Australian Government

Department of Health

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

AUSTRALIAN GOVERNMENT
DEPARTMENT OF HEALTH

SUBMISSION

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Executive Summary

The Australian Government Department of Health believes a precautionary approach to e-cigarettes and personal vaporisers is warranted, consistent with the harm minimisation principles which underpin the National Tobacco Strategy (NTS) 2012-2018 and Australia's policy framework for other drugs.

There is currently 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. The wide variation in e-cigarette products and ingredients make it difficult to assess the safety of e-cigarettes as a group, and their long-term health effects remain unknown.

In addition to the lack of evidence about the effectiveness of e-cigarettes as smoking cessation aids, or about the extent of their potential harms, the Department is concerned about evidence suggesting that e-cigarettes may provide a gateway to nicotine addiction or tobacco use (particularly among youth), and may re-normalise 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.

In Australia, all products making therapeutic claims, including those claiming to help people quit smoking, are required to be authorised by the Therapeutic Goods Administration (TGA). No e-cigarettes have yet been approved by the TGA as smoking cessation aids, meaning that unlike all approved smoking cessation therapies available for sale in Australia, they have not been evaluated for their quality, safety and efficacy.

Currently, there is no international consensus on the most appropriate regulatory framework for e-cigarettes and there is significant variation in the regulatory treatment of e-cigarettes within and between countries. In Australia, the 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.

It is important that e-cigarette regulation takes a comprehensive, precautionary, evidence-based and proportionate approach that can be adapted as new evidence emerges. Regulation should aim to protect the Australian community from the potential harms of e-cigarette use and ensure that e-cigarette use does not undermine Australia's significant tobacco control efforts.

This submission will respond to each term of reference of the inquiry, in turn.

E-cigarettes and personal vaporisers

Personal vaporisers are considered to be a heterogeneous category of products which deliver an aerosol and/or vapour via inhalation. Broadly, these products (and/or their components):

- May or may not contain tobacco and/or nicotine;
- May to a greater or lesser extent resemble tobacco products and/or simulate the act of smoking;

- May or may not use electrical power to generate an aerosol; and
- Include but are not limited to e-cigarettes.[1]

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

Australian Government Department of Health position on e-cigarettes

The Department is concerned about the marketing and use of e-cigarettes due to the limited evidence on their safety and efficacy for smoking cessation or harm reduction. There are also concerns about the risks they pose to population health, in particular their impact on Australia's tobacco control efforts and the unknown inhalation toxicity of their ingredients (including for bystanders).

The Department is taking a precautionary approach to e-cigarettes and is continuing to examine the current regulatory framework governing these products. The Department's precautionary approach to e-cigarettes is consistent with the current regulatory controls governing access to nicotine for use in e-cigarettes in Australia. This approach is also based on the need to consider the overall impacts that e-cigarettes may have on population health, including on non-smokers and smokers.

There is also a need to consider the most appropriate policy response to e-cigarettes for the Australian context, in particular with regard to their potential use in smoking cessation.

Despite nicotine being widely available for use in e-cigarettes in a number of regions overseas, this alone does not justify widespread access to nicotine for use in e-cigarettes in Australia, especially given Australia's favourable progress in tobacco control to date.

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

General considerations
There is currently insufficient evidence to demonstrate that e-cigarettes are effective in assisting people to quit smoking[2]. Current available evidence in this area 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.[3]

A systematic review undertaken by the Cochrane Collaboration in 2016 identified some evidence that e-cigarettes with nicotine may assist people to quit smoking.[4] Of the 24 completed studies considered by the review's authors, however, only two showed that the use of e-cigarettes with nicotine increased the chances that people would cease smoking in the long term compared with e-cigarettes without nicotine. The remaining 22 studies

1 Also commonly referred to as electronic cigarettes, electronic nicotine delivery systems (ENDS) and electronic non-nicotine delivery systems (ENNDS).

2 NHMRC CEO Statement: Electronic Cigarettes (E-Cigarettes). 2017. Available at: https://www.nhmrc.gov.au/_files_nhmrc/file/publications/17072_nhmrc_-_electronic_cigarettes-web_final.pdf.

