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Committee Secretary
House of Representatives Standing Committee on Health, Aged Care and Sport
PO Box 6021
Parliament House
Canberra ACT 2600

Dear Committee Secretary

Thank you for the opportunity to provide a submission to the House of Representatives Standing Committee on Health, Aged Care and Sport's inquiry into the use and marketing of electronic cigarettes (e-cigarettes) and personal vaporisers in Australia (the inquiry).

As Australia's peak body for supporting health and medical research, for developing health advice for the Australian community, health professionals and governments, and for providing advice on ethical behaviour in health care and in the conduct of health and medical research, NHMRC has an obligation to deliver evidence-based health advice.

Accordingly, on 3 April 2017, I issued an updated[a] *CEO Statement: Electronic Cigarettes (E-Cigarettes)*, to raise community awareness and to provide advice to the Commonwealth, and to the States and Territories about the safety and efficacy of e-cigarettes. This Statement, based on a literature review of the evidence up to 4 January 2017, concludes that despite a proliferation of research on e-cigarettes in recent years the evidence base remains insufficient to enable definitive conclusions about the safety and efficacy of e-cigarettes to be drawn.

NHMRC's submission to the inquiry is drawn from the CEO Statement and from the evidence identified as part of its development. This submission responds to the first two terms of reference of the inquiry:

1. The use and marketing of e-cigarettes and personal vaporises to assist people to quit smoking.
2. The health impacts of the use of e-cigarettes and personal vaporisers.

Please do not hesitate to contact [redacted]

Yours sincerely

[redacted]

Professor Anne Kelso AO

Chief Executive Officer
27 June 2017

[a] The original CEO Statement was issued on 25 March 2015. The 2017 update took into account recently published evidence.

NHMRC submission to the Parliamentary Inquiry into the use and marketing of electronic cigarettes in Australia

In March 2015, the former CEO of the NHMRC, Professor Warwick Anderson AM, issued a CEO Statement to inform the Australian community about the current status of the evidence in relation to electronic cigarettes (e-cigarettes). At that time, the evidence-base for e-cigarettes was insufficient to enable unequivocal statements to be made. In the absence of a formal NHMRC evidence review and its associated recommendations, the CEO Statement was developed to provide advice to consumers and policymakers about the key issues surrounding e-cigarettes. CEO Statements are not NHMRC guidelines and NHMRC did not undertake a systematic review of the comparative harms of e-cigarettes and tobacco cigarettes.

Following a request from the state and territory Chief Health Officers, the CEO Statement was updated in 2017 to incorporate recently published evidence. To inform the development of the 2017 CEO Statement, a literature review of the published evidence up to 4 January 2017 was conducted. The literature review aimed to identify relevant research across a range of topics, including:

- the use of e-cigarettes for smoking cessation
- the health effects associated with use of e-cigarettes
- passive exposures
- adverse events
- whether e-cigarettes may provide a gateway to conventional tobacco cigarette smoking or nicotine addiction.

The literature searches identified 3,180 publications, of which 387 were considered in full text. A total of 69 publications are cited in the 2017 CEO Statement, including systematic reviews, primary studies and reports from the World Health Organisation (WHO).

This submission is drawn from the CEO Statement[b] (Attachment 1) and from the evidence identified as part of its development.

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

E-cigarettes remain a topic of contention among public health and tobacco-control advocates. Some argue that they have the potential to minimise harm to smokers. Others argue that e-cigarettes pose a threat to tobacco-control measures and that they should not be promoted as a 'lower risk' option for smokers, when their long-term safety is unknown.

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 for this purpose. Although a 2016 systematic review conducted by the Cochrane Collaboration[2] found some evidence that e-cigarettes with nicotine may assist smokers to quit, the

[b] https://www.nhmrc.gov.au/guidelines-publications/ds13a-ds13

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 six 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.[2]

NHMRC is funding a range of research projects (Attachment 2) that will assist in informing the evidence base regarding the role of e-cigarettes in smoking cessation.

It is also important to note that the manufacturing quality of e-cigarettes is highly variable, with a number of issues relating to quality control reported in the literature. These issues include:

- Labelling of e-cigarettes and e-liquids has been found to be incomplete or inaccurate.[3, 4]
- Products have been found to contain chemicals that were not listed on the label [3, 4, 5] or to state incorrectly that they did not contain potentially toxic chemicals, despite analyses confirming their presence.[6,7]
- There may also be wide variation between the levels of nicotine declared on packaging and the amount contained in e-liquid.[4, 8, 9, 10, 11, 12] 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.[13] Furthermore, some products that are labelled as nicotine free have been found to contain nicotine.[3, 5, 9, 12, 14, 15, 16, 17]
- The way in which a person uses an e-cigarette may affect the exposure to toxicants and nicotine delivery.[18]

This wide variation in products, and the ability of users to customise their vaping experience, make 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.

