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The Royal Australasian College of Physicians' submission to Tobacco Harm Reduction Inquiry

November 2020

About The Royal Australasian College of Physicians (RACP)

The RACP trains, educates and advocates on behalf of 18,000 physicians and 8,500 trainee physicians, across Australia and Aotearoa New Zealand. The RACP represents a broad range of medical specialities including general medicine, paediatrics and child health, cardiology, gastroenterology, respiratory medicine, infectious diseases, neurology, oncology, public health medicine, occupational and environmental medicine, sexual health medicine, rehabilitation medicine, geriatric medicine, addiction medicine and palliative medicine.

Executive Summary

To protect youth, never smokers and former smokers, **access to nicotine e-cigarettes must be confined to smokers who are unable to quit smoking as the treatment option of last resort**. Non-nicotine containing e-cigarettes must be included in and subject to state tobacco control legislation to tighten their sale and promotion.

Encouraging smokers to quit or any easing of access to nicotine e-cigarettes by smokers must not be made at the expense of increasing the number of young people who take up vaping and nicotine addiction. Indeed, only 0.3% of Australian smokers are using e-cigarettes to help them quit.

There are also serious long-term side effects of e-cigarettes which has resulted in outbreaks of e-cigarette, or vaping, associated lung injury (EVALI). This includes 2087 cases, including deaths, in the United States.

The RACP strongly supports a precautionary approach to e-cigarette regulation by the Australian Government and the Therapeutic Goods Administration (TGA). Any regulatory changes require careful deliberations with long-sightedness, considering it will impact generations to come. Our stance and recommendations with respect to this inquiry are summarised below (also available on RACP's May 2018 Position Statement[1])

- The RACP is a strong advocate of smoking cessation. We advocate that **not smoking tobacco or using e-cigarettes remain the safest options for the community,** as the long-term implications of using vaping devices are not yet known. The proven and registered smoking cessation technologies, including pharmacotherapies, is advised to be used ahead of vaping. Should patients wish to use e-cigarettes for smoking cessation, the RACP urges physicians to advise patients of all potential risks and benefits before commencing. However, the RACP maintains that **the current evidence base for e-cigarettes is still insufficient to ascertain long-term impacts and health risks at the individual and the population levels**.

- **Australia must treat e-cigarettes with caution** on account of the highly addictive nature of nicotine[2], together with the lack of long-term data and large population studies. It is possible that e-cigarettes may have a potential role in tobacco harm reduction and smoking cessation for smokers unable or unwilling to quit. The 2020 government commissioned **Australian National University preliminary report did not find nicotine e-cigarettes to be more effective than no intervention, non-nicotine e-cigarettes, or nicotine replacement therapy in aiding smoking cessation**. It found that nicotine e-cigarettes contribute to prolonged nicotine use[3].

- Improving the current evidence base and data collection for e-cigarettes must be urgently prioritised to inform evidence-based policy-making in Australia. Thus, we urge:
  - **any additional recommendations to changing the regulatory framework for e-cigarettes await the outcomes of the current investigations underway by the National Health and Medical Research Council (NHMRC) and the Therapeutic Goods Administration (TGA).**
  - the collection of high-quality research and data on the impact of e-cigarettes on overall smoking rates and smoking initiation rates and the overall health of the population.

- In Australia, the 2019 National Drug Strategy Household Survey (NDSHS) has found that roughly two-thirds of current smokers and 1 in 5 non-smokers aged 18–24 reported having tried e-cigarettes[4]. A wide range of **advertising and marketing strategies have been used to particularly target the youth market**, including production innovation and celebrity endorsement[5.] **Availability of e-**

[1] Policy on Electronic Cigarettes, RACP May 2018 accessed at; https://www.racp.edu.au/docs/default-source/advocacy-library/policy-on-electronic-cigarettes.pdf 30 October 2020
[2] World Health Organization. Gender, women, and the tobacco epidemic 2010 [137-49]. Available from: http://www.who.int/tobacco/publications/gender/en_tfi_gender_women_addiction_nicotine.pdf
[3] Australian National University. Summary report on use of e-cigarettes and relation to tobacco smoking uptake, smoking cessation, relevant to Australian context. Available from: https://openresearch-repository.anu.edu.au/bitstream/1885/211618/3/E-cigarettes%20smoking%20behaviour%20summary%20report%20final%20200924.pdf
[4] National Drug Strategy Household Survey 2019. Chapter 2:Tobacco Smoking Available at: https://www.aihw.gov.au/getmedia/3564474e-f7ad-461c-b918-7f8de03d1294/aihw-phe-270-NDSHS-2019.pdf.aspx?inline=true
[5] US Department of Health and Human Services. E-cigarette use among youth and young adults: A report of the Surgeon General.

cigarettes should not provide an enticement for non-smokers, especially youth[6]. The RACP is significantly concerned that any easing of access restrictions would be a contributing factor to ongoing and alarming increases in vaping amongst teens, which is currently seen in jurisdictions such as the US and Canada.

- **Most smokers quit smoking unassisted**[7]. E-cigarettes do not appear to be primarily used for smoking cessation. Less than 10% of smokers in Australia are currently using e-cigarettes and within that group of smokers who use e-cigarettes, only one-third say they are using them to help with cessation[8]. Moreover, there is evidence showing **many e-cigarette users are dual users[9] which provides little to no beneficial impact on health risk and effects**, as outlined by the WHO[10].

- To protect youth, never smokers and former smokers, **access to nicotine e-cigarettes must be confined to smokers who are unable to quit smoking as the treatment option of last resort**. Non-nicotine containing e-cigarettes must be included in and subject to state tobacco control legislation to tighten their sale and promotion.

- The 2020 Australian Summary report attributes the recent declines in smoking primarily to very low smoking uptake by young people – 97% of young people aged 14 to 17 were never smokers in 2019[11]. It is therefore **essential that continuing efforts are directed at maintaining the very low smoking uptake rate by young people in Australia and any 'gateway' effect of e-cigarettes is neutralised**.

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

- There are **risks of prescribing a wide range of commercial products outside usual standards of required scientific evidence of safety and effectiveness**, where doctors have no high-quality knowledge to base any such prescribing decisions on. Prescribing must align with the principles of evidence-based practice or QUM framework.

- A number of measures should be put in place to further strengthen the **public health protection aspect of the proposed regulatory changes** resulting from the TGA's interim decision to amend the nicotine scheduling, including:
  - E-cigarette products should be manufactured to suitable quality and safety standards
  - **E-cigarette product packaging and labelling requirements should be implemented, including disclosure of all ingredients and their concentrations in e-liquid, child-resistant packaging, plain packaging rules and health warning labels**.
  - The sale and supply of e-cigarettes (with or without nicotine) to minors, including access through personal importation scheme, must be prohibited and stringently enforced in all Australian states and territories. E-cigarettes must not be allowed to be promoted in a way that encourages youth uptake or smoking initiation
  - The use of e-cigarettes should be banned in all areas that are designated to be smoke-free by Australia's state and territory laws.

Chapter 4: Activities of the E-Cigarette Companies. https://www.ncbi.nlm.nih.gov/books/NBK538679/

[6]Cummings KM, Hammond D. E-cigarettes: striking the right balance. The Lancet Public Health. 2020 Apr 1;5(4):e180-1.

[7] Greenhalgh EM, Stillman S, Ford C. Tobacco in Australia: Facts and Issues. 7.6 How smokers go about quitting. Available at: http://www.tobaccoinaustralia.org.au.

8 Australian Institute of Health and Welfare. National Drug Strategy Household Survey 2019. Canberra: AIHW; 2020.

9 Banks E, Beckwith K, Joshy G. Summary report on use of e-cigarettes and impact on tobacco smoking uptake and cessation, relevant to the Australian context. Commissioned Report for the Australian Government Department of Health. Canberra: Australian National University; 2020.