3 Electronic nicotine delivery systems and electronic non-nicotine delivery systems. 2016. Conference of the Parties to the WHO Framework Convention on Tobacco Control. Available at: http://www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf

4 J. Hartmann-Boyce, H. McRobbie, C. Bullen, R. Begh, L. F. Stead and P. Hajek, "Electronic Cigarettes for Smoking Cessation (Review)" *Cochrane Database of Systematic Reviews*, no. 9, 2016.

either did not follow participants for a sufficient length of time to allow robust conclusions to be drawn, or did not place participants into treatment groups and therefore could not directly compare the effectiveness of e-cigarettes with other possible smoking cessation aids. The authors considered that the quality of the evidence overall was low, as it was based only on a small number of studies. In the authors' views, more studies of e-cigarettes are needed.

Concerns about the effectiveness of e-cigarettes as smoking cessation aids have been raised in a number of additional studies and by a number of leading public health bodies. In its 2015 position on tobacco smoking and e-cigarettes, the Australian Medical Association (AMA) expressed 'significant concerns about e-cigarettes'.[5] The AMA recommended that e-cigarettes 'must not be marketed as smoking cessation aids as such claims are not supported by evidence at this time'. Similar concerns have been expressed by the Royal Australian College of General Practitioners (RACGP) [6], which has noted that 'further research is needed before recommendations for their use can be confidently made', including in the context of smoking cessation and harm reduction. The Cancer Council of Australia[7] has expressed concern that claims that e-cigarettes can assist smokers in quitting smoking are 'unsubstantiated'. Broadly similar views to these have been put forward by a substantial number of public health bodies and experts.[8]

In addition to those in Australia, various public health bodies and experts based overseas have also formed the view that current evidence does not provide a sufficient basis for supporting e-cigarettes as smoking cessation aids. The United States Surgeon-General has stated that the evidence supporting the effectiveness of e-cigarettes as aids for quitting smoking is unproven. Furthermore, the World Health Organization (WHO), in its report to the seventh session of the Conference of the Parties to the WHO Framework Convention on Tobacco Control (FCTC) noted that 'scientific evidence regarding the effectiveness of ENDS/ENNDS as a smoking cessation aid is scant and of low certainty, making it difficult to draw credible inferences'.[9]

Additional considerations

The optimal health outcome for smokers is to quit smoking. Despite this, there is no definitive evidence that users of e-cigarettes (with or without nicotine) are more likely than smokers using other methods (including those who quit unaided) to quit smoking.

However, there is evidence suggesting that a considerable number of existing smokers who use e-cigarettes may become dual users of cigarettes and e-cigarettes.[10,11] Whilst this

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5 Australian Medical Association. AMA Position Statement: Tobacco Smoking and E-cigarettes. 2015. Available at: https://ama.com.au/position-statement/tobacco-smoking-and-e-cigarettes-2015.

6 Royal Australian College of General Practitioners. Clinical Guidelines, Supporting Smoking Cessation: A Guide for Health Professionals. Unproven approaches to smoking cessation. Melbourne: The Royal Australian College of General Practitioners, 2011. Available at: http://www.racgp.org.au/your-practice/guidelines/smoking-cessation/behavioural-and-advice-based-support-for-smoking-cessation/unproven-approaches-to-smoking-cessation/.

7 Cancer Council of Australia. Position Statement – Electronic Cigarettes. 2015. Available at: http://wiki.cancer.org.au/policy/Position_statement_-_Electronic_cigarettes.

8 See, eg, S. Chapman, "Twelve myths about e-cigarettes that failed to impress the TGA", 2017, The Conversation. Available at: https://theconversation.com/twelve-myths-about-e-cigarettes-that-failed-to-impress-the-tga-72408.

9 Electronic nicotine delivery systems and electronic non-nicotine delivery systems. 2016. Conference of the Parties to the WHO Framework Convention on Tobacco Control. Available at: http://www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf.

10 Kaufman AR, Land S, Parascandola M, et al. Tobacco use transitions in the United States: The National Longitudinal Study of Adolescent Health. Prev med 2015;81.

