Dear Select Committee on Tobacco Harm Reduction,

The National Health and Medical Research Council (NHMRC) welcomes the opportunity to provide a submission to the Select Committee on Tobacco Harm Reduction.

I am writing to advise the Select Committee of the work that is currently underway at NHMRC on the safety and efficacy of electronic cigarettes (e-cigarettes).

As Australia's lead agency for health and medical research, NHMRC works actively and collaboratively to promote the highest research standards and develop evidence-based health advice. The *National Health and Medical Research Council Act 1992* charges NHMRC with promoting the development of individual and public health standards, fostering national consistency in health standards, supporting research and training, and fostering consideration of relevant ethical issues. This work includes developing evidence-based guidelines, health advice and companion resources that aim to improve the health and wellbeing of the Australian population.

In 2017, I released an updated1 CEO Statement: Electronic Cigarettes (the Statement) which summarises evidence on the safety and efficacy of e-cigarettes. The Statement (Attachment 1) aims to assist consumers, policy makers, health professionals and those advising people considering the uptake of e-cigarettes. It concluded that:

- there was insufficient evidence to support claims that e-cigarettes are safe;
- further research was needed to enable the long-term safety, quality and efficacy of e-cigarettes to be assessed; and
- until such evidence was produced, health authorities and policy-makers should act to minimise harm to users and other vulnerable groups.

Recent deaths in the United States (US) linked to e-cigarette use, as well as emerging evidence, have prompted both the US and Australian Governments to review e-cigarette evidence, policy and regulation. In April 2020, the Commonwealth Department of Health contracted NHMRC, as part of a suite of projects on e-cigarettes, to update the 2017 Statement.

NHMRC has established an expert committee, the Electronic Cigarette Working Committee (the Committee) to advise on the update of the Statement. The Committee is comprised of members with expertise in public health, toxicology, respiratory medicine, marketing, epidemiology and smoking cessation. NHMRC is now seeking reviewers to evaluate current evidence relevant to the marketing and use of e-cigarettes and their impacts on individual

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1 The 2017 Statement was an update of the 2015 Statement and was developed in consultation with, and supported by, the Chief Health Officers from all Australian states and territories.
and population health. The Committee will use the findings of these evidence evaluations to inform the updated Statement.

In addition to updating the Statement, NHMRC is funding research on e-cigarettes. Since 2011, NHMRC has funded 13 grants, committing over $12.4 million for research into e-cigarettes to investigate the:

- efficacy of e-cigarettes for smoking cessation, including amongst disadvantaged and vulnerable populations
- health effects of e-cigarettes
- uptake of e-cigarettes in children and adolescents
- potential impact of e-cigarettes on smoking uptake, and
- effect of new media platforms on e-cigarette promotion and consumer behaviour.

Further information about these research grants is provided in Attachment 2.

NHMRC’s submission is drawn from the 2017 CEO Statement (Attachment 1) and from the evidence identified as part of its development. The submission addresses the following aspects of the Select Committee’s Terms of Reference:

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

Stakeholders hold a range of views about the safety of e-cigarettes and whether they can minimise harm to smokers or help them to quit smoking all together. Concerns have been raised about the potential for e-cigarettes to undermine existing tobacco-control measures, by renormalising smoking, or providing young people with an alternative entryway into nicotine addiction and tobacco cigarette smoking.²

Many proponents contend that e-cigarettes are likely to be less harmful than tobacco cigarettes, because they expose users to fewer toxic chemicals. However, there is insufficient evidence to quantify the reduction in risk when e-cigarettes are used instead of tobacco cigarettes. The World Health Organisation has stated that “no specific figure about how much ‘safer’ the use of these products is compared to smoking can be given any scientific credibility at this time.” The CEO Statement found that there was insufficient evidence to quantify the reduction in risk when e-cigarettes are used instead of tobacco cigarettes.²

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

Experts disagree about whether e-cigarettes may help smokers to quit, or whether they will become ‘dual users’ of both e-cigarettes and tobacco cigarettes. The 2017 Statement found that there is insufficient evidence to demonstrate that e-cigarettes are effective in assisting people to quit smoking and no brand of e-cigarette has been approved by the Therapeutic Goods Administration (TGA) for this purpose.²
A 2016 systematic review conducted by the Cochrane Collaboration found some evidence that e-cigarettes with nicotine may assist smokers to quit, but there was a low level of confidence in this finding due to the small volume of evidence. The Cochrane Collaboration has recently updated their systematic review.

NHMRC will review new evidence in this area in the update of the Statement. NHMRC is also funding a range of research projects (Attachment 2) that will assist in informing the evidence base on the role of e-cigarettes in smoking cessation.