[10] WHO Report on the Global Tobacco Epidemic, 2019. Geneva: World Health Organization; 2019. Licence: CC BY-NC-SA 3.0 IGO.

[11] Banks E, Beckwith K, Joshy G. Summary report on use of e-cigarettes and impact on tobacco smoking uptake and cessation, relevant to the Australian context. 2020. Available at http://hdl.handle.net/1885/211618

- **Tobacco companies have no genuine interest and motive in pursuing harm reduction**[12]. Their discourse in harm reduction is an opportunistic tactic in response to policy change and to be involved in the development of next generation products such as heated tobacco products and e-cigarettes, instead of a genuine interest and motive in pursuing harm reduction [13] [14]. These industries are not experts in health policy and have major conflicts between their vested commercial interests and public health. **The RACP maintains that e-cigarette and tobacco industries must not be involved in the design of e-cigarette regulatory framework**, and the associated implementation and clinical guideline development in Australia.

- Public health and safety must be a core public interest consideration for government. **Tobacco industry donations can be used as a mechanism of influence over e-cigarette debate; declaration of financial donations to health advocates and organisations should be made mandatory.**

Introduction

The RACP welcomes the opportunity to provide input to the Select Committee on Tobacco Harm Reduction.

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

The House of Representatives Standing Committee on Health, Aged Care and Sport held an inquiry into the use and marketing of e-cigarettes and personal vaporisers in 2017. After almost one-year of thorough examination of the available evidence from multiple perspectives arising from public consultation and hearings, a report and recommendations were produced in 2018. These included that the NHMRC and the TGA review the emerging evidence on e-cigarettes and recommend future regulation. The RACP strongly supports the completion of this work before further recommendations on regulation are made.

- It is expected that the updated NHMRC CEO Statement on E-cigarettes will be released in mid-2021, which will reflect the best available evidence to inform consumers and policy makers and assist in understanding the current evidence relevant to the marketing and use of e-cigarettes and their health impacts.

- The TGA is set to make a final decision on its interim decision on the scheduling of nicotine within the Poisons Standard by the end of this year.

Australia must support evidence-based policy so as to further improve public health. Improving the evidence base for e-cigarettes is the key to realising this. The RACP urges that the current investigations undertaken by the independent regulator and statutory agency be left to run their course and deliver their findings. To safeguard public health, the Australian Government must be alert to and resist the tobacco and vaping groups' attempts to favourably misrepresent the scientific evidence base and to influence the e-cigarette debate.

This submission now addresses each of the Inquiry's Terms of Reference.

[12] Dewhirst T. Co-optation of harm reduction by Big Tobacco. Available at: https://tobaccocontrol.bmj.com/content/early/2020/08/11/tobaccocontrol-2020-056059
[13] Dewhirst T. Co-optation of harm reduction by Big Tobacco. Available at: https://tobaccocontrol.bmj.com/content/early/2020/08/11/tobaccocontrol-2020-056059
[14] Peeters S, Gilmore AB. Understanding the emergence of the tobacco industry's use of the term tobacco harm reduction in order to inform public health policy. Tobacco control. 2015 Mar 1;24(2):182-9.

a. The treatment of nicotine vaping products (electronic cigarettes and smokeless tobacco) in developed countries similar to Australia (such as the United Kingdom, Aotearoa New Zealand, the European Union and United States), including but not limited to legislative and regulatory frameworks;

Regardless of the regulatory approach to e-cigarettes of a countries similar to Australia, e-cigarette products marketed for therapeutic use (e.g. for treatment of nicotine addiction) are regulated as medicine and require review and approval from the respective regulators[15] [16] [17]. There are currently no approved nicotine vaping products for the purpose of therapeutic smoking cessation aid in the Australia, Aotearoa New Zealand and the United States[1819]. The UK Medicines and Healthcare Products Regulatory Agency (MHRA) approved British American Tobacco (BAT)'s e-Voke device as a smoking cessation aid in 2016. However, no e-cigarettes are currently available from the National Health Service (NHS) England on prescription for smoking cessation[20].

E-cigarettes that have not undergone regulators' stringent review processes and secured approval are considered as unapproved therapeutic goods; their effectiveness, safety and quality as medicinal products for smoking cessation have not been evaluated[21]. Being a relatively new development, the evidence on their short-term and long-term health effects is still unclear and will take years to develop.

Governments have taken different approaches to regulating e-cigarettes. Both Australian and Aotearoa New Zealand governments recognise the potential risks of e-cigarettes to children and adolescents, as well as to the wider population, and regulate their promotion, sale and use. As of March 2017, Aotearoa New Zealand has legalised the sale of nicotine-containing e-cigarettes as a consumer product, while Australia continues to ban the retail sale of nicotine containing e-liquids and proposed a ban on the personal importation of nicotine e-cigarettes and refills from next year, unless on prescription from a doctor[22]. The RACP supports the precautionary approach of the Australian Government.

In Australia and Aotearoa New Zealand, it is illegal to sell e-cigarettes making a claim of therapeutic benefit for smoking cessation, which have not been approved by the Therapeutic Goods Administration (Australia) or Medsafe (Aotearoa New Zealand). There are 100 countries that have national/federal laws regulating e-cigarettes including laws related to the sale (including minimum age), advertising, promotion, sponsorship, packaging (child safety packaging, health warning labelling and trademark), product regulation (nicotine volume/concentration, safety/hygiene, ingredients/flavours), reporting/notification, taxation, use (vape-free) and classification of e-cigarettes" [23]. There is compelling evidence from studies done on tobacco that product regulation such as plain packaging and advertising has significant effects on youth uptake. Indeed, no specific e-cigarette product can be recommended as effective and safe for smoking cessation[24].

[15] GOV.UK. Guidance on licensing procedure for e-cigarettes as medicines. https://www.gov.uk/guidance/licensing-procedure-for-electronic-cigarettes-as-medicines
[16] New Zealand Medsafe. Guideline on the regulation of therapeutic products in New Zealand. https://www.medsafe.govt.nz/regulatory/Guideline/GRTPNZ/overview-of-therapeutic-product-regulation.pdf
[17] FDA. Vaporizers, E-Cigarettes, and other Electronic Nicotine Delivery Systems (ENDS), 2017. https://www.fda.gov/tobaccoproducts/labeling/productsingredientscomponents/ucm456610.htm
[18] CDC. Adult Smoking Cessation of E-cigarettes. https://www.cdc.gov/tobacco/data_statistics/sgr/2020-smoking-cessation/fact-sheets/adult-smoking-cessation-e-cigarettes-use/index.html#:~:text=The%20FDA%20has%20not%20approved,health%20effects%20of%20e%2Dcigarettes.
[19] New Zealand Ministry of Health. Electronic Cigarettes: Information for Health Workers. 2016
[20] NHS. Using e-cigarettes to stop smoking. https://www.nhs.uk/live-well/quit-smoking/using-e-cigarettes-to-stop-smoking/
[21] TGA: Assessing e-cigarettes containing liquid nicotine. https://www.tga.gov.au/accessing-e-cigarettes-containing-liquid-nicotine#:~:text=Information%20for%20consumers,for%20quality%2C%20safety%20and%20effectiveness.
[22]Ministers Hunt's media. Prescription nicotine based vaping. 2020. Available at: https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/prescription-nicotine-based-vaping
[23]Global tobacco control. E-cigarette policy scan. Country laws regulation. Available at: https://www.globaltobaccocontrol.org/e-cigarette_policyscan
[24]Global tobacco control. E-cigarette policy scan. Country laws regulation. Available at: https://www.globaltobaccocontrol.org/e-cigarette_policyscan

b. The impact nicotine vaping products have had on smoking rates in these countries, and the aggregate population health impacts of these changes in nicotine consumption

According to the 2019 Organisation for Economic Co-operation and Development (OECD) health statistics, daily adult smoking rates have reduced from an average of 23% to 18% from 2007 to 2017 across most OECD countries. [25] Although there is data revealing declines in smoking rates in countries similar to Australia, the first time series analysis based on repeated cross-sectional population surveys in the UK revealed no clear relationship between e-cigarette use and smoking reduction in the UK between 2006 and 2016. The study thus concluded that if e-cigarette use had contributed to reduced smoking consumption, the effect was likely to be very small at a population level[26].