11 Reid JL, Rynard VL, Czoli CD, et al. Who is using e-cigarettes in Canada? Nationally representative data on the prevalence of e-cigarette use among Canadians. Prev Med 2015.

outcome may reduce daily consumption of cigarettes[12,13,14], 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. [15,16, 17, 18]

Statements provided by a number of organisations, including the National Health and Medical Research Council, AMA, and the RACGP have noted that instead of reducing the prevalence of smoking, e-cigarette use may conversely provide a gateway to nicotine addiction or tobacco use, and may re-normalise smoking. While no firm conclusions in this area can be drawn based on current available evidence, key studies have supported these statements.[19, 20, 21] Recent studies have also shown that e-cigarette use is related to increases in the frequency and quantity of cigarette smoking[22] and may make it more difficult for smokers to quit.[23] Concerns that flavoured e-cigarettes have magnified the potential for increased tobacco use are well documented, particularly in the context of their appeal to youth and young adults.[24] Some studies have also indicated that perceptions, again particularly those among youth, that e-cigarettes are less harmful than cigarettes are motivations for their use.[25]

In summary, the Department is concerned that e-cigarettes may be perpetuating the tobacco epidemic by reducing smoking cessation and expanding the nicotine market, including by attracting people (particularly youth) who would otherwise be unlikely to initiate smoking with the use of conventional cigarettes.[26]

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12 McRobbie H, Bullen C, HartmannBoyce J, Hajek P. Electronic cigarettes for smoking cessation and reduction. Cochrane Database of Systematic Reviews. 2014(12).

13 Bullen C, Howe C, Laugesen M, McRobbie H, Parag V, Williman J, et al. Electronic cigarettes for smoking cessation: a randomised controlled trial. Lancet. 2013;382(9905):1629-37.

14 Adkison SE, O'Connor RJ, Bansal-Travers M, Hyland A, Borland R, Yong HH, et al. Electronic nicotine delivery systems: international tobacco control four-country survey. American journal of preventive medicine. 2013;44(3):207-15.

15 Pisinger C, Godtfredsen NS. Is there a health benefit of reduced tobacco consumption? A systematic review. Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco. 2007;9(6):631-46.

16 Tverdal A, Bjartveit K. Health consequences of reduced daily cigarette consumption. Tob Control. 2006;15(6):472-80.

17 Hart C, Gruer L, Bauld L. Does smoking reduction in midlife reduce mortality risk? Results of 2 long-term prospective cohort studies of men and women in Scotland. American journal of epidemiology. 2013;178(5):770-9.

18 Song YM, Sung J, Cho HJ. Reduction and cessation of cigarette smoking and risk of cancer: a cohort study of Korean men. Journal of clinical oncology: official journal of the American Society of Clinical Oncology. 2008;26(31):5101-6.

19 SK. Chatterjee, B. Alzghoul, A. Innabi and N. Meena, "Is Vaping a Gateway to Smoking: a Review of the Longitudinal Studies" *Int J Adolesc Med Health*, 2016.

20 J. L. Barrington-Trimis, R. Urman, K. Berhane, J. B. Unger, T. B. Cruz, M. A. Pentz, J. M. Samet, A. M. Leventhal and R. McConnell, "E-Cigarettes and Future Cigarette Use" *Pediatrics*, vol. 138, no. 1, 2016.

21 T. R. Spindle, M. M. Hiler, M. E. Cooke and T. Eissenberg, "Electronic Cigarette Use and Uptake of Cigarette Smoking: A Longitudinal Examination of U.S. College Students" *Addictive Behaviors*, vol. 67, pp. 66-72, 2017.

22 T. A. Wills and J. D. Sargent, "Do E-cigarettes reduce smoking?" Preventative Medicine, no. 100, 2017. N Doran et al, "Does e-cigarette use predict cigarette escalation? A longitudinal study of young adult non-daily smokers", *Preventative Medicine*, no. 100, 2017. See also Gmel G, Baggio S, Mohler-Kuo M, Daeppen JB, Studer J. E-cigarette use in young Swiss men: is vaping an effective way of reducing or quitting smoking? Swiss Med Wkly. 2016 Jan 11;146:w14271. doi: 10.4414/smw.2016.14271. eCollection 2016. http://www.smw.ch/content/smw-2016-14271/. This study found that non-smokers who used e-cigarettes were more likely to be smokers one year later than non-smokers who did not use e-cigarettes. Further, smokers who used e-cigarettes were less likely to have quit smoking a year later.

23 See Kalkhoran, Sara et al. *The Lancet Respiratory Medicine*, Volume 4, Issue 2, 2016, 116 – 128.

24 NHMRC CEO Statement: Electronic Cigarettes (E-Cigarettes). 2017. Available at: https://www.nhmrc.gov.au/_files_nhmrc/file/publications/17072_nhmrc_-_electronic_cigarettes-web_final.pdf.

