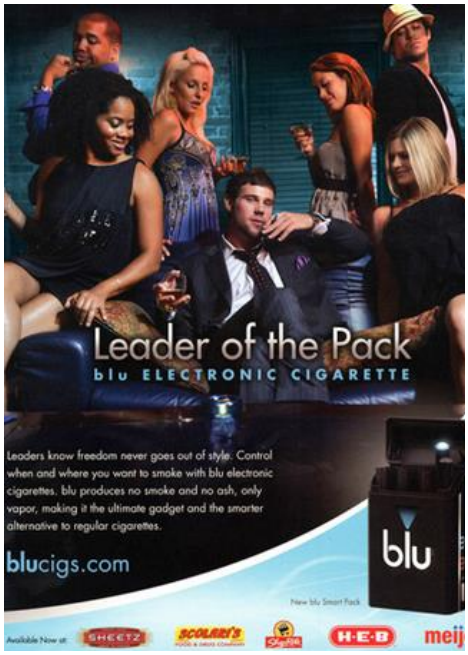
A Google search on multiple keyword combinations (e.g. “e-cigarettes + buy online”, “e-cigarettes + flavours” etc.) will bring up thousands of hits, directing the user to websites and purchasing options – many of which feature flavours such as traditional tobacco, energy drink, cookies and cream, vanilla, ganja, tutti-frutti and bubble gum. The deliberate enticements to young people, and the allusions to tobacco, are in our view highly inappropriate for the promotion of goods which claim to aid smoking cessation and/or minimise the harms of chemical addiction. Moreover, some e-cigarette advertising, with its allusions to smoking behaviour, would potentially be a breach of advertising restrictions aimed at de-glamorising smoking.

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 (see full submission).

Unsubstantiated health claims that pervade e-cigarette advertising further highlight the risks of bypassing Australia’s statutory health and medical authorities, and their role in assessing goods making such claims and regulating how they are labelled and promoted. Below are examples of how e-cigarettes are promoted in the US, without the protections provided in Australia – noting that these types of promotions are difficult to enforce online. These include enticements to vape around babies and small children, despite evidence of noxious emissions and nicotine as a poison hazard.*







*C/O: http://tobacco.stanford.edu/tobacco_main/subtheme.php?token=fm_tn_mt035.php

Appendix 2

E-cigarette regulation by country

A recent review of e-cigarette regulations by the Institute for Global Tobacco Control found that 79 countries have national or federal laws regulating e-cigarettes, as detailed in the table below. The Table has been developed to represent the information provided by the Institute for Global Tobacco Control.[1]

Policy Domain	Number of Countries	Countries
Prevention of Sale to Minors		
Minimum age for purchase (ranging from 18 to 21 years)	28	Bulgaria, Costa Rica, Croatia, Cyprus, Denmark, Ecuador, Estonia, Fiji, Finland, France, Germany, Honduras, Italy, Lithuania, Malaysia, Netherlands, New Zealand, Norway, Poland, Portugal, Republic of Korea, Scotland, Slovenia, Spain, Togo, Ukraine, United States and Vietnam
Regulation of Retail Sale		
Ban on the sale of all types of e-cigarettes	27	Argentina, Bahrain, Brazil, Brunei Darussalam, Cambodia, Colombia, Gambia, Greece, Jordan, Kuwait, Lebanon, Mauritius, Nepal, Nicaragua, Oman, Panama, Qatar, Saudi Arabia, Seychelles, Singapore, Suriname, Thailand, Turkey, Turkmenistan, Uganda, United Arab Emirates and Uruguay
Marketing/authorisation requirement or cross-border sale restrictions	33	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, England, Estonia, Fiji, Finland, France, Germany, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Northern Ireland, Norway, Philippines, Poland, Portugal, Romania, Scotland, Slovakia, Slovenia, United States, Venezuela and Wales
Ban on the sale of nicotine e-cigarettes	9	Australia, Canada, Costa Rica, Jamaica, Japan, Malaysia, Mexico, New Zealand and Switzerland
Advertising, Promotion and Sponsorship		
Prohibition or restrictions on the advertising, promotion and sponsorship of all types of e-cigarettes	58	Argentina, Australia, Austria, Bahrain, Belgium, Brazil, Bulgaria, Canada, Colombia, Costa Rica, Croatia, Cyprus, Czech Republic, Denmark, Ecuador, England, Estonia, Fiji, Finland, France, Gambia, Germany, Greece, Honduras,