In the US, those described as current smokers has declined from 20.9% in 2005 to 13.7% in 2018, and the proportion of ever smokers who have quit has also increased**.**[27]. A US National survey showed that 3.2% of adults were current e-cigarette users and 14.9% had ever tried using e-cigarettes in 2018; former cigarette smokers who quit within the past year were more likely to be adults who had ever tried using e-cigarettes or were current e-cigarette users, with the proportion of 57% and 25.2% respectively[28].

In the UK, a 2018 national data study found that 14.7% of adults were current smokers, a five-percentage point reduction since 2011, but a similar proportion to 2017. 6.3% of adults reported to be current e-cigarette user in Great Britain alone[29].

The RACP considers the current data inadequate to inform the unequivocal impact of nicotine e-cigarettes on smoking rates, or the impact on the aggregate population health, including amongst populations who experience negative impacts across the social determinants, in that the effectiveness of e-cigarettes in smoking cessation is unclear. Moreover, there is evidence showing many e-cigarette users are dual users, which further complicates the impact analysis[3031]. One of the key issues with the available studies is the lack of examination into net nicotine use and dependence (e.g. aggregate smoking and vaping rates). High-quality research and data collection are needed to examine the impact of e-cigarettes on overall smoking rates (including ongoing nicotine use from either smoking, vaping, or dual use), smoking initiation rates and the overall health of population.

It is important to note that the concept of 'harm minimisation' in the context of nicotine addiction focuses on removing the tobacco-related harms to smokers, rather than on people quitting nicotine completely[32]. A low-powered cross-sectional study showed that e-cigarette use may deliver similar nicotine levels as tobacco cigarettes and is also linked to reduced exposure to known tobacco-related carcinogens and toxins, but these benefits are not associated with dual use of e-cigarettes and tobacco cigarettes. It therefore suggests that the potential benefits of e-cigarettes may be realised provided there is full cessation of tobacco smoking[33]. Otherwise, there is little to no beneficial impact on health risk and effects, as outlined by the WHO[34].

[25] OECD iLibrary. Health at a Glance 2019: OECD Indicators. https://www.oecd-ilibrary.org/sites/21ac51dd-en/index.html?itemId=/content/component/21ac51dd-en
[26] Beard E, Brown J, Michie S, et al. Is prevalence of e-cigarette and nicotine replacement therapy use among smokers associated with average cigarette consumption in England? A time-series analysis. BMJ Open 2018; 8: e016046.
[27] CDC. Current Cigarette Smoking Among Adults in the United State. Available at: https://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.htm
[28] CDC. National Center for Health Statistics. Electronic cigarettes among U.S adults 2018. Available at: https://www.cdc.gov/nchs/products/databriefs/db365.htm
[29] UK Office for National Statistics. Adult smoking habits in the UK: 2018. Available at: https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandlifeexpectancies/bulletins/adultsmokinghabitsingreatbritain/2018
[30] Action on Smoking and Health (UK). Use of e-cigarettes (vapourisers) among adults in Great Britain 2017
[31] Grana R, Benowitz N, Glantz SA. E-Cigarettes: A Scientific Review. Circulation. 2014;129(19):1972- 86
[32] International Harm Reduction Association. What is Harm Reduction? 2010. Available at: http://www.ihra.net/files/2010/08/10/Briefing_What_is_HR_English.pdf
[33] Shahab L, Goniewicz ML, Blount BC, Brown J, McNeill A, Alwis KU, et al. Nicotine, Carcinogen, and Toxin Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users A Cross-sectional Study E-Cigarettes and Toxin Exposure. Annals of internal medicine. 2017;166(6):390-400
[34] WHO Report on the Global Tobacco Epidemic, 2019. Geneva: World Health Organization; 2019. Licence: CC BY-NC-SA 3.0 IGO.

Australia has seen a steady decline in daily tobacco smoking since 1991[35], with a substantial decline from 2016 to 2019. The 2020 Australian Summary report attributes the recent declines in smoking primarily to very low smoking uptake by young people – 97% of young people aged 14 to 17 were never smoker in 2019[36]. It is therefore essential that continuing efforts are directed at maintaining the very low smoking uptake rate by young people in Australia. Equally important is the strengthened commitment and efforts of the Australian Government towards further driving down persistent high smoking rates among Aboriginal and Torres Strait Islander people, which is critical to closing the gap in tobacco related health burden and life expectancy[37].

Further discussion of the impact of e-cigarettes on the potential 'gateway' effect into tobacco smoking for youth and young people is contained in section D of this submission.

It is worth noting that most smokers quit smoking unassisted[38]. However, for those smokers who seek assistance in quitting, the RACP advocates for the proven and well regulated smoking cessation technologies, including pharmacotherapies, ahead of vaping. The RACP urges physicians to advise patients of all potential risks and benefits should patients wish to use e-cigarettes for smoking cessation. E-cigarettes should not be the first-line treatment for smoking cessation. Whilst government regulators intend to strike the balance in relation to potential harm reduction, the ease of availability of e-cigarettes should not provide an enticement for non-smokers, especially youth[39].

c. The established evidence on the effectiveness of e-cigarettes as a smoking cessation treatment

To date, evidence on the effectiveness of e-cigarettes as a viable tool for smoking cessation remains limited and inconsistent. It is widely agreed that more robust and thorough studies are urgently required to fill the evidence gap.

The literature review conducted by the Thoracic Society of Australia and Aotearoa New Zealand (TSANZ)[40] found that reports from the NASEM, CSIRO, and the NHMRC all have concluded that the evidence on e-cigarettes as an effective smoking cessation aid is limited and that whether they are more or less superior than conventional smoking cessation aids or no treatment is unclear. The specific conclusions drawn from these reports are excerpted in the table below.

Organisation	Concluding statements (Excerpted from the report)
CSIRO[41]	In many countries **where appropriate evidence is available**, it appears that e-cigarette use occurs with cigarette use. However, the evidence is consistent in suggesting that use of e-cigarettes by non-smoking youth predicts future smoking. While many smokers and former smokers state a preference for e-cigarettes as a smoking cessation method, the effectiveness of this method compared with other smoking cessation methods is not known.
NASEM[42]	Conclusion 17-1. Overall, there is **limited evidence** that e-cigarettes may be effective aids to promote smoking cessation.

[35] AIHW. Alcohol, tobacco & other drugs in Australia. 2020. Available at: https://www.aihw.gov.au/reports/alcohol/alcohol-tobacco-other-drugs-australia/contents/drug-types/tobacco
[36] Banks E, Beckwith K, Joshy G. Summary report on use of e-cigarettes and impact on tobacco smoking uptake and cessation, relevant to the Australian context. 2020. Available at http://hdl.handle.net/1885/211618
[37] Australian Indigenous Health Bulletin Vol20 No2, April-June 2020. Available at: http://healthbulletin.org.au/wp-content/uploads/2020/06/AOD-Review-of-tobacco_Interactive-WEB_FINAL.pdf
[38] Greenhalgh EM, Stillman S, Ford C. Tobacco in Australia: Facts and Issues. 7.6 How smokers go about quitting. Available at: http://www.tobaccoinaustralia.org.au.
[39] Cummings KM, Hammond D. E-cigarettes: striking the right balance. The Lancet Public Health. 2020 Apr 1;5(4):e180-1.
[40] Electronic cigarettes: A position statement from the Thoracic Society of Australia and New Zealand. 2020. Available at: https://onlinelibrary.wiley.com/doi/full/10.1111/resp.13904
[41] Byrne S, Brindal E, Williams G, Anastasiou K, Tonkin A, Battams S, Riley M. E-Cigarettes, Smoking and Health. A Literature Review Update. Canberra, CSIRO, 2018.
[42] National Academies of Sciences, Engineering. Available at: https://www.ncbi.nlm.nih.gov/books/NBK507163/

	Conclusion 17-3. There is **insufficient evidence** from randomized controlled trials about the effectiveness of e-cigarettes as cessation aids compared with no treatment or to Food and Drug Administration–approved smoking cessation treatments.
NHMRC[43]	There is currently **insufficient evidence** to conclude whether e-cigarettes can assist smokers to quit. Smokers wishing to quit should consult the Quitline or their general practitioner.