25 See, eg, Gorukanti A, Delucchi K, Ling P, Fisher-Travis R, Halpern-Felsher B. 2017. Adolescents' attitudes towards e-cigarette ingredients, safety, addictive properties, social norms, and regulation. *Prev Med* 94: 65-71.

26 See S. Soneji, JL Barrington-Trimis, TA Wills, A Leventhal, JB Unger, et al. 2017. E-Cigarette Use and Subsequent Cigarette Smoking Among Adolescents and Young Adults: A Systematic Review and Meta-Analysis. *JAMA Pediatrics*. This study reported that there is consistent and strong evidence that e-cigarette use is associated with increased odds of subsequent cigarette smoking initiation and current cigarette smoking among adolescents and young adults.

The health impacts of the use of e-cigarettes and personal vaporisers [27,28]

General considerations

The Department is aware of claims made by some stakeholders that e-cigarettes are around 95 per cent safer to users than smoking tobacco products. However, the Department also notes that this estimate has been disputed in several leading international medical journals, such as the Lancet[29] and British Medical Journal[30], and by experts.[31] It is also inconsistent with the position of numerous public health bodies, including the WHO, US Centers for Disease Control and Prevention and the European Commission. On the basis of currently available evidence, the relative safety of e-cigarettes compared to tobacco smoking cannot be scientifically established.[32]

Summary of potential health risks associated with e-cigarettes

Even e-cigarettes that do not contain nicotine have been associated with health risks. 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. The health impacts of exposure to the toxicants in e-cigarette aerosol are not well understood, though several are known carcinogens. The detection and level of these carcinogens depend on several factors, including the concentration of the e-liquid and the strength of the heating device itself. The wide variation in products and the ability of users to customise their vaping experience, makes it difficult to assess the safety and efficacy of e-cigarettes as a group, because the results from research involving one particular product may not be applicable to all e-cigarettes or all users.

Potential health risks associated with nicotine in e-cigarettes

There are significant risks associated with exposure to nicotine. Nicotine is highly addictive and there is a risk of nicotine dependence when used with e-cigarettes.[33] Additionally, nicotine is highly toxic and poses significant health risks including adverse cardiovascular, respiratory, and reproductive effects and negative effects on foetal and adolescent development.[34] Evidence from the International Agency for Research on Cancer suggests that nicotine is associated with DNA damage and other pathways of carcinogenesis.[35] Exposure to nicotine in adolescents via e-cigarettes may have long-term consequences for brain development, potentially leading to learning and mood

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27 U.S. Department of Health and Human Services. *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General.* Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.

28 NHMRC CEO Statement: Electronic Cigarettes (E-Cigarettes). 2017.

29 The Lancet, "Public Health England's Evidence-Based Confusion". *The Lancet*, vol. 386, p. 829, 2015.

30 M. Mckee and S. Capewell, "Evidence about Electronic Cigarettes: Foundation Built on Rock or Sand?" BMJ, vol. 351, 2015.

31 See, eg, S. Chapman, "Keep TGA control of e-cigarettes or risk repeating the smoking health disaster", 20 June 2017, available at: http://www.smh.com.au/comment/keep-tga-control-of-ecigarettes-or-risk-repeating-the-smoking-health-disaster-20170619-gwtyux.html.

32 Electronic nicotine delivery systems and electronic non-nicotine delivery systems. 2016. Conference of the Parties to the WHO Framework Convention on Tobacco Control. Available at: http://www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf.

33 U.S. Department of Health and Human Services. *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014. M. J. Schroeder and A. C. Hoffman, "Electronic cigarettes and nicotine clinical pharmacology", *Tobacco Control*, 23, 2016.

34 U.S. Department of Health and Human Services, 2014.

35 WHO IARC. 2014. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Report to the Advisory Group to Recommend Priorities for IARC Monographs during 2015-2019. Available at: https://monographs.iarc.fr/ENG/Publications/internrep/14-002.pdf.

disorders.[36]

Some overseas studies suggest that e-cigarettes containing nicotine may be dangerous, delivering unreliable doses of nicotine (above or below the stated quantity), or containing toxic chemicals or carcinogens, or leaking nicotine. Dangerous and lethal doses of nicotine can be absorbed through the skin. Exposure to e-cigarette nicotine liquid is a poisoning hazard for the user of electronic cigarettes, as well as others around them, particularly children. United States studies have shown significant increases in calls to poison centres regarding e-cigarette exposures.[37] For example, calls to the United States National Poison Data System regarding e-cigarette exposures in children under the age of six increased 1,492.9 per cent between 2012 and 2015, and a one year old child died following exposure to nicotine liquid in the United States in 2014.[38]

Further information about the potential health effects associated with e-cigarettes including reported adverse events and passive exposure to e-cigarette vapour is provided in a recently updated statement published by the Chief Executive Officer of the National Health and Medical Research Council on 3 April 2017, available at: https://www.nhmrc.gov.au/_files_nhmrc/file/publications/17072_nhmrc_-_electronic_cigarettes-web_final.pdf.