		Hungary, Iceland, Ireland, Italy, Japan, Jordan, Latvia, Lithuania, Malta, Mexico, Nepal, Netherlands, New Zealand, Norway, Panama, Poland, Portugal, Qatar, Republic of Korea, Romania, Saudi Arabia, Scotland, Seychelles, Slovakia, Slovenia, Spain, Togo, Turkmenistan, United Arab Emirates, United States, Uruguay, Venezuela, Viet Nam and Wales
Advertising restrictions on nicotine e-cigarettes only, or on e-cigarettes that are regulated as medicines	6	Canada, Costa Rica, Ecuador, Japan, Mexico and New Zealand
Product Packaging		
Requirement for child safe packaging	27	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, England, Estonia, Finland, France, Germany, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Northern Ireland, Philippines, Poland, Portugal, Romania, Scotland, Slovakia, Slovenia, United States and Wales
Mandatory health warnings	28	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, England, Finland, France, Germany, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Northern Ireland, Poland, Portugal, Republic of Korea, Romania, Scotland, Slovakia, Slovenia, United States and Wales
Product Regulation		
Restriction on the concentration of nicotine in e-liquids	26	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, England, Estonia, Finland, France, Germany, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Northern Ireland, Poland, Portugal, Romania, Scotland, Slovakia, Slovenia, and Wales
Prohibition on the use of ingredients (other than nicotine) in e-liquids that pose a risk to human health	26	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, England, Estonia, Finland, France, Germany, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Northern Ireland, Poland, Portugal, Romania, Scotland, Slovakia, Slovenia, and Wales
Regulations affecting the quality of nicotine and other ingredients and the use of flavours	26	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, England, Estonia, Finland, France, Germany, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Northern Ireland, Philippines, Poland, Portugal,

		Romania, Scotland, Slovakia, Slovenia, and Wales
Reporting/Notification		
Manufacturers/retailers required to notify authorities prior to entering the market, and to submit sales reports and other specified information	27	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, England, Estonia, Finland, France, Germany, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Northern Ireland, Poland, Portugal, Romania, Scotland, Slovakia, Slovenia, United States and Wales
Product Use		
Restrictions or prohibition on the use of e-cigarettes in public places	39	Argentina, Australia, Austria, Bahrain, Barbados, Belgium, Brazil, Brunei Darussalam, Cambodia, Colombia, Costa Rica, Croatia, Cyprus, Denmark, Ecuador, Estonia, Fiji, Finland, France, Greece, Honduras, Jamaica, Jordan, Malta, Nepal, Panama, Philippines, Poland, Portugal, Republic of Korea, Slovenia, Spain, Thailand, Togo, Turkmenistan, Ukraine, United Arab Emirates, Venezuela and Vietnam
Total ban on the use of e-cigarettes	6	Cambodia, Jordan, Nepal, Panama, Turkmenistan and United Arab Emirates
Ban on the use of e-cigarettes by minors	3	Estonia, Germany and Lithuania
Ban on the use of e-cigarettes in vehicles with minors	3	Cyprus, Finland and Slovenia

[1] Institute for Global Tobacco Control. Country Laws Regulating E-cigarettes: A Policy Scan. Baltimore, MD: Johns Hopkins Bloomberg School of Public Health. http://globaltobaccocontrol.org/e-cigarette/country-laws-regulating-e-cigarettes [June 5, 2017]