A 2018 randomised controlled trial found that the 1-year abstinence rate was 18.0% in the e-cigarette group, as compared with 9.9% in the nicotine-replacement group when both groups had regular face-to-face meetings with clinicians. However, the study also pointed out that the rate of continuing e-cigarette use was substantially higher – around 80%[44], after 1 year among those who were tobacco abstinent, indicating that people were simply replacing tobacco cigarettes with e-cigarettes rather than ceasing smoking altogether.

A 2020 review of 13 studies concluded that e-cigarette use does not lead to significant increase in smoking cessation among smokers. The difference in smoking cessation was found to be similar among e-cigarette users compared with non–e-cigarette users. The pattern of use had an impact on outcomes for e-cigarette users. The study found that smokers who use e-cigarettes daily for at least a month were more likely to quit smoking compared with those who use e-cigarettes intermittently[45].

One of the conclusions drawn from the 2020 US Surgeon General's report is that as e-cigarettes are continually evolving and heterogenous products used in different ways, efficacy of a particular e-cigarette product demonstrated in clinical trials cannot draw generalisations. The report also emphasises that there is insufficient evidence to conclude that e-cigarettes, in general, increase smoking cessation at this point in time and that approved smoking cessation medicines, in conjunction with behavioural counselling are cost effective smoking cessation modalities[46].

A recent Cochrane review of 50 studies, with 4 of these rated at low risk of bias, concludes that there is moderate-certainty evidence (limited by imprecision) that nicotine e-cigarettes increased smoking cessation rates at six months or longer compared to non-nicotine e-cigarettes and nicotine replacement therapy, with the findings arising from the small number of randomised controlled trials. The absolute impact might be an additional 4 successful quitters in every 100. Moreover, there was very low-certainty evidence showing that nicotine e-cigarettes increased smoking cessation rates compared to behavioural support alone or no support. However, the need for more studies to ascertain the extent of effect, particularly when using modern e-cigarette products was highlighted in the review [47]. We note that the review did not address important questions such as sustained nicotine dependence or the risks associated with continuing use of e-cigarettes[48].

Conversely the 2020 Australian summary report did not find nicotine e-cigarettes to be more effective than no intervention, non-nicotine e-cigarettes, or nicotine replacement therapy in aiding smoking cessation. Instead, it found that nicotine e-cigarettes contribute to prolonged nicotine use and that the large majority of smokers successfully quit smoking without any aids[49]. The summary report also highlights that:

- Reviews and large-scale cross-sectional studies suggest a softening of the smoking population over time – declining smoking prevalence has generally been accompanied by increasing motivation to

[43]NHMRC. CEO Statement: Electronic Cigarettes. 2017. Available at: https://www.nhmrc.gov.au/about-us/resources/ceo-statement-electronic-cigarettes
[44] Hajek P, Phillips-Waller A, Przulj D, et al. A randomized trial of e-cigarettes versus nicotine-replacement therapy. N Engl J Med. 2019;380(7):629-637.
[45] Patil S, Arakeri G, Patil S, et al. Are electronic nicotine delivery systems (ENDs) helping cigarette smokers quit?-Current evidence. J Oral Pathol Med. 2020;49(3):181-189
[46] US Surgeon General Report: Smoking Cessation. 2020. Available at: https://www.hhs.gov/sites/default/files/2020-cessation-sgr-executive-summary.pdf
[47] Cochrane database of systemic reviews: electronic e-cigarettes for smoking cessation. 2020. Available at: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub4/full
[48] Cochrane database of systemic reviews: electronic e-cigarettes for smoking cessation. 2020. Available at: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub4/full
[4949] Australian National University. Summary report on use of e-cigarettes and relation to tobacco smoking uptake, smoking cessation, relevant to Australian context. Available at: https://openresearch-repository.anu.edu.au/bitstream/1885/211618/3/E-cigarettes%20smoking%20behaviour%20summary%20report%20final%20200924.pdf

quit, reduced dependency and greater quit rates among smokers. Only about 2% of adults aged 18 or over were smokers who were unmotivated or unable to quit in Australia.

- The concept of the “hardening hypothesis” - that as smoking prevalence decreases, the remaining smokers will be less willing to stop smoking should be dismissed, and be substituted with the evidence based conclusion that there is “softening” of the smoking population, who become more readily able to quit.

d. The established evidence on the uptake of e-cigarettes amongst non-smokers and the potential gateway effect onto traditional tobacco products

The 2018 NASEM report finds substantial evidence that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults[50].

In the US, a significant number of young people are using two or more tobacco products – the current use in the past 30 days and experimental use in 2019 are 4% and 11.5% among middle school students. The figures for high school students are 10.8% and 29.9% respectively[51].

The Canadian student tobacco, alcohol, and drug survey 2018-19 found that nicotine e-cigarettes are commonly used in students who vaped in the past 30 days – 90 per cent used nicotine containing products and 57 per cent used non-nicotine containing products. Moreover, of all those students, 42 per cent were never smokers. Among students who had tried both cigarettes and vaping products, 41 per cent experimented with an e-cigarette first and 47 per cent experimented with a tobacco cigarette first[52].

A recent Australian report[53] using a meta-analysis of data showed that never smokers who have used e-cigarettes were, on average, three times more likely to try and progress to tobacco smoking than those who have not used e-cigarettes. All studies found evidence of an increased risk of varying magnitude. Where information on types of e-cigarettes is available, nicotine e-cigarettes were the subject of research in the majority of these studies.

Nicotine is a highly addictive substance, and even the Australian Department of Health states that there is no safe level of tobacco use[54]. The RACP expresses strong concerns that nicotine e-cigarettes could be used as a ‘gateway’ to establish addiction to nicotine and smoking behaviour, and so lead to new tobacco cigarette smokers. E-cigarette use by young people is unsafe, even if they do not progress to cigarette smoking. To achieve harm reduction from nicotine, Australia must retain an environment in which it is difficult for young people to acquire nicotine products, be they tobacco cigarettes or e-cigarettes.

e. Evidence of the impact of legalising nicotine vaping products on youth smoking and vaping rates and measures that Australia could adopt to minimise youth smoking and vaping

Growth of e-cigarette use among youth has increased the most in in countries which have liberalised the e-cigarette regulatory environment.

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[50] National Academies of Sciences, Engineering. Available at: https://www.ncbi.nlm.nih.gov/books/NBK507163/
[51] CDC. Data and Statistic. Fast Facts and Fact Sheets: Youth and Tobacco use. Available at: https://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/index.htm
[52] Summary of results for the *Canadian Student Tobacco*, *Alcohol and Drugs Survey.* https://www.canada.ca/en/health-canada/services/canadian-student-tobacco-alcohol-drugs-survey/2018-2019-summary.html
[53] Banks E, Beckwith K, Joshy G. Summary report on use of e-cigarettes and impact on tobacco smoking uptake and cessation, relevant to the Australian context. 2020. Available at http://hdl.handle.net/1885/211618
[54] Australian Government Department of Health. Are there safe smoking and tobacco options? https://www.health.gov.au/health-topics/smoking-and-tobacco/about-smoking-and-tobacco/are-there-safe-smoking-and-tobacco-options

In the US, e-cigarettes have been the most commonly used tobacco products among young people since 2014[55]. A US survey found that the number of secondary students who had vaped in past 30 days doubled from 2017 to 2019. The increase is also found in the number of students who had vaped nicotine within the past 12 months and who had ever tried vaping from 2018 to 2019[56]. However, between 2019 to 2020, the use of e-cigarettes in the past 30 days has decreased from 10.5% to 4.7% among middle school students and from 27.5% to 19.6% among high school students[57].