International approaches to legislating and regulating the use of e-cigarettes and personal vaporisers

General considerations
There is currently no international consensus on the most appropriate regulatory framework for e-cigarettes.

In the Department's view, the fact that e-cigarettes with nicotine are legal in some other jurisdictions in the European Union and the United States are not reasons to allow widespread access to nicotine for use in e-cigarettes in Australia, especially with the success in decreasing smoking in Australia without them.

The regulatory arrangements applicable to e-cigarettes vary considerably within and across counties, ranging from prohibition to minimal or no regulation. Broadly, e-cigarettes may be regulated under various regulatory frameworks that apply to tobacco products, poisons, medicines (including medical devices) and consumer products. In some countries such as the United Kingdom, e-cigarettes containing nicotine are regulated either as consumer tobacco products or as medicines depending whether smoking cessation claims are made for the particular product.

Summary of regulatory arrangements applicable to e-cigarettes in Australia
In Australia, e-cigarette regulation is a shared responsibility between the Commonwealth, state and territory governments. The current regulatory framework draws on existing legislation and regulations that may apply to tobacco products, poisons, therapeutic goods

36 U.S. Department of Health and Human Services, 2016.

37 K. Chatham-Stephens, R. Law, E. Taylor, S. Kieszak, P. Melstrom, R. Bunnell, B. Wang, H. Day, B. Apelberg, L. Cantrell, H. Foster and J. G. Schier, "Exposure Calls to U. S. Poison Centers Involving Electronic Cigarettes and Conventional Cigarettes-September 2010-December 2014" *Journal of Medical Toxicology*, 2016.

38 A. Kamboj, H. A. Spiller, M. J. Casavant, T. Chounthirath and G. A. Smith, "Pediatric Exposure to E-Cigarettes, Nicotine, and Tobacco Products in the United States" Pediatrics, vol. 137, no. 6, 2016.

and consumer goods. Further information about the regulatory arrangements applicable to e-cigarettes in Australia is provided at **Attachment A**.

United States[39]

In August 2016, the United States Food and Drug Administration (FDA) finalised a new deeming rule for tobacco products, including e-cigarettes. The FDA now regulates the manufacture, import, packaging, labelling, advertising, promotion, sale, and distribution of e-cigarettes. A range of restrictions apply, including bans on the sale of e-cigarettes to minors and bans on free e-cigarette samples. Although e-cigarettes (with or without nicotine) are currently available for sale in the United States, following a transition period, e-cigarette manufacturers will have to show that their products meet the applicable public health standard set by the law, and will have to receive marketing authorisation from the FDA. Sub national laws may also apply to e-cigarettes in the United States. For example, in some states, taxes apply to e-cigarettes and/or nicotine for use in e-cigarettes.

Europe [40]

The regulatory arrangements applicable to e-cigarettes in Europe vary considerably, including among countries that are Members of the European Union (EU). From May 2016, new rules applied to Members of the EU (including the United Kingdom) under the Tobacco Products Directive. The Tobacco Products Directive is applicable to e-cigarettes containing nicotine and includes safety and quality requirements (including maximum nicotine concentrations), packaging and labelling requirements and monitoring and reporting requirements for e-cigarette manufactures, importers, EU Member States and the European Commission.

New Zealand (NZ)[41]

Currently, the regulation of e-cigarettes (including restrictions on the supply of nicotine for use in e-cigarettes) is broadly comparable to Australia. However, subject to the passage of legislation by the New Zealand Parliament, the sale and supply of e-cigarettes (including nicotine for use in e-cigarettes) will be legalised as consumer products from 2018 at the earliest. As part of this approach, new measures are proposed in relation to age restrictions, sale in vending machines, advertising, smoke-free areas and product safety.

Other Countries

As at 2014, a number of other countries, including Brazil,[42] Singapore,[43] Uruguay,[44] Jordan,[45] Oman[46] and Qatar,[47] have also banned the sale of e-cigarettes (with or without nicotine).

