



The Hon Roger Cook MLA
Deputy Premier
Minister for Health; Mental Health

Janine Freeman MLA
Education and Health Standing Committee
Parliament House
PERTH WA 6000

Dear Ms Freeman

The Education and Health Standing Committee (Committee) has asked that I report back on any considerations that have been given to the regulation of electronic cigarettes (e-cigarettes). I am pleased to report to the Committee on the status of regulatory and non-regulatory activity on this emerging issue.

The emergence of e-cigarettes in recent years has presented new complexity to issues associated with tobacco control and smoking cessation. Proponents of e-cigarettes have lauded them as a safer alternative to regular cigarettes and an aid to smoking cessation.

I can advise the Committee that I have recently made submissions to two Federal Parliamentary Inquiries into e-cigarettes:

- The Standing Committee on Health, Aged Care and Sport's 'Inquiry into the use and marketing of electronic cigarettes and personal vaporisers in Australia'; and
- The Senate Community Affairs Legislation Committees 'Inquiry into the *Vaporised Nicotine Products Bill 2017*'.

The submissions to these inquiries are attached for your information. You'll note that within these submissions I have made reference to this Committee's report titled 'Clearing the air on e-cigarettes'.

The precautionary principle places the burden of proof on the proponents of a particular activity - in this case, manufacturers/importers of e-cigarettes - to demonstrate the safety and utility of their product.

In Australia, the prevalence of usage of these products is low. In 2013, approximately 3.2% of the Australian general population aged 14 and over reported using e-cigarettes in the past twelve months. However, in the current climate of sporadic media publicity and comparative ease of access in some jurisdictions, it is likely that experimentation and use of e-cigarettes will increase. It is prudent public health policy to take a precautionary, evidence based approach.

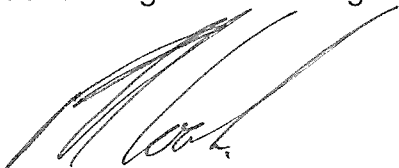
The Western Australian Government is committed to protecting and promoting the health of the Western Australian population by applying primary preventive health measures, promoting healthy behaviours and environments, and intervening to reduce hazards to health.

The Western Australian Department of Health (DOH) is taking population-wide steps to develop, coordinate and deliver a range of state-wide public health policies and programs pertinent to e-cigarettes. The DOH continues to monitor evidence about e-cigarettes as it emerges. It is not legal to sell e-cigarettes containing nicotine anywhere in Australia, and Western Australian legislation also bans the sale of these and other products designed to resemble tobacco products.

In 2018, the DOH will conduct a review of the *Tobacco Products Control Act 2006*. Given that research is ongoing, I will ask the DOH to consider the latest evidence around the safety and efficacy of e-cigarettes and the appropriateness of our State laws to protect and promote public health, within the scope of this review.

At the Federal level appropriate infrastructure and a regulatory framework currently exists to carry out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard. The Federal government is therefore well positioned to determine the efficacy of e-cigarettes as a smoking cessation aid and the Western Australian Government will closely monitor determinations of Federal agencies.

I trust that this information is helpful in informing the Committee of consideration being given to the regulation of e-cigarettes in Western Australia.



ROGER COOK MLA
DEPUTY PREMIER;
MINISTER FOR HEALTH; MENTAL HEALTH

13 SEP 2017



**The Hon Roger Cook MLA
Deputy Premier
Minister for Health; Mental Health**

Our Ref: 60-01988

Mr Trent Zimmerman MP
Chair, Standing Committee on Health, Aged Care and Sport
PO Box 6021
Parliament House
CANBERRA ACT 2600

Dear Mr Zimmerman

Thank you for your letter of 30 May 2017 addressed to the Premier of Western Australia regarding a submission re: inquiry into the use and marketing of electronic cigarettes and personal vaporisers in Australia. The Premier has requested that a response be submitted via my office.

The Western Australian Government is committed to protecting and promoting the health of the Western Australian population by applying primary preventive health measures, promoting healthy behaviours and environments, and intervening to reduce hazards to health.

The Western Australian Legislative Assembly's Education and Health Standing Committee recently tabled a report titled "Clearing the air on e-cigarettes: Factors regarding regulation that require consideration" (attached). The report reviews Western Australian laws governing electronic cigarettes and highlights areas for consideration for regulating electronic cigarettes in the future.

While the work of this Parliamentary Committee looks at regulatory arrangements, the Western Australian Department of Health (DOH) is also taking population-wide steps to develop, coordinate and deliver a range of state-wide public health policies and programs pertinent to electronic cigarettes.

The DOH continues to monitor evidence about electronic cigarettes as it emerges. It is not legal to sell electronic cigarettes containing nicotine anywhere in Australia, and Western Australian legislation also bans the sale of these and other products designed to resemble tobacco products.

The following submission (Attachment A) is forwarded on behalf of the Government of Western Australia to the Standing Committee on Health, Aged Care and Sport with regard to the inquiry into the use of electronic cigarettes in Australia.

Thank you for your consideration of our submission.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Roger Cook', written over a horizontal line.