In the US, the impact of a more liberalised regulatory environment can be seen as many young people view vaping as socially acceptable[58]. When young people were asked about their peers' attitudes to vaping, 44 percent said their peers approved of nicotine vaping, compared to only 23 percent who said their peers approved of cigarette smoking. This is of significant concern as the RACP advises that not smoking tobacco or using e-cigarettes remain the safest options for the community.

A recent US Morbidity and Mortality Weekly report revealed that 27.5% of high school students were current e-cigarette users and 73.4% of high school students had seen e-cigarette use on campus in 2019. This increase occurred with the rising popularity of pod mods, which usually use nicotine salts to allow easier inhalation of high level of nicotine with less irritation to throat[59]. During the 2018–19 school year, roughly 1,000 vaping products were confiscated from 25 high schools located in California and North Carolina[60].

A recent paper by the Substance Abuse and Mental Health Services Administration (SAMHSA) in the US on reducing vaping amongst youth and young adults[61] outlined the following challenges in relation to preventing youth vaping:

- Access and availability of vaping products – despite a federal law being passed in December 2019, to raise the federal legal age to purchase tobacco, including e-cigarettes, to 21, youths are able to obtain vaping products either online or from stores without age verification. In addition, sharing devices and getting older friends or siblings to purchase them was common.

- Marketing that targets young people – marketing aimed at youth (including flavouring) and sponsorship of youth focused events normalises vaping and vaping devices are able to advertise on television, in movies, magazines, newspapers, social media, and other mediums.

- Perception of vaping as low risk to health – because there is no combustion, youth see vaping as far less harmful or even harmless in comparison to tobacco cigarettes.

- Use of vaping products in public places – while some states in the US include vaping under smoke/tobacco free laws, other states do not so there is confusion. This leads to people vaping in designated smoke/tobacco free areas, one study noting[62] 60% of people who vape doing so in smoke free areas such as restaurants, movie theatres and shopping malls.

- Regulatory environment – in the US, while the FDA has federal regulatory authority over e-cigarettes and vaping devices, states and local jurisdictions may also have the authority to pass policies to

[55] CDC Data and Statistics: Youth and Tobacco use. https://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/index.htm
[56] Miech R, Johnston L, O'Malley PM, Bachman JG, Patrick ME. Trends in adolescent vaping, 2017–2019. *N Engl J Med* 2019; 381: 1490–91.
[57] CDC Data and Statistics: Youth and Tobacco use. https://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/index.htm
[58] Substance Abuse and Mental Health Services Administration (SAMHSA): Reducing Vaping Among Youth and Young Adults. SAMHSA Publication No. PEP20-06-01-003. Rockville, MD: National Mental Health and Substance Use Policy Laboratory, Substance Abuse and Mental Health Services Administration, 2020
[59] CDC. US Morbidity and Mortality Weekly report. Characteristics of E-cigarette, or Vaping, Products Confiscated in Public High Schools in California and North Carolina — March and May 2019 .October 2020. Available at: https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6942a7-H.pdf
[60] CDC. US Morbidity and Mortality Weekly report. Characteristics of E-cigarette, or Vaping, Products Confiscated in Public High Schools in California and North Carolina — March and May 2019 .October 2020. Available at: https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6942a7-H.pdf
[61] Substance Abuse and Mental Health Services Administration (SAMHSA): Reducing Vaping Among Youth and Young Adults. SAMHSA Publication No. PEP20-06-01-003. Rockville, MD: National Mental Health and Substance Use Policy Laboratory, Substance Abuse and Mental Health Services Administration, 2020
[62] Shi, Y., Cummins, S. E., & Zhu, S. (2017). Use of Electronic Cigarettes in Smoke-Free Environments. Tobacco Control, 26(e1), e19–e22. https://doi. org/10.1136/tobaccocontrol-2016-053118

reduce access to, and availability of, these products. Because of this complicated environment, evidence-based approaches to policy to ensure rates of youth vaping are reduced are required.

- Cultural considerations – the social relationships that develop a culture of vaping, such as sharing and borrowing devices and the element of peer group pressure all add to the embedding and normalisation of the behaviour. YouTube channels and social media dedicated to vaping are proliferating.

The issues raised by SAMHSA echo the concerns that e-cigarette advertising and role-modelling could restore the social norms around smoking and undermine or even reverse the decades-long work to remove any positive associations with smoking[63].

While similarly to other countries, rates of cigarette use amongst youth in the US continues to decline, there is no clear evidence to show a causal relationship between increases in vaping and reduction in cigarette use. In fact, research has found that adolescents who reported never smoking but tried e-cigarettes were more likely to try cigarettes in the future[64].It is not yet clear whether vaping is associated with continued cigarette smoking in the long term, or primarily with initial experimentation.

In the UK, the prevalence of ever use of e-cigarettes among young people aged 11 to 15 years old was 25% in 2018, the same as in 2016, but an increase compared to 2014[65]. Current e-cigarette use increases with age – ranging from less than 1% of young people aged 11 to 11% of young people aged 15[66]. Figure one shows the prevalence of e-cigarette use in the UK between 2014 to 2018 from the NHS data. It is noteworthy that a minimum age of e-cigarettes of 18 was imposed in October 2015 in the UK[67].

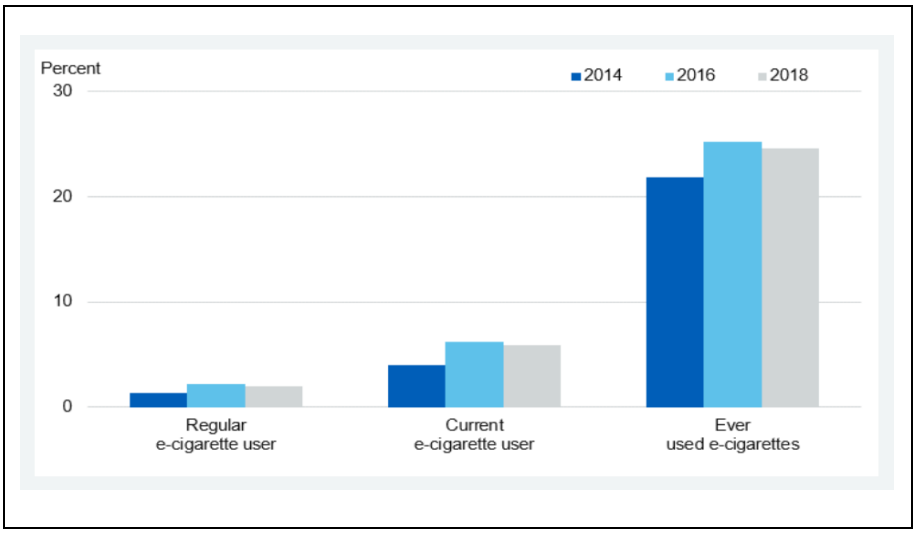

Figure 1 shows the prevalence of e-cigarette use in the UK between 2014-18 (from NHS digital)

A Canadian survey found 20% of student had used e-cigarettes in the past 30 days between 2018 and 2019, an increase from 10% in 2016-17[68].

[63] RACP policy on e-cigarettes 2018. Available at: https://www.racp.edu.au/docs/default-source/advocacy-library/policy-on-electronic-cigarettes.pdf
[64] Substance Abuse and Mental Health Services Administration (SAMHSA): Reducing Vaping Among Youth and Young Adults. SAMHSA Publication No. PEP20-06-01-003. Rockville, MD: National Mental Health and Substance Use Policy Laboratory, Substance Abuse and Mental Health Services Administration, 2020
[65] NHS digital data / Smoking, Drinking and Drug Use among Young People in England 2018. Available at: https://digital.nhs.uk/data-and-information/publications/statistical/smoking-drinking-and-drug-use-among-young-people-in-england/2018
[66] NHS digital data / Smoking, Drinking and Drug Use among Young People in England 2018. Available at: https://digital.nhs.uk/data-and-information/publications/statistical/smoking-drinking-and-drug-use-among-young-people-in-england/2018
[67] NHS digital data / Smoking, Drinking and Drug Use among Young People in England 2018. Available at: https://digital.nhs.uk/data-and-information/publications/statistical/smoking-drinking-and-drug-use-among-young-people-in-england/2018
[68] Summary of results for the Canadian Student Tobacco, Alcohol and Drugs Survey. https://www.canada.ca/en/health-canada/services/canadian-student-tobacco-alcohol-drugs-survey/2018-2019-summary.html

In Aotearoa New Zealand, a cross sectional survey of almost half of all school students aged 14-15 found that between 2014 and 2019, the number of students who had ever tried e-cigarettes increased significantly from 20.8% to 37.3%, while the number for those who had ever smoked cigarettes decreased significantly from 23.1% to 19.6 %. However, between 2018-2019 (a period of marked increase in access to nicotine e-cigarettes in NZ), an increase was found in the number of students who had ever tried e-cigarettes, from 33.3% to 37.3%; a small but significant increase was also found in the number of students who had ever smoked a cigarette, from 18.9% to 19.6%[69].The authors of the study were unable to determine whether these changes were directly related to the March 2018 change in access to nicotine e-cigarettes in Aotearoa New Zealand. The authors suggest that future data collection should be focused on daily use of e-cigarettes in the context of daily smoking prevalence as well as the types of e-cigarette use (with or without nicotine)[70].

The very low smoking uptake by young people – 97% of young people aged 14 to 17 were never smokers in 2019[71] is the primary reason behind Australia's decreasing smoking rate. It is therefore essential that continuing efforts are directed at maintaining the very low smoking uptake rate by young people in Australia.

The RACP is significantly concerned that any easing of access restrictions would be a contributing factor to ongoing and alarming increases in vaping amongst teens, which is currently seen in jurisdictions such as the US and Canada. There is evidence suggesting youth access to e-cigarettes through illegal retailer sales[72] or through legal purchasers inside their social circles[73] e.g. peers, relatives or strangers – and this warrants the Australian Government's attention. This increased access to e-cigarettes and the evidence linking e-cigarette use with uptake of tobacco use amongst youth[74], poses a concerning dilemma if we are to maintain the very low smoking uptake rate by young Australians. The access to nicotine containing e-cigarettes for smokers who are unable to quit with other approved therapies should not come at the expense of the continued declining rates of smoking uptake by Australian young people.

As we see from these studies that the decline in ever smoking rates occurs concurrently with an increase in e-cigarette ever use, the RACP notes we must factor in the aggregate rates of ongoing nicotine use and dependence, as well as the related future health and social risks and harms. Further, Australia has seen a steady decline in daily tobacco smoking since 1991[75]. If this declining trend continues, this means that the balance of harm and benefit or the net public health effect with regard to e-cigarettes will continually change as a result.

Studies have shown that children develop nicotine dependence, even at low levels of consumption within days of starting to smoke, and so the uptake of nicotine-containing e-cigarettes among children and adolescents is a cause for concern[76].

An Australian online survey in 2018 looked into nicotine and flavouring product preferences among young adult e-cigarette users aged 18-25 years old[77].The study found that a substantial number of young adult e-cigarette users, including never smokers, favoured nicotine (64%) and flavoured (89%) e-cigarettes. The finding of this study suggests the need to better enforce authorised supply of nicotine e-cigarettes through

[69] Walker N, Parag V, Wong SF et al. Beaglehole R. Use of e-cigarettes and smoked tobacco in youth aged 14–15 years in New Zealand: findings from repeated cross-sectional studies (2014–19). The Lancet Public Health. 2020 Jan 22.
[70] Walker N, Parag V, Wong SF et al. Beaglehole R. Use of e-cigarettes and smoked tobacco in youth aged 14–15 years in New Zealand: findings from repeated cross-sectional studies (2014–19). The Lancet Public Health. 2020 Jan 22.
[71] Banks E, Beckwith K, Joshy G. Summary report on use of e-cigarettes and impact on tobacco smoking uptake and cessation, relevantto the Australian context. 2020. Available at http://hdl.handle.net/1885/211618
[72] FDA News. FDA takes new steps to address epidemic of youth e-cigarette use, including a historic action against more than 1,300 retailers and 5 major manufacturers for their roles perpetuating youth access. Available at: https://www.fda.gov/news-events/press-announcements/fda-takes-new-steps-address-epidemic-youth-e-cigarette-use-including-historic-action-against-more
[73] Substance Abuse and Mental Health Services Administration (SAMHSA): Reducing Vaping Among Youth and Young Adults. SAMHSA Publication No. PEP20-06-01-003. Rockville, MD: National Mental Health and Substance Use Policy Laboratory, Substance Abuse and Mental Health Services Administration, 2020
[74] Substance Abuse and Mental Health Services Administration (SAMHSA): Reducing Vaping Among Youth and Young Adults. SAMHSA Publication No. PEP20-06-01-003. Rockville, MD: National Mental Health and Substance Use Policy Laboratory, Substance Abuse and Mental Health Services Administration, 2020
[75] AIHW. Alcohol, tobacco & other drugs in Australia. 2020. Available at: https://www.aihw.gov.au/reports/alcohol/alcohol-tobacco-other-drugs-australia/contents/drug-types/tobacco
[76] RACP policy on e-cigarettes 2018. Available at: https://www.racp.edu.au/docs/default-source/advocacy-library/policy-on-electronic-cigarettes.pdf
[77] Jongenelis MI, Kameron C, Brennan E, et al. E-cigarette product preferences among Australian young adult e-cigarette users. Australian and New Zealand Journal of Public Health. 2018 Dec;42(6):572-4.

personal importation from oversees, to regulate flavourings in e-liquids and to monitor the characteristics of e-cigarettes used[78].

To prevent vaping uptake by youth, the RACP supports appropriate regulatory controls on the sale, supply, use and promotion of e-cigarette devices, with a focus on youth protection. Specifically, we also recommend:

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

It is vitally important for the Australian government to continue monitoring the uptake of vaping by young people, so an appropriate government response can be elicited in a timely manner.

f. Access to e-cigarette products under Australia's current regulatory frameworks

Under the current regulatory framework, nicotine e-cigarettes are illegal under Commonwealth, state and territory legislation (due to the current scheduling of nicotine – Schedule 4 and 7) , while non-nicotine containing e-cigarettes are legal and have been included into the majority of state tobacco control legislation to tighten their sale, supply, use and promotion. The only legal avenues to access nicotine containing e-cigarettes are through two TGA schemes – Personal importation or Special Access Scheme/ Authorised Prescriber – that allow the import of unapproved therapeutic goods.

1. Personal importation – Where an importer must hold a prescription from an Australian registered medical practitioner and the quantity imported must be no more than three months' supply at any one time. The importation of nicotine-containing e-cigarettes must be for smoking cessation purposes and are to be used by importer himself/ herself only or an immediate family member, if they have a valid prescription.

2. Special Access Scheme/ Authorised Prescriber – Where medical practitioners are required to apply to access the unapproved therapeutic goods on behalf of their patients.

The current regulatory framework is not watertight, as the TGA's personal importation scheme does not prohibit the importation or possession of nicotine-containing e-cigarettes for recreational use[79].

The recent announcement from the Australian Government foreshadowed a ban on the personal importation of nicotine e-cigarettes and refills from 1 January 2021, unless on prescription from a doctor. This proposed ban has been deferred, with the TGA making the following statement on 22 October:

The Delegate's interim decision published on 23 September 2020 and open for public consultation to 6 November 2020 to include nicotine for all human use in Schedule 4 of the Poisons Standard was made primarily on the basis of two considerations. These are:

- *To prevent the rapid growth of youth uptake in vaping seen overseas and already occurring in Australia - avoid the ON RAMP for non-smokers especially youth*

- *To facilitate simple and legal access to nicotine containing e-cigarettes for smoking cessation – provide the OFF RAMP for smokers.*

[78] Jongenelis MI, Kameron C, Brennan E, et al. E-cigarette product preferences among Australian young adult e-cigarette users. Australian and New Zealand Journal of Public Health. 2018 Dec;42(6):572-4.
[79] Parliament of Australia: Report on Vaporised Nicotine Products Bill 2017. Chapter 2: Issues https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/VaporisedNicotine/Report/c02

Pending the final outcome of the process required by law, it has been decided to defer the proposed restriction on importation of nicotine for use in e-cigarettes and, separately, e-cigarette devices (by an amendment to the Customs (Prohibited Imports) Regulations 1956). To proceed, at the present time, with such an amendment, would unnecessarily pre-empt any further deliberations the Delegate is required by the therapeutic goods regulatory scheme to take in reaching a final decision.

The TGA will be making a final decision by the end of this year on the scheduling of nicotine in the Poisons Standard. The interim decision made in September 2020, outlines that when included in Schedule 4 medicines, in item 5 of Appendix D, that possession of Schedule 4 products containing nicotine must be in accordance with a legal prescription. The final decision on the scheduling of nicotine will further inform the implementation of the Government's proposed prohibition on the importation of e-cigarettes containing vaporiser nicotine.

The RACP supports the precautionary approach to e-cigarettes taken by the Australian government to date, including the proposed ban on personal importation as well as the proposed amendment to the scheduling of nicotine. However, we have concerns about the proposed regulatory mechanism with regard to doctors prescribing unapproved nicotine e-cigarette products, for which there is no safety, effectiveness and quality data and assessment. The RACP recommends the TGA provide further time to properly deal with the issues of the lack of high-quality evidence to inform prescribing decisions and the medico- legal responsibilities for prescribing unapproved therapeutic products to ensure safe prescribing. Without proper planning and consultation, the regulatory changes may not be implemented as intended.

g. Tobacco industry involvement in the selling and marketing of e-cigarettes

Global tobacco companies, such as British American Tobacco, Imperial Tobacco, Reynolds American Inc. and Lorillard, have now either established or acquired e-cigarettes as part of their product line[80]. These acquisitions are their strategy of diversification to increase sales by establishing new markets and new products[81] [82]. Their discourse in harm reduction is an opportunistic tactic in response to policy change and to be involved in the development of next generation products such as heated tobacco products and e-cigarettes, instead of a genuine interest and motive in pursuing harm reduction[83] [84].

Tobacco companies have been utilising a multitude of strategies to drive sales growth and maximise profits[85]. A recent Australian study uncovers that tobacco companies have invested significantly in relationship marketing tactics in the retail environment[86]. The tobacco retail marketing and promotion strategies utilised have included: price promotions, cash payments and rebates, all-expenses paid vacations, exclusive parties and events, as well as target marketing and education[87].

The Australian government must remain mindful of the tobacco industry's historical tactics and attempts to influence and resist tobacco control policy and that there are often major conflicts between the vested commercial interests of the tobacco industry and public health[88]. Public health and safety must be a core public interest consideration for government. Industry and retail considerations and their consumers' "convenience" are primarily private commercial interests and should not be components of the policy decision-

[80] Grana R, Benowitz N, Glantz SA. E-cigarettes: a scientific review. *Circulation*. 2014;129(19):1972-1986.
[81] Dewhirst T. Co-optation of harm reduction by Big Tobacco. Available at: https://tobaccocontrol.bmj.com/content/early/2020/08/11/tobaccocontrol-2020-056059
[82] Mathers A, Hawkins B, Lee K. Transnational tobacco companies and new nicotine delivery systems. American journal of public health. 2019 Feb;109(2):227-35.
[83] Dewhirst T. Co-optation of harm reduction by Big Tobacco. Available at: https://tobaccocontrol.bmj.com/content/early/2020/08/11/tobaccocontrol-2020-056059
[84] Peeters S, Gilmore AB. Understanding the emergence of the tobacco industry's use of the term tobacco harm reduction in order to inform public health policy. Tobacco control. 2015 Mar 1;24(2):182-9.
[85] Dewhirst T. Co-optation of harm reduction by Big Tobacco. Available at: https://tobaccocontrol.bmj.com/content/early/2020/08/11/tobaccocontrol-2020-056059
[86] Watts C, Burton S, Freeman B. 'The last line of marketing': Covert tobacco marketing tactics as revealed by former tobacco industry employees. Glob Public Health. 2020 Sep 18:1-14. doi: 10.1080/17441692.2020.1824005. Epub ahead of print. PMID: 32946326.
[87] Watts C, Burton S, Freeman B. 'The last line of marketing': Covert tobacco marketing tactics as revealed by former tobacco industry employees. Glob Public Health. 2020 Sep 18:1-14. doi: 10.1080/17441692.2020.1824005. Epub ahead of print. PMID: 32946326.
[88] Grana RA, Benowitz N, Glantz SA. Background Paper on E-cigarettes (Electronic Nicotine Delivery Systems). WHO Tobacco Control Papers. 2013.

making process[89]. Tobacco industry donations can be used as a mechanism of influence over e-cigarette debate; declaration of financial donations to health advocates and organisations should be made mandatory.

The RACP maintains that e-cigarette and tobacco industries must not be involved in the design of e-cigarette regulatory framework, and the associated implementation and clinical guideline development in Australia. These industries are not experts in health policy; there are major conflicts between their vested commercial interests and public health.

Many e-cigarette products are promoted in ways that glamorise smoking. Despite conflicting evidence on their efficacy as a smoking cessation aid, they are also frequently marketed for this purpose. An analysis of e-cigarette retail websites found that almost all made explicit or implicit health-related claims[90]—including many that featured doctors—and the majority had a smoking cessation-related claim. Such sites generally lack adequate information regarding nicotine and addiction, or potential health risks of using the products.

As outlined in section E, above, the proliferation of vaping related content on online and on social media, including advertising, where e-cigarette advertising is often youth focused, is also associated with a greater risk for e-cigarette use among adolescents[91].

Online marketing of e-cigarettes is more difficult to regulate than point of sale marketing, which tends to more readily reflect country specific policies ie. less marketing in countries with stricter policies[92]. The RACP reiterates that e-cigarettes must not be allowed to be promoted in a way that encourages youth uptake or smoking initiation. Prohibition of marketing tactics such as messaging and commercial strategy used by tobacco and e-cigarette industries aiming at young people and prescribing doctors to increase the sale of nicotine e-cigarettes should be considered.

The concept of corporate capture is a critical new consideration requiring our attention. In the context of harm reduction, it refers to the process by which corporations present a case for purported harm reduction with the aim to influence decision making through deliberately attempting to dominate the information environment[93]. Casting doubt on independent evidence from trusted sources is a key strategy to achieve this. Other tactics utilised encompasses misrepresenting unfavourable strong evidence and promoting favourable weak evidence[94].

The RACP emphasises that the current evidence base for e-cigarettes is limited and conflicting on many fronts, in particular their role in smoking cessation, impacts and health risks, which calls into question their impact on smoking rates. We note that it is possible for differing views to be expressed on the basis of the same evidence. The Australian Government needs to be alert to and resist the tobacco and vaping groups' attempts to favourably misrepresent the scientific evidence base[95], as part of their effort to influence opinions and decision-making.

h. Any other related matter

The RACP would like to highlight three important issues in relation to e-cigarettes:

1) Nicotine toxicity

[89] Brown T. Legislative capture: a critical consideration in the commercial determinants of public health. J Law Med. 2019;26(4):764–85.
[90] Grana RA and Ling PM. "Smoking revolution": A content analysis of electronic cigarette retail websites. American Journal of Preventive Medicine, 2014; 46(4):395-403. Available at: https://www.ncbi.nlm.nih.gov/pubmed/24650842
[91] Vogel EA, Ramo DE, Rubinstein ML, Delucchi KL, Darrow S, et al. Effects of social media on adolescents' willingness and intention to use e-cigarettes: An experimental investigation. Nicotine & Tobacco Research, 2020. Available at: https://www.ncbi.nlm.nih.gov/pubmed/31912147
[92] Cho YJ, Thrasher J, Cummings M, Yong HH, Hitchman SC, et al. Cross-country comparison of cigarette and vaping product marketing exposure and use: Findings from 2016 ITC four country smoking and vaping survey. Tobacco Control, 2019. Available at: https://www.ncbi.nlm.nih.gov/pubmed/31152116
[93] McCambridge J, Kypri K, Drummond C, Strang J. Alcohol harm reduction: corporate capture of a key concept. PLoS Med. 2014 Dec 9;11(12):e1001767.
[94] McCambridge J, Kypri K, Drummond C, Strang J. Alcohol harm reduction: corporate capture of a key concept. PLoS Med. 2014 Dec 9;11(12):e1001767.
[95] Miller D, Harkins C. Corporate strategy, corporate capture: food and alcohol industry lobbying and public health. Critical social policy. 2010 Nov;30(4):564-89.

The risk of accidental exposure or ingestion of nicotine in e-liquid is a growing problem in that there is currently no regulation on child resistant packaging. Since e-cigarettes became available on the market, the number of calls to poisons control centres relating to unintentional exposure to nicotine in e-liquids among young children has increased considerably in Australia and other countries[96] [97] [98]. These incidents primarily involved ingestion of nicotine e-liquid and inhalation of the aerosol.

The RACP is particularly concerned about nicotine ingestion in children and infants. Ingestion of nicotine can result in a range of side effects, including burning sensation in mouth and throat, nausea, vomiting, and confusion, at low to moderate toxic dose. Higher doses are associated with arrhythmias, bradycardia, convulsions, coma, respiratory failure, rapid progression to hypotension, and death[99]. A case study in Korea proved that nicotine ingestion in infants can be fatal[100].

2) Poor product safety and quality of e-cigarettes

Presently, e-cigarettes are largely unregulated products. There is little conclusive evidence available about the product safety and quality of e-cigarettes. Some safety issues have been reported due to the lack of quality control and standards:

- Incorrect nicotine concentration labelling[101]
- Variation in the composition and concentrations of e-liquids, across and within brands[102].
- Explosion of the batteries, e-liquid leaking, and operational risks, resulting in burns or poisoning in children[103].

These are serious concerns that need to be looked into and addressed, if Australia is considering to allow prescribing unapproved nicotine e-cigarette products. In our view, these concerns can be addressed through the establishment of quality and safety standards for e-cigarette products and the enforcement of the packaging and labelling requirements, including disclosure of all ingredients and their concentrations in e-liquid, child-resistant packaging, plain packaging rules and health warning labels.

Another cause of concern of the RACP is the flavouring chemicals used in e-cigarettes. There is a wide range of choices of flavoured e-cigarettes currently available on the market. The safety of inhaling heated flavouring chemicals is unknown and has not been well studied. The NHMRC cautions that several studies have reported the harmful effects of inhaling certain flavourings that are approved for ingestion such as cherry, cinnamon and popcorn flavours. Moreover, the NHMRC also underlines that a growing body of evidence has found that the long-term use of flavours in e-cigarettes is likely to pose a risk to health.

3) Vaping related lung illness in the United States

On another note, the 2019 outbreak of e-cigarette, or vaping, product use–associated lung injury (EVALI) in the United States led to a total of 2087 reported cases or death (68 deaths in 29 states and the District of Columbia), as of February 2020[104]. Many patients were hospitalised, requiring critical care and respiratory support, but recovered with the cessation of e-cigarette use and administration of steroid therapy. 63% of patients with fatal cases were diagnosed with acute respiratory distress syndrome, which can progress to life

[96] Wylie C, Heffernan A, Brown JA, Cairns R, Lynch AM, Robinson J. Exposures to e-cigarettes and their refills: calls to Australian Poisons Information Centres, 2009–2016. The Medical Journal of Australia. 2019 Jan 28;210(3):126.
[97] Centers for Disease Control and Prevention. Calls to Poison Centers for Exposures to Electronic Cigarettes — United States, September 2010–February 2014 2014. Available at: https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6313a4.htm?s_cid=mm6313a4_w
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threatening acute hypoxemic respiratory failure. This diagnosis is more common among hospitalised patients with EVALI who have chronic conditions, for example cardiac and respiratory diseases and mental health condition[105].

The EVALI outbreak illustrated that e-cigarette use is not confined to nicotine but being used to consume cannabis among young people. Although vitamin E acetate was identified as a primary cause, the US Centers for Disease Control and Prevention (CDC) highlights that evidence is not sufficient to exclude the contribution of other chemicals of concern in some of these injuries[106]. It is noteworthy that before this outbreak, there were already at least 30 reports of lung illnesses linked to e-cigarettes in the literature, starting from 2012. A wide range of lung conditions were highlighted in these reports, encompassing organizing pneumonia and diffuse alveolar damage to interstitial lung disease[107].

The RACP holds that the EVALI outbreak underscores the risks associated with e-cigarette use and proves the need for caution in allowing the supply of and access to such product. E-cigarette products must not be used by youths and young people; youth access to e-cigarette products through personal importation scheme or legal purchasers inside their social circles must be strongly prohibited.

Concluding Comments

The RACP strongly supports that no recommendations be made with respect to the current regulatory framework for e-cigarettes until the completion of the evidence review by the National Health and Medical Research Council (NHMRC) and the public consultation by the Therapeutic Goods Administration (TGA), as recommended by the previous House of Representatives Standing Committee inquiry. Any changes to the e-cigarette regulatory framework must consider the impact of e-cigarettes on overall smoking rates (including the aggregated data on ongoing nicotine use and dependence from smoking, vaping and dual use), as well as smoking initiation rates and the overall health of population.

Although there may be a role of e-cigarettes in smoking cessation, the current evidence base about its effectiveness compared with conventional smoking cessation and its impact on the broader population health is limited and insufficient, as per NHMRC Levels of Evidence or Grades of Recommendations, to inform such recommendations[108].

There is evidence suggesting significant youth vaping uptake, transition to tobacco smoking, nicotine addiction in countries where e-cigarette markets are liberalised, as well as dual e-cigarette and tobacco use. All these issues are also identified in the first Australian Government commissioned report on the use of e-cigarettes and are critical to determine the net public health impact of e-cigarettes.

The RACP urges that attention should be given to the findings of the first Australian Government commissioned report on use of e-cigarettes and the relationship to tobacco smoking uptake and cessation, in particular that:

- The recent significant declines in smoking in Australia is primarily ascribed to very low smoking uptake by young people – 97% of young people aged 14 to 17 were never smoker in 2019.
- A vast majority of former smokers successfully quit smoking without any aid.
- Declining smoking prevalence has generally been accompanied by increasing motivation to quit, reduced dependency and greater quit rates among smokers in Australia and other higher income countries.

Approved conventional smoking cessation methods are proven to be effective and safe. **Encouraging smokers to quit or any easing of access to nicotine e-cigarettes by smokers must not be made at the expense of increasing the number of young people who take up vaping and nicotine addiction.**

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