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

39 Further information is available at: https://www.fda.gov/tobaccoproducts/labeling/productsingredientscomponents/ucm456610.htm.

40 Further information is available at: http://europa.eu/rapid/press-release_IP-16-1762_en.htm.

41 Further information is available at: http://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/e-cigarettes.

42 Further information is available at: http://www.who.int/tobacco/surveillance/policy/country_profile/bra.pdf

43 Further information is available at: http://www.who.int/tobacco/surveillance/policy/country_profile/sgp.pdf?ua=1

44 Further information is available at: http://www.who.int/tobacco/surveillance/policy/country_profile/ury.pdf?ua=1

45 Further information is available at: http://www.who.int/tobacco/surveillance/policy/country_profile/jor.pdf?ua=1

46 Further information is available at: http://www.who.int/tobacco/surveillance/policy/country_profile/omn.pdf?ua=1

47 Further information is available at: http://www.who.int/tobacco/surveillance/policy/country_profile/qat.pdf?ua=1

The Department recognises the importance of taking an evidence-based approach to e-cigarettes. Evidence from the evaluation of tobacco control measure suggests that a comprehensive response to e-cigarettes may be required, which is consistent with best practice as outlined in the WHO FCTC.

Globally, e-cigarettes may to a greater or lesser extent be perceived as a smoking cessation therapy, despite their as yet unproven role for this purpose. As such, future potential national policy directions for e-cigarettes will need to consider the marketing and use of e-cigarettes in this context. In this regard, the Department notes that unlike any e-cigarette product, all other smoking cessation therapy products (such as nicotine replacement therapies [NRTs]) lawfully available for commercial sale in Australia have been evaluated for quality, safety and efficacy and have been registered with the TGA. This includes products that are on general sale in supermarkets and other outlets.
A comprehensive range of controls are in place to minimise potential risks associated with the marketing and use of TGA-approved smoking cessation therapies. Marketing approaches (including advertising and availability) of TGA-approved smoking cessation therapies remains flexible and open to change in light of new evidence.

The Department also considers it vital that any future potential national policy and regulatory directions for e-cigarettes in Australia should:

- 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.

Any other related matter

Australia's leadership role in tobacco control and public health
The Australian Government is recognised as a world leader in tobacco control, in part due to our commitment to our obligations under the WHO FCTC, and willingness to tackle significant reform in order to achieve the best possible health outcomes for all Australians. Australia was, for instance, the first country to implement tobacco plain packaging, and we have defended this important and effective measure against sustained and in one case abusive[48] challenges both domestically in the High Court of Australia, and internationally, including in the World Trade Organization.

This international reputation is recognised and respected domestically by the Australian community, and is a pillar on which the support and confidence of the Australian

[48] PCA Case No. 2012-12: Philip Morris Asia Limited (Hong Kong) v. The Commonwealth of Australia, Award on Jurisdiction and Admissibility, 17 December 2015, paragraph 588:

"In light of the foregoing discussion, the Tribunal cannot but conclude that the initiation of this arbitration constitutes an abuse of rights, as the corporate restructuring by which the Claimant acquired the Australian subsidiaries occurred at a time when there was a reasonable prospect that the dispute would materialise and as it was carried out for the principal, if not sole, purpose of gaining Treaty protection. Accordingly, the claims raised in this arbitration are inadmissible and the Tribunal is precluded from exercising jurisdiction over this dispute."

community rests in respect of Australian Government tobacco control interventions. This has provided the Australian Government significant momentum to lead on, and to continue to implement, tobacco control measures.

Further, Australia's international reputation and good standing, built over decades but bolstered recently by our leadership in tobacco control, means we can be influential on a world stage, and not just with regard to tobacco control issues. The ability of the Department and Australian Government to play a leadership role in critical international health fora including, for instance, the World Health Assembly (the decision making body of the World Health Organization) is of significant benefit to Australia, and the Australian community.

It is important that Australia's response to e-cigarettes upholds its reputation as a world leader in tobacco control by adopting the outcomes-based approach to significant health reforms upon which that reputation has been built.