HON ROGER COOK MLA
DEPUTY PREMIER
MINISTER FOR HEALTH; MENTAL HEALTH

10 JUL 2017
Att:



Government of Western Australia

ATTACHMENT A

SUBMISSION TO THE STANDING COMMITTEE ON HEALTH, AGED CARE AND SPORT

Inquiry into the use and marketing of electronic cigarettes and personal vaporisers in Australia

Response to the Terms of Reference

In response to the Terms of Reference 1) to 5) the Western Australian Government submits the following.

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

Multiple statements issued by authoritative national and international health agencies agree that there is currently insufficient evidence to confirm that e-cigarettes assist smokers in quitting.^{1,2,3,4}

In the interests of consumer protection, it is wholly appropriate that products which are intended to fulfil a therapeutic purpose are demonstrated to be safe and effective. The Therapeutic Goods Administration's (TGA) regulation process provides a well-established pathway for manufacturers of e-cigarettes to obtain approval to sell their products as smoking cessation products. To date, the TGA has not approved any application to sponsor importation or supply of e-cigarettes as an aid to reducing cigarette use.¹ However the TGA has approved a range of nicotine replacement therapy (NRT) and other products, which are available from supermarkets and pharmacies.

1. Therapeutic Goods Administration. Electronic cigarettes Canberra: Department of Health; 2013 [cited 2017 16 June 2017]. Available from: <http://www.tga.gov.au/consumers/ecigarettes.htm>.
2. National Health and Medical Research Council. NHMRC CEO Statement: Electronic Cigarettes (E-cigarettes) Canberra: Australian Government 3 April 2017 [cited 2017]. Available from: https://www.nhmrc.gov.au/_files_nhmrc/file/publications/17072_nhmrc_-_electronic_cigarettes-web_final.pdf.
3. Cancer Council Australia, Heart Foundation. Position statement - electronic cigarettes: Cancer Council Australia; 2015 [cited 4 December 2015]. Available from: http://wiki.cancer.org.au/policy/Position_statement_-_Electronic_cigarettes.
4. World Federation of Public Health Associations. Statement by the World Federation of Public Health Associations on electronic cigarettes Geneva: World Federation of Public Health Associations; 2015 [cited 4 January 2016]. Available from: http://www.wfpha.org/images/events/141218_WFPHA_ECig_Statement_FINAL.pdf.

In August 2016, in a report to the Seventh Session of the Conference of the Parties to the World Health Organisation (WHO) Framework Convention on Tobacco Control (FCTC), the WHO concluded that the evidence for the safety of e-cigarettes and their capacity to aid smoking cessation has not been established, and that there are possible risks from active and passive exposure to electronic cigarette vapour.

Sales of e-cigarettes containing nicotine are not legal anywhere in Australia. Nicotine is a dangerous (Schedule 7) poison, even in small quantities, and in Western Australia (WA) it is strictly regulated under the *Medicines and Poisons Act 2014*.

In WA, products that resemble tobacco products, regardless of whether they contain nicotine or not, cannot be sold: it is an offence under the *Tobacco Products Control Act 2006 – Section 106* to sell such products. In a 2016 Supreme Court of WA decision⁵, e-cigarettes were found to resemble a tobacco product.

Given the lack of evidence regarding e-cigarettes and the recognised dangers of nicotine, the Western Australian Government is of the view that e-cigarettes should neither be marketed, nor legally available as quit aids.

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

The recent advent of e-cigarettes in the market place means that there is no information on the effects of their long-term use, whether or not they contain nicotine.

In the Australian setting all e-cigarettes are imported, and in many cases they are manufactured in an unregulated environment, without quality control over design, content or consumer information. Studies analysing product samples have pointed to inconsistencies between stated and actual contents, and poorly-manufactured cartridges which leak nicotine. Some e-cigarettes which claim to be nicotine-free have been found on analysis to contain nicotine. In May 2017, following independent testing and legal action by the Australian Competition and Consumer Commission (ACCC), the Australian Federal Court ordered three online e-cigarette retailers to pay penalties for making false and misleading claims about the exposure to harmful chemicals when smoking e-cigarettes.⁶ This reiterates the importance of balancing commercial interests in e-cigarettes with an overriding interest in protecting public health.

5. Supreme Court of Western Australia (Court of Appeal). Decision: Van Heerden v Hawkins 2016 WASCA 42.

6. Australian Competition and Consumer Commission. E-cigarette companies to pay penalties. ACCC Media Release Number MR 61/17 Canberra: ACCC; 8 May 2017 [cited 16 June 2017]. Available from: <https://www.accc.gov.au/media-release/e-cigarette-companies-to-pay-penalties>.

It is not uncommon to hear from promoters of e-cigarettes that the disease-causing element of conventional cigarettes is the tar; and that nicotine itself is not harmful. This is not the case. The 2016 report of the US Surgeon General *E-cigarette Use Among Youth and Young Adults* states that, 'the use of products containing nicotine poses dangers to youth, pregnant women, and fetuses. The use of products containing nicotine in any form among youth, including in e-cigarettes, is unsafe'.⁷

The International Agency for Research on Cancer (IARC) Advisory Group has flagged nicotine as a 'high priority' for assessment due to increasing population exposure via e-cigarettes and existing mechanistic data suggestive of an association between nicotine exposure and DNA damage and other pathways of carcinogenesis. The IARC utilises specific criteria to inform priority for substance assessment. Nicotine is considered a 'high priority' by the IARC because it has: a potential for direct impact on public health, scientific literature to support suspicion of carcinogenicity, evidence