



RACP
Specialists. Together

EDUCATE ADVOCATE INNOVATE

From the President

6 July 2017

Committee Secretariat
Standing Committee on Health, Aged Care and Sport
PO Box 6021
Parliament House
CANBERRA ACT 2600

Email: Health.Reps@aph.gov.au

Dear Committee members

Re: Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia

The Royal Australasian College of Physicians (RACP) welcomes the opportunity to contribute to the Standing Committee's *Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia*.

The RACP represents medical specialists from across more than 33 medical specialties – including public health, oncology, thoracic and respiratory medicine, cardiology, clinical pharmacology and addiction medicine. The RACP's aims are to educate, innovate and advocate for excellence in health and medical care. We draw on the skills and expertise of our members to develop policies that support the delivery of high quality health services and promote a healthier society.

The RACP is currently developing a policy on electronic cigarettes¹, articulating our position on the emergence and rapidly increasing use of e-cigarettes and its potential impacts on health.

This document is being developed through a process of rigorously reviewing the available evidence and consulting widely with our expert Fellows. The document will shortly be publicly released for consultation, and at that time, we will be happy to forward a copy to the Committee for your consideration.

In recent years, the use of e-cigarettes both in Australia and globally has grown rapidly, especially amongst young people. As a result, many countries are now implementing measures to regulate their promotion, sale, supply and use. However, our review of the

¹ The term 'e-cigarette' in this submission refers to electronic devices designed to deliver aerosol from a heated liquid into a person's lungs.

evidence has found that there are an insufficient number of studies and sometimes contradictory findings. This, coupled with a rapidly evolving e-cigarette market, has resulted in e-cigarette policy being fragmented, complex and often unclear. A range of opinions has been promulgated with regard to their role in helping people quit or reduce smoking, their direct effect on a person's health, and their potential impact on the decades-long move towards a tobacco-free society.

This submission focuses on addressing the first four terms of reference for this inquiry.

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

Presently, the evidence base is unable to support or refute the role e-cigarettes play in smoking cessation. There is a limited number of studies, and the evidence that exists is mixed on their effectiveness in helping smokers reduce or completely quit smoking.

A 2016 Cochrane systematic review with a meta-analysis of two randomised controlled trials (RCTs) found that, compared with non-nicotine e-cigarettes, the use of nicotine-containing e-cigarettes is more likely to achieve six months' continuous abstinence from cigarette smoking. The quality of this evidence was graded as low due to the limited number of trialsⁱ. However a meta-analysis of 20 studies (mostly non-randomised cohort studies), where the use of e-cigarettes was found to reduce the likelihood of smokers quitting by 28 per cent, compared with smokers who didn't use them, regardless of interest in smoking cessationⁱⁱ.

A longitudinal study in the UK reported a weak association between the use of e-cigarettes and smoking cessation, though their use was found to increase attempts to quit smoking and to reduce the number of cigarettes smoked per dayⁱⁱⁱ. Another longitudinal study in the US reported little difference in smoking cessation rates between short-term e-cigarette users and non-users, however long-term use of e-cigarettes resulted in a higher smoking cessation rate^{iv}. Furthermore, a review found that some prospective studies reported no change or negative correlations between the use of e-cigarettes and smoking cessation^v.

With regard to the efficacy of e-cigarettes compared with nicotine replacement therapy (NRT), some studies have reported that for smokers seeking to quit, nicotine-containing e-cigarettes can improve abstinence from tobacco^{vi vii viii ix}. A review reported that both RCTs and population-based studies with more precise evaluations of how e-cigarettes were used (e.g. duration and for cessation purpose) suggesting that e-cigarettes are as effective as NRT in assisting smokers to quit or to reduce their tobacco cigarette consumption^x.

The paucity of clear findings on the long-term use and efficacy of e-cigarettes as an aid to quitting smoking leaves this a contested issue and signals the urgent need for more independent and thorough studies.

To date, no e-cigarette device has been approved by the Therapeutic Goods Administration (TGA) for use to aid smoking cessation. No such claims should be allowed without this TGA approval.

The RACP shares concerns voiced by other groups, for example the Australian Medical Association (AMA)^{xi}, Public Health Association Australia (PHAA)^{xii}, Cancer Council and the National Heart Foundation^{xiii}, that the approaches being taken to advertise e-cigarettes have the potential to restore the social norms around smoking and undermine or even reverse the decades-long work to remove any positive associations with smoking. These techniques include a focus on youth and a strong use of role-models.