WHO FCTC
The WHO FCTC, to which Australia is a Party, aims to advance international cooperation to protect present and future generations from the preventable and devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke. The WHO FCTC and its guidelines commit nations to implementing a range of demand and supply-side tobacco control measures and to act to protect these measures from commercial and other vested interests of the tobacco industry in accordance with national law.[49]

WHO FCTC and nicotine
Article 5.2 (b) of the WHO FCTC states that each Party shall: "*adopt and implement effective legislative, executive, administrative and/or other measures…for preventing and reducing tobacco consumption,* [and] *nicotine addiction*…". Consistent with this obligation, the Conference of the Parties to the WHO FCTC has repeatedly invited Parties to the Convention to consider regulating and/or prohibiting ENDS/ENNDS, taking into account a high level of protection for human health[50] and as appropriate to national laws and public health objectives.[51]

Current progress in tobacco control in Australia
At the national level, the Australian Government's broad range of tobacco control measures include: staged excise increases on tobacco products; education programs and campaigns; plain packaging of tobacco products; labelling tobacco products with updated and larger graphic health warnings; prohibiting tobacco advertising, promotion and sponsorship; and providing support for smokers to quit. Additionally, state and territory governments have also implemented a broad range of measures, such as restrictions on the advertising, promotion and sponsorship of tobacco products, measures to reduce

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49 'Tobacco Control' in the WHO FCTC context refers to a range of supply, demand and harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke.

50 Decision FCTC/COP6(9) of the sixth session of the Conference of the Parties to the WHO FCTC regarding electronic nicotine delivery systems and electronic non-nicotine delivery systems. Available from: http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6(9)-en.pdf

51 Decision FCTC/COP7(9) of the seventh session of the Conference of the Parties to the WHO FCTC regarding electronic nicotine delivery systems and electronic non-nicotine delivery systems. Available from: http://www.who.int/fctc/cop/cop7/FCTC_COP7_9_EN.pdf?ua=1

exceptions to smoke-free workplaces, public places and other settings, and education programs and campaigns.

Findings from the Australian Institute of Health and Welfare show that the daily smoking rates in Australia for those aged 14 years or older over the past 25 years has nearly halved, from 24.3% in 1991 to 12.2% in 2016.[52] These results show that considerable progress has been made in reducing smoking rates in Australia in recent years, even when compared to most other developed countries. Nevertheless, smoking rates in Australia remain too high, and continued momentum in tobacco control is needed. Tobacco use remains a leading cause of preventable death and disability in Australia and was estimated to kill almost 19,000 Australians in 2011.[53] Additionally, the Australian Institute of Health and Welfare has recently reported that almost one quarter (22 per cent) of the total cancer burden in Australia can be attributed to tobacco use.[54]

National Tobacco Strategy (NTS) 2012-2018
The NTS 2012-2018 was developed as a sub-strategy under the National Drug Strategy 2010-2015 with the goal to improve the health of all Australians by reducing the prevalence of smoking and its associated health, social and economic costs, and the inequalities it causes. The NTS 2012-2018 includes nine priority areas for action, including Priority Area 6.7 to '*consider further regulation of the contents, product disclosure and supply of tobacco products and alternative nicotine delivery systems*'.

E-cigarettes, nicotine addiction and tobacco use
As noted above, the Department is concerned about the potential for e-cigarettes to provide a gateway to nicotine addiction or tobacco use, and the potential for e-cigarettes to contribute to the renormalisation of smoking. While no firm conclusions in this area can be drawn based on current available evidence, a precautionary approach is warranted. In this regard, there are some studies reporting the rapid uptake of e-cigarettes among adolescents in many countries, particularly the United States, where trend data are available. There are also a number of recent longitudinal studies which have reported an association between e-cigarette use in non-smokers and the uptake of tobacco cigarette smoking in the future.

E-cigarettes and harm minimisation
Consistent with the NTS 2012-2018 and Australia's policy framework for other drugs, future policy and regulatory responses to e-cigarettes should be underpinned by the principles of harm minimisation. This approach includes the three pillars of demand reduction, supply reduction and harm reduction, which apply to all drug types but in different ways.

Prevalence of e-cigarette use in Australia
Recent results from the 2016 National Drug Strategy Household Survey (NDSHS) showed that:

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52 National Drug Strategy Household Survey (NDSHS) 2016 key findings. Available at: http://www.aihw.gov.au/alcohol-and-other-drugs/data-sources/ndshs-2016/key-findings/.

53 AIHW 2016. Australian Burden of Disease Study: impact and causes of illness and death in Australia 2011. Australian Burden of Disease Study series no. 3. Cat. no. BOD 4. Canberra: AIHW.