E-cigarettes and e-liquids can be found in a variety of flavours including various fruit flavours, popcorn, coffee, cinnamon and chocolate, and the appeal of flavoured e-cigarettes to children and adolescents is of concern. Some studies have reported a rapid uptake of e-cigarettes among adolescents in many countries where trend data are available.[19, 20, 21, 22, 23]

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

It is widely believed that e-cigarettes are likely to be less harmful than tobacco cigarettes, because they expose users to fewer toxic chemicals.[18, 24, 25] However, there is insufficient evidence to quantify the reduction in risk when e-cigarettes are used instead of tobacco cigarettes.[1, 26] Although a 2014 study reported that e-cigarettes are 95% less harmful than tobacco cigarettes,[27] this finding was based on opinion rather than empirical evidence, and concerns have been raised about potential conflicts of interest in this study.[28, 29] The WHO 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.[8, 14, 15, 30, 31, 32, 33, 34, 35] Although these chemicals are typically found in lower concentrations than in tobacco cigarettes,[15, 24, 25, 30] in some studies e-

cigarettes and tobacco cigarettes were found to produce similar levels of formaldehyde,[14, 33] which is classified as a cancer-causing agent.[36] E-cigarette liquids or vapour may also contain potentially harmful chemicals which are not present in smoke from tobacco cigarettes.[1, 14, 37]

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.[38, 39, 40, 41] 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)[34, 42, 43, 44, 45] that may worsen existing illnesses or increase the risk of developing diseases such as cardiovascular or respiratory disease.[46] The WHO has warned that exposure to any level of particulate matter may be harmful and that levels of exposure should be minimised.[47]

E-cigarettes may also expose users to metals such as aluminium, arsenic, chromium, copper, lead, nickel and tin,[15, 24, 48, 49, 50] 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, 48]

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.[51] However, exposure to certain metals such as nickel and silver may be greater for e-cigarettes than tobacco cigarettes.[51] 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.[52]

In summary, there is currently insufficient evidence to support claims that e-cigarettes are safe and further research is required to enable the long-term safety and efficacy of e-cigarettes to be assessed. 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.

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Attachment 2

Further research

NHMRC recognises the need for high-quality research in this area. Since 2011, NHMRC has committed nearly $6.5 million in funding for research into e-cigarettes to investigate such things as the efficacy of e-cigarettes for smoking cessation and the health effects of these devices. There are currently eight NHMRC-funded research projects on e-cigarettes in progress (listed below).

Grant ID:	1020123
Institution:	University of Queensland
Grant period:	2011- 2018
Title:	Can using nicotine as a long-term substitute enhance smoking cessation over using it only as a cessation aid?
Grant amount:	$1,053,910
Description:	Many smokers who try to quit fail in their attempt. Medicinal nicotine is currently only used as a short-term quit aid. This trial will test if offering smokers the option of using these products as long-term substitutes for cigarettes will help more smokers to successfully quit. We will also determine if offering smokers low toxicity smokeless tobacco and electronic nicotine devices in addition to medicinal nicotine products further increases the number of smokers who quit successfully.
Grant ID:	1061978
Institution:	University of Queensland
Grant period:	2014-2018
Grant title:	Public health policies and interventions to reduce tobacco-related harms among socially disadvantaged populations and 'low probability quitters'
Grant amount:	$404,884
Description:	Tobacco continues to be a leading cause of preventable death and disease in Australia. Those who are socially disadvantaged are at higher risk of smoking, which contributes to the health gap between the rich and poor. This research will provide evidence for policy makers on interventions which could reduce smoking among the most disadvantaged in society. It will also examine whether less harmful nicotine products could a reduce health risks in smokers who find quitting difficult.

Grant ID:	1089403
Institution:	University of Sydney
Grant period:	2015-2019
Grant title:	Harnessing new media to translate prevention research evidence in to practice and policy
Grant amount:	$309,436
Grant ID:	1095880
Institution:	Cancer Council Victoria
Grant period:	2015-2020
Grant title:	Enhancing pharmacological and behavioural support to reduce smoking relapse: A factorial RCT
Grant amount:	$913,218
Grant ID:	1106451
Institution:	Cancer Council Victoria
Grant period:	2016-2021
Grant title:	Understanding the impacts of Vaporised Nicotine Products on smoking in Australia
Grant amount:	$1,625,603
Description:	Vaporised nicotine products (e.g., e-cigarettes) are widely used in Australia, even though possession of the nicotine fluid without a permit is an offence. They are primarily used by smokers as a means of quitting. However, there is concern about their potential attractiveness and uptake by non-smokers. The aim is to identify how these products might be used to both maximise smoking cessation and minimise nicotine use, especially smoking uptake by non-smokers.

Grant ID:	1111136
Institution:	University of Queensland
Grant period:	2016-2020
Grant title:	Cardiometabolic health of people with severe and persistent mental illness
Grant amount:	$187,322
Description:	People with schizophrenia have much higher rates of smoking, obesity and diabetes. To date, psycho-social interventions to reduce these physical health risk factors have had limited success. This research aims to conduct clinical trials among people with schizophrenia of 1. a novel diabetes medication to help people lose weight and gain better control of their sugars; and 2. newly developed vaporised nicotine products to help reduce cigarette smoking.
Grant ID:	1127390
Institution:	University of New South Wales
Grant period:	2017-2021
Grant title:	Adding an electronic-cigarette to standard behavioural treatment for low-socioeconomic status smokers: A randomised trial.
Grant amount:	$1,381,127
Description:	Behavioural and pharmacological approaches to smoking cessation are effective at helping people to quit but long-term quit rates remain low, especially among low-SES Australians. The electronic cigarette may complement current treatment approaches. We will conduct a large-scale trial to determine if “e-cigarettes” can improve on the efficacy of existing treatments. The findings would have immediate practical implications that could reduce the preventable deaths of many tobacco smokers.
Grant ID:	1128231
Institution:	University of Western Australia
Grant period:	2017-2019
Grant title:	The health effects of electronic-cigarettes
Grant amount:	$ 571,260
Description:	The health effects of electronic cigarette use are virtually unknown. They have only recently been introduced into widespread use, and as such their effects on human health will not be known for many years. We will use our expertise in exposure models and health outcome measurement to provide timely hard-data on their potential to impact health – data that are urgently required to guide policy makers in this area.