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

The 2017 Statement found that there was some evidence that e-cigarettes could act as a gateway into nicotine addiction or cigarette smoking, with some studies showing the effect of e-cigarettes on future smoking behaviour was greatest among those who were otherwise at low risk of taking up smoking. Similarly, some studies indicated an association between e-cigarette use in non-users and future use of marijuana or other tobacco products such as hookahs, cigars or pipes.

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

As part of updating the 2017 Statement, NHMRC will engage an evidence reviewer to evaluate the evidence on the impact of marketing and advertising on the uptake and consumption of electronic cigarettes.

In scoping this work, NHMRC staff have found the following on the marketing of e-cigarettes:

- Although research is still emerging, there is evidence indicating that there may be a link between the marketing of e-cigarettes and e-cigarette use.

- International evidence regarding e-cigarette use is increasing; however Australian research and data remains limited.

- E-cigarette marketing in Australia is found online, in print media and in retail outlets.

- Currently, the portrayal of e-cigarettes online is strongly influenced by e-cigarette companies and advertisers, and an analysis in the US of online and social media platforms suggests that e-cigarettes are discussed in a neutral or positive context. Public health concerns do not appear to be reflected in ongoing social media dialogue.

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A market traditionally dominated by small companies, the e-cigarette market has grown rapidly with large tobacco companies and manufacturers now buying into or developing e-cigarette products.\textsuperscript{7}

NHMRC will evaluate the evidence on this topic in updating the 2017 Statement.

Updating the Statement will ensure that Australians are provided with the most up-to-date information on the safety and potential health implications of e-cigarettes and the impact of marketing and advertising on the uptake of e-cigarettes.

It is anticipated that the updated CEO Statement will be released in late 2021. Once released, the Statement will be publicly available on the NHMRC website.

We look forward to following the outcomes of the Select Committee on Tobacco Harm Reduction.

Yours sincerely,

Professor Anne Kelso AO
Chief Executive Officer

NHMRC CEO Statement: Electronic Cigarettes (E-Cigarettes)

Summary

Electronic cigarettes (e-cigarettes, also known as electronic nicotine delivery systems (ENDS) or electronic non-nicotine delivery systems (ENNDS)) are often marketed as a method to assist smokers to quit, or as a ‘safe alternative’ to conventional tobacco cigarettes. However, there is currently insufficient evidence to support claims that e-cigarettes are safe and further research is needed to enable the long-term safety, quality and efficacy of e-cigarettes to be assessed.

Key messages

• E-cigarettes may expose users to fewer toxic chemicals than conventional tobacco cigarettes; however the extent to which this reduces harm to the user has not been determined.

• E-cigarettes may expose users to chemicals and toxins such as formaldehyde, heavy metals, particulate matter and flavouring chemicals, at levels that have the potential to cause adverse health effects.

• 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.

• There is some evidence from longitudinal studies to suggest that e-cigarette use in non-smokers is associated with future uptake of tobacco cigarette smoking.

• Health authorities and policy-makers should act to minimise harm to users and bystanders, and to protect vulnerable groups such as young people, until evidence of safety, quality and efficacy can be produced.

• NHMRC is currently funding a number of studies into the safety and efficacy of e-cigarettes.

• Consumers should seek further information about e-cigarettes from reliable sources, such as the relevant State or Territory Health Department or quit smoking services.

E-cigarettes are battery operated devices that heat a liquid (called ‘e-liquid’) to produce a vapour that users inhale. Although the composition of this liquid varies, it typically contains a range of chemicals, including solvents and flavouring agents, and may or may not contain nicotine. E-cigarettes have evolved as a product group since first entering the market, with products now ranging from early ‘first generation’ devices that resemble cigarettes, to second and third generation devices that enable users to modify characteristics of the device, such as adjusting the voltage.1

This wide variation in products, and the ability of users to customise their vaping experience, makes it difficult to assess the safety and efficacy of e-cigarettes as a group, because the results from research involving one particular product may not be applicable to all e-cigarettes or all users. However, by examining the evidence to identify common findings across a range of different products, or results that are replicated in a number of studies, it is possible to gain some insight into the efficacy of e-cigarettes, their potential harms, and areas where further research is required.

NHMRC recognises the need for high-quality research in this area and is currently funding a number of studies investigating the effects of e-cigarettes.