54 Australian Institute of Health and Welfare 2017. Burden of Cancer in Australia: Australian Burden of Disease Study 2011. Australian Burden of Disease Study series no. 12. Cat. no. BOD 13. Canberra: AIHW. Available at: http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=60129559772.

- Between 2013 and 2016, lifetime use of e-cigarettes significantly increased across almost all age groups;[55]
- In 2016, e-cigarettes were most commonly tried by smokers aged under 25 years with 1 in 2 trying e-cigarettes in their lifetime; and
- In 2016, nearly one third of smokers (31 per cent) had tried e-cigarettes in their lifetime, but the majority had only tried them once or twice (20 per cent) and only 4.4 per cent currently use them (the remaining 6.8 per cent no longer use them).

Personal vaporisers other than e-cigarettes

While the focus of this submission has been on e-cigarettes, the Department is also aware of other types of personal vaporisers currently available on the global market, such as Philip Morris's iQOS system[56] and Japan Tobacco International's Ploom TECH[57], which may be referred to as 'heat not burn' tobacco products.

There are concerns about the marketing and use of heat not burn tobacco products, because of the limited evidence on their ability to reduce the risk associated with conventional tobacco products and the risks they may pose to population health, such as their potential to disrupt the decline in tobacco use in Australia. The most reliable epidemiological evidence shows that the best way to avoid tobacco-related premature death and disease is to prevent exposure or to cease the use of tobacco products entirely.[58, 59] There is no safe level of tobacco consumption.[60]

Personal vaporisers and commercial interests

The Department is aware of recent reports indicating that all major tobacco companies have invested in e-cigarettes.[61] Under Article 5.3 of the WHO FCTC, Parties are obliged to act to protect their public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry, in accordance with national law. Consistent with this obligation, the Department acknowledges the need to protect tobacco control activities from all commercial and other vested interests related to e-cigarettes, including interests of the tobacco industry.[62]

The Department notes research on publicly available tobacco industry documents which concluded that transnational tobacco companies, and in particular, British American Tobacco, have invested in 'harm reduction' products, as a means to re-engage with policy

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55 Questions on e-cigarettes were included in the 2013 NDSHS for the first time and then revised in the 2016 NDSHS. These changes mean that 2016 and 2013 e-cigarette related data from the NDSHS are not fully comparable. However, this data may still be used to give an indication of the change in use of e-cigarettes between 2013 and 2016. Further information is available at: http://www.aihw.gov.au/alcohol-and-other-drugs/data-sources/ndshs-2016/tobacco/.

56 See https://www.pmi.com/science-and-innovation/heated-tobacco-products.

57 See http://www.jti.com/our-products/emerging-products/tobacco-vapor/.

58 Doll R, Peto R, Boreham J, Sutherland I. (2004) Mortality in relation to smoking: 50 years' observations on male British doctors. BMJ Jun 26;328(7455):1519.

59 Banks et.al (2015). Tobacco smoking and all-cause mortality in a large Australian cohort study: findings from a mature epidemic with current low smoking prevalence. BMC Medicine. Available at: http://www.biomedcentral.com/1741-7015/13/38

60 U.S. Department of Health and Human Services (2010). How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health.

61 For example, see: http://www.tobaccoatlas.org/topic/e-cigarettes/.

62 Electronic nicotine delivery systems and electronic non-nicotine delivery systems. 2016. Conference of the Parties to the WHO Framework Convention on Tobacco Control. Available at: http://www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf.

makers, and to 'rehabilitate' the tobacco industry's image as a 'responsible business', rather than as a genuine commitment to reducing harm.[63]

The Department also notes that the statement on e-cigarettes published by the Chief Executive Officer of the National Health and Medical Research Council in April 2017[64] encouraged consumers and policy-makers to consider the extent to which authors of e-cigarette related research hold any conflicts of interest that could potentially bias their findings, and whether the research is funded by an organisation with a financial interest in the outcomes, such as e-cigarette manufacturers. [65]

63 Peeters S & Gilmore AB (2013) Transnational tobacco company interests in smokeless tobacco in Europe: analysis of internal industry documents and contemporary industry materials. PLOS Medicine 19;9.

64 NHMRC CEO Statement: Electronic Cigarettes (E-Cigarettes). 2017.

65 C. Pisinger and M. Døssing, "A Systematic Review of Health Effects of Electronic Cigarettes" Preventive Medicine, vol. 69, pp. 248-260, 2014.