Below is an example of an image used on the *Vapor Kings* website (<https://www.vaporkings.com.au/>) accessed 28 June 2017.



There is evidence showing the positive association between exposures to e-cigarettes marketing and increased likelihood of current and future use of e-cigarettes among young people^{xiv}. The marketing of e-cigarettes that has the effect of promoting smoking should not be allowed. It is worth noting that a number of global tobacco companies, such as British American Tobacco, Imperial Tobacco, and Reynolds American Inc., have now either established or acquired e-cigarettes as part of their product line.

Stopping smoking completely is the most effective approach to reducing mortality and morbidity from tobacco-related disease. As a medical body, the advice we provide to our members regarding the use of e-cigarettes is that physicians should be aware that the current evidence base for the role of e-cigarette in smoking cessation is both limited and at times conflicting. Careful clinical judgement should be applied in giving advice to their patients. If pharmacotherapy is required to assist smokers to quit smoking, nicotine replacement therapy (NRT) should be used as first line treatment; NRT has been proven to be safe and effective for increasing abstinence rates.

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

The health impacts of the use of e-cigarettes, and in particular their long term health effects, are currently unclear due to the limited number of studies undertaken in this area to date. The RACP acknowledges that when compared with traditional tobacco cigarettes, e-cigarettes do not contain as many unsafe chemicals and therefore may not be as harmful. However, this does not mean that they are completely harmless or risk-free. A Food and Drug Administration (FDA) review identified various known human carcinogens and toxins in e-cigarette aerosols, cartridge, and refill liquids, many of which are known to have adverse health effects^{xv}. A study in 2016 suggested that nicotine-containing e-cigarettes are linked to an elevated risk of aortic stiffness and increased blood pressure in young smokers^{xvi}.

In terms of population-level health impacts, a longitudinal study of 5 cohorts of Southern Californian adolescents attaining 12th grade in 1995, 1998, 2001, 2004, and 2014 suggests that e-cigarettes are also being taken up by adolescents who would not otherwise have initiated using tobacco products^{xvii}. Another longitudinal non-randomised study in the US has shown that high school students who had used e-cigarettes were more likely to report initiation of tobacco smoking over the next year than non-users^{xviii}. In addition to individual-level health impacts, research into population-level health impacts must also be given due consideration, as at this stage, we are unclear about whether e-cigarettes will renormalise smoking or recruit new tobacco smokers to nicotine addiction.

To date, there is little conclusive evidence available about the product safety and quality of e-cigarettes. The flavoring chemicals used are a particular concern. At present there is no evidence that the large number and wide-ranging additives in e-cigarettes are safe when

heated, vapourised and repeatedly inhaled deep into the lungs. Moreover, concentrations of their components – both nicotine and non-nicotine elements – often vary within and between brands, and it has been found that some do not clearly or accurately state the ingredients and their concentrations, whilst a number of e-cigarette devices have reportedly leaked nicotine and some have exploded^{xixxx}.

In light of these findings, the RACP is concerned that there is a lack of attention to the quality control processes used to manufacture these products and their labelling requirements. Henceforth, we recommend the following measures be put in place to mitigate the risks:

- E-cigarette products should be manufactured to appropriate quality and safety standards and be subject to consumer law. All e-cigarettes and e-liquids should provide evidence that national Good Manufacturing Practice (GMP) policies have been followed and are safe for use for consumers.
- Governments should fund high quality evidence based research into e-cigarettes, in particular the short- and long-term health effects of e-cigarettes; overall impact on population health; and the safety of inhaling flavouring chemicals.
- Packaging and labelling requirements should be implemented, including:
 - Disclosure of all ingredients and their concentrations in e-liquids
 - Child-proof packaging standards to prevent accidental poisonings
 - Packaging rules to reduce the appeal of e-cigarettes to youth
 - Health warning labels

All levels of government should cooperate to improve data collection on e-cigarette sales and use, together with the prevalence and characteristics of e-cigarette users by age groups and smoking status, to accurately estimate the population and group-specific effects.

3. International approaches to legislating and regulating the use of E-cigarettes and personal vaporisers

Given the unknown health impacts of e-cigarettes and their increasing use of, some countries have introduced new regulatory mechanisms or amended existing tobacco control and associated legislation (e.g. smoke-free laws) to manage their sale, supply, use, promotion, and packaging.

3.1 *New Zealand*^{xxxi}

As of April 2017, the New Zealand Government has in principle made a decision to amend the Smoke-free Environments Act 1990 (SFEA) to legalise the sale and supply of nicotine containing e-cigarettes as consumer products by mid-2018. However, the sale of e-cigarette products with/without nicotine is prohibited to people under 18 years and from the vending machines in R18 settings. In terms of promotion and advertising, only point-of-sale display for all retailers and in store display is permitted. Individual businesses and local authorities are allowed to extend its smoke-free workplace policy to the use of e-cigarettes. E-cigarettes with a therapeutic claim, irrespective of whether they contain nicotine or not, will continue to be classified as medicines; their sale requires authorisation by MedSafe.

United States^{xxii-xxiii}

As of August 2016, the FDA extended its oversight to all tobacco products, including all electronic nicotine delivery systems. This means 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 electronic nicotine delivery systems 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.

Non-nicotine e-cigarette laws vary from state to state. E-cigarettes that are marketed for therapeutic purposes continue to be regulated by the FDA Center for Drug Evaluation and Research.

3.2 *United Kingdom*^{xxiv}

Under new 2016 regulations, e-cigarettes are regulated either under the revised EU Tobacco Products Directive (TPD) as tobacco products or, if they are making a therapeutic claim, under the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) as medicines. The revised TPD requires that all e-cigarette products sold fully meet the standards stipulated in the Tobacco and Related Products Regulations 2016 to ensure minimum standards for the safety and quality of all e-cigarettes and prevent youth initiation.

3.3 *Canada*^{xxv}

Under the Canadian Food and Drugs Act, nicotine-containing e-cigarettes, with or without a therapeutic claim, are regulated as medicines. Authorisation is required prior to their importation, advertisement or sale in Canada. Non-nicotine e-cigarettes that do not make health claims are unregulated.

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

Most Australian state and territory governments have examined potential policy options to regulating e-cigarettes. As a result, most state and territories have already or will soon institute laws to regulate their sale, supply, use and promotion, with a particular focus on limiting their access and use by young people². However, these regulations are not consistent across states and territories. 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.

In designing such a national framework, it is essential that the Australian Government ensures it is compatible with tobacco control policies articulated in the World Health Organization (WHO) mPOWER strategy³ and in the WHO Framework Convention on Tobacco Control (FCTC); that it is based on the highest quality evidence available, and that it strikes an appropriate balance between potential risks and benefits. The current approach to nicotine regulation should continue and be closely monitored with regard to its use in e-liquids on the grounds that nicotine is classified as a poison in Australia and is highly addictive. Additionally, we recommend the following measures be considered by the Australian Government:

- 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.
- The use of e-cigarette, with or without nicotine, should be banned in all areas that are designated to be smoke-free, to protect non-users from potential harms due to exposure to secondhand e-cigarette aerosol.

² Please refer to Section 4.1.2 of the draft policy for more detailed information on state and territory regulation

³ MPOWER is a policy package introduced by the WHO Framework Convention on Tobacco Control (FCTC) to help the country-level implementation of effective interventions to reduce the demand for tobacco. Claire comment: Add reference

- E-cigarettes with or without nicotine should be subject to Australia's excise tax, at a lower rate than that of tobacco cigarettes to discourage any e-cigarettes users switching to tobacco cigarettes".

It is clear that the current evidence base is insufficient to properly ascertain the role of e-cigarettes and their potential impact on public health. Building the evidence base is key to informing ongoing improvement of tobacco control and e-cigarette policy. The RACP calls upon the Government to commission and/or provide funding for high quality research into e-cigarettes, particularly randomised clinical trials and population-level studies that are independent of vested interests. The RACP is committed to contributing to the development of health policies that help lead Australia to a healthier future, and looks forward to future consultation opportunities on this matter of significant interest and relevance to our members.

Should you require any further information regarding this response, please contact [REDACTED]

Yours sincerely

[REDACTED]

Dr Catherine Yelland PSM
President RACP

ⁱ Hartmann-Boyce J, McRobbie H, Bullen C, Begh R, Stead LF, Hajek P. Electronic cigarettes for smoking cessation. The Cochrane Library. 2016.

ⁱⁱ alkhoran S, Glantz SA. E-cigarettes and smoking cessation in real-world and clinical settings: a systematic review and meta-analysis. *The Lancet Respiratory Medicine*. 2016;4(2):116-28

ⁱⁱⁱ Brose LS, Hitchman SC, Brown J, West R, McNeill A. 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 (Abingdon, England)*. 2015;110(7):1160-8

^{iv} Zhuang Y-L, Cummins SE, Sun JY, Zhu S-H. Long-term e-cigarette use and smoking cessation: a longitudinal study with US population. *Tobacco control*. 2016;25(Suppl 1):i90-i5

^v Glasser AM, Collins L, Pearson JL, Abudayyeh H, Niaura RS, Abrams DB, et al. Overview of Electronic Nicotine Delivery Systems: A Systematic Review. *American journal of preventive medicine*. 2016.

^{vi} Etter JF, Bullen C. Electronic cigarette: users profile, utilization, satisfaction and perceived efficacy. *Addiction (Abingdon, England)*. 2011;106(11):2017-28

-
- ^{vii} Bullen C, Howe C, Laugesen M, McRobbie H, Parag V, Williman J, et al. Electronic cigarettes for smoking cessation: a randomised controlled trial. *The Lancet*. 2013;382(9905):1629-37
- ^{viii} Brown J, Beard E, Kotz D, Michie S, West R. Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study. *Addiction (Abingdon, England)*. 2014;109(9):1531-40
- ^{ix} Bullen C, McRobbie H, Thornley S, Glover M, Lin R, Laugesen M. Effect of an electronic nicotine delivery device (e cigarette) on desire to smoke and withdrawal, user preferences and nicotine delivery: randomised cross-over trial. *Tobacco control*. 2010;19(2):98-103
- ^x Glasser AM, Collins L, Pearson JL, Abudayyeh H, Niaura RS, Abrams DB, et al. Overview of Electronic Nicotine Delivery Systems: A Systematic Review. *American journal of preventive medicine*. 2016.
- ^{xi} E-cigs a gateway to smoking for young: study. <https://ama.com.au/ausmed/e-cigs-gateway-smoking-young-study>
- ^{xii} Statement by the Public Health Associations of Australia on Electronic Cigarettes. <https://www.phaa.net.au/documents/item/704>
- ^{xiii} Position Statement- Electronic cigarettes. http://wiki.cancer.org.au/policy/Position_statement_-_Electronic_cigarettes
- ^{xiv} Mantey DS, Cooper MR, Clendennen SL, Pasch KE, Perry CL. E-cigarette marketing exposure is associated with e-cigarette use among US youth. *Journal of Adolescent Health*. 2016;58(6):686-90.
- ^{xv} Ioakeimidis N, Vlachopoulos C, Tousoulis D. Efficacy and Safety of Electronic Cigarettes for Smoking Cessation: A Critical Approach. *Hellenic Journal of Cardiology*. 2016;57(1):1-6
- ^{xvi} Vlachopoulos C, Ioakeimidis N, Abdelrasoul M, Terentes-Printzios D, Georgakopoulos C, Pietri P, et al. Electronic Cigarette Smoking Increases Aortic Stiffness and Blood Pressure in Young Smokers. *Journal of the American College of Cardiology*. 2016;67(23):2802-3
- ^{xvii} Barrington-Trimis JL, Urman R, Leventhal AM, Gauderman WJ, Cruz TB, Gilreath TD, et al. E-cigarettes, Cigarettes, and the Prevalence of Adolescent Tobacco Use. *Pediatrics*. 2016;138(2):e20153983.
- ^{xviii} Leventhal AM, Strong DR, Kirkpatrick MG, et al. Association of electronic cigarette use with initiation of combustible tobacco product smoking in early adolescence. *The Journal of the American Medical Association*. 2015;314(7):700-7
- ^{xix} Yang L, Rudy SF, Cheng JM, Durmowicz EL. Electronic cigarettes: incorporating human factors engineering into risk assessments.
- ^{xx} Buettner-Schmidt K, Miller DR, Balasubramanian N. Electronic cigarette refill liquids: child-resistant packaging, nicotine content, and sales to minors. *Journal of pediatric nursing*.
- ^{xxi} Ministry of Health. Regulatory Impact Statement: Regulation of e-cigarettes and emerging tobacco and nicotine-delivery products. 2017.
- ^{xxii} FDA. The Facts on the FDA's New Tobacco Rule 2016. Available from: <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm506676.htm>.
- ^{xxiii} FDA. Vaporizers, E-Cigarettes, and other Electronic Nicotine Delivery Systems (ENDS), 2017. Available from: <https://www.fda.gov/tobaccoproducts/labeling/productingredientscomponents/ucm456610.htm>.
- ^{xxiv} Action on Smoking and Health (UK). The impact of the EU Tobacco Products Directive on e-cigarette regulation in the UK. 2016
- ^{xxv} Propel centre for population health impact. Tobacco use in Canada. Special Supplement: E-cigarettes 2015.