The following information is provided to assist consumers and policy-makers in understanding the current evidence about the safety and efficacy of e-cigarettes. This information is current at the time of writing but is subject to change as more research becomes available.
Health and safety

Potential health risks

It is widely believed that e-cigarettes are likely to be less harmful than tobacco cigarettes, because they expose users to fewer toxic chemicals.\(^2\)\(^3\)\(^4\) However, there is insufficient evidence to quantify the reduction in risk when e-cigarettes are used instead of tobacco cigarettes.\(^1\)\(^5\) Although a 2014 study reported that e-cigarettes are 95% less harmful than tobacco cigarettes,\(^6\) this finding was based on opinion rather than empirical evidence, and concerns have been raised about potential conflicts of interest.\(^7\)\(^8\) The World Health Organisation has stated that “no specific figure about how much ‘safer’ the use of these products is compared to smoking can be given any scientific credibility at this time.”\(^1\)

E-cigarettes are not likely to be risk free, and may expose users to chemicals and toxins at levels that have the potential to cause health effects. These include solvents such as propylene glycol, glycerol or ethylene glycol, which may form toxic or cancer-causing compounds when vaporised.\(^9\)\(^10\)\(^11\)\(^12\)\(^13\)\(^14\)\(^15\)\(^16\)\(^17\) Although these chemicals are typically found in lower concentrations than in tobacco cigarettes,\(^3\)\(^4\)\(^10\)\(^15\) in some studies e-cigarettes and tobacco cigarettes were found to produce similar levels of formaldehyde,\(^11\)\(^14\) which is classified as a cancer-causing agent.\(^18\) E-cigarette liquids or vapour may also contain potentially harmful chemicals which are not present in smoke from tobacco cigarettes.\(^1\)\(^11\)\(^19\)

While some of the chemicals in e-liquid are also used in food production and are generally considered safe when eaten, this does not mean that these chemicals are safe when inhaled as a vapour directly into the lungs. A number of studies have reported harmful effects when certain flavourings that are approved for use in food production, including cherry, cinnamon and popcorn flavours, are inhaled.\(^20\)\(^21\)\(^22\)\(^23\) There is growing evidence to suggest that the long-term inhalation of flavourings used in most e-liquids is likely to pose a risk to health.\(^1\)

Studies also show that e-cigarettes expose both users and bystanders to particulate matter (very small particles)\(^16\)\(^24\)\(^25\)\(^26\)\(^27\) that may worsen existing illnesses or increase the risk of developing diseases such as cardiovascular or respiratory disease.\(^28\) The World Health Organisation has warned that exposure to any level of particulate matter may be harmful and that levels of exposure should be minimised.\(^29\)

E-cigarettes may also expose users to metals such as aluminium, arsenic, chromium, copper, lead, nickel and tin,\(^3\)\(^15\)\(^30\)\(^31\)\(^32\) with these elements having been detected in e-liquid and in the vapour produced during use. In some cases these metals have been detected at levels greater than, or similar to, those found in tobacco cigarettes.\(^1\)\(^30\)

Adverse events

Studies that have tested e-cigarettes for use as a smoking cessation tool found that users of e-cigarettes typically experience a low rate of adverse events in the short term,\(^33\)\(^34\) with mouth and throat irritation the most commonly reported symptoms. However, more serious adverse events have also been reported, with over 200 incidents of e-cigarettes overheating, catching fire or exploding reported to date in the US and UK alone.\(^35\) In some cases, these events have resulted in life-threatening injury, permanent disfigurement or disability, and major property damage.

The rising popularity of e-cigarette use internationally has also corresponded with an increasing number of reported nicotine poisonings due to exposure to or ingestion of e-liquids.\(^36\)\(^37\)\(^38\)\(^39\)\(^40\)\(^41\)\(^42\) The effects of exposure range from relatively mild, including irritation of the eyes and skin, nausea and vomiting,\(^36\)\(^37\)\(^40\) to severe life-threatening illness,\(^39\) and in some cases, death.\(^36\)\(^38\)\(^42\)

Passive exposure

A recent systematic review of 16 studies concluded that e-cigarette vapour has the potential to pose a health risk to bystanders, although the risk is likely to be lower than that posed by conventional cigarette smoke.\(^43\) However, exposure to certain metals such as nickel and silver may be greater for e-cigarettes than tobacco cigarettes.\(^43\)

A 2016 study found that the most common symptoms reported by those passively exposed to e-cigarettes included respiratory difficulties, eye irritation, headache, nausea and sore throat or throat irritation.\(^44\)
Smoking cessation

Experts disagree about whether e-cigarettes may help smokers to quit, or whether they will become ‘dual users’ of both e-cigarettes and tobacco cigarettes. There is currently insufficient evidence to demonstrate that e-cigarettes are effective in assisting people to quit smoking\(^1\) and no brand of e-cigarette has been approved by the Therapeutic Goods Administration (TGA) for this purpose. Although a 2016 systematic review conducted by the Cochrane Collaboration\(^3\) found some evidence that e-cigarettes with nicotine may assist smokers to quit, the review authors had a low level of confidence in this finding, due to the small volume of evidence. The review also reported results from one study comparing e-cigarettes with nicotine replacement therapy, which found that both methods resulted in similar rates of smoking cessation at 6 months follow-up. However, the reviewers noted that more research is required to enable confidence in these estimates and that further research is likely to change the estimate of effect.\(^3\)

Smokers wishing to quit are advised to consult their general practitioner. First-line treatments include a range of TGA-approved nicotine replacement therapies and prescription medications that have been tested for safety and efficacy. Support and information are also available from the Quitline (13 78 48) or via the Quit Now website (www.quitnow.gov.au).

E-cigarettes and tobacco control policies

Concerns have been raised that the potential benefits of e-cigarettes in reducing harm to smokers may be outweighed by the risks that they may undermine tobacco control efforts. This includes the potential for e-cigarettes to provide a gateway to nicotine addiction or tobacco product use, or that they may renormalise smoking. The appeal of flavoured e-cigarettes to children and adolescents is also of concern, with studies reporting rapid uptake of e-cigarettes among adolescents in many countries, where trend data are available.\(^45,46,47,48,49\)

This provides some cause for concern given uncertainties about the long-term safety of e-cigarettes.

There is some evidence that e-cigarettes could act as a gateway into nicotine addiction or tobacco cigarette smoking. A number of longitudinal studies have reported an association between e-cigarette use in non-smokers and the uptake of tobacco cigarette smoking in the future.\(^50,51,52,53\) This association remained even when the studies controlled for other risk factors that might make people more likely to take up smoking. In some studies, the effect of e-cigarettes on future smoking behaviour was greatest among those who were otherwise at low risk of taking up smoking.\(^51,54\) A number of studies have also reported an association between e-cigarette use in non-users and future use of marijuana\(^52\) or tobacco products such as hookahs, cigars or pipes.\(^51,55,56\)

In view of the above concerns, the World Health Organisation has recommended that policy-makers act to prevent the initiation of e-cigarette use by non-smokers and youth, with special attention given to protecting vulnerable groups.\(^1\)

Manufacturing quality

The manufacturing quality of e-cigarettes is highly variable, with a number of issues relating to quality control reported in the literature. Labelling of e-cigarettes and e-liquids has been found to be incomplete or inaccurate.\(^57,58\) Products have been found to contain chemicals that were not listed on the label,\(^57,58,59\) or to state incorrectly that they did not contain potentially toxic chemicals, despite analyses confirming their presence.\(^60,61\)

There may also be wide variation between the levels of nicotine declared on packaging and the amount contained in e-liquid.\(^5\)\(^58,62,63,64,65\) One study that compared identical models of e-cigarettes found that nicotine content varied by up to 20% when the products came from different manufacturing batches, with variation of up to 12% reported for products manufactured in the same batch.\(^66\) Furthermore, some products that are labelled as nicotine free have been found to contain nicotine.\(^11,15,57,59,62,65,67,68\)
Where can I get more information?

When seeking information about e-cigarettes online, it is important to look at websites that provide a reliable source of information, such as government websites or quit smoking services. Information on websites sponsored by retailers or manufacturers may reflect a commercial interest in promoting the sale of certain products.

Similarly, when reading published research on e-cigarettes it is important to consider whether the authors of the research held any conflicts of interest that could potentially bias their findings, or whether the research was funded by an organisation with a financial interest in the outcomes, such as e-cigarette manufacturers.

The following websites may provide further information of use to consumers:

**Evidence-based reports**


**Information, fact sheets and FAQs from government departments**

ACT Health – *Electronic Cigarettes*


New South Wales Department of Health – *Electronic Cigarettes*


Product Safety Australia – *Electronic Cigarette Safety*


Therapeutic Goods Administration – *Electronic Cigarettes*


Western Australia Department of Health – *Electronic cigarettes (e-cigarettes)*


State and Territory Health Departments – *Contact Details*


**Position statements**


Cancer Council Australia and The Heart Foundation – *Joint Position Statement on Electronic Cigarettes*


Public Health Association of Australia – *Statement by the Public Health Associations of Australia on Electronic Cigarettes*

https://www.phaa.net.au/documents/item/704
References


# Attachment 2 - NHMRC funded research on e-cigarettes

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<td>Dr Michelle Jongenelis</td>
<td>Minimising uptake of e-cigarettes and encouraging cessation among Australian adolescents and adults</td>
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<td>GNT1176137</td>
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<td>Dr Chung Kai Chan</td>
<td>E-cigarettes and vaping: Holy grail of tobacco control or gateway to a public health disaster?</td>
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<td>A trial of vaporised nicotine products for smoking cessation following discharge from drug and alcohol residential withdrawal services</td>
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<td>GNT1148497</td>
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<td>Reducing the social gradient in tobacco smoking rates: The road less travelled: Novel and innovative paths for improved cessation rates and outcomes</td>
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<td>GNT1124264</td>
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<td>A Pragmatic Randomised Clinical Trial of Nicotine Vaporisers added to Smoking Cessation Treatment for Priority Populations Living with Comorbidities</td>
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**Total:** $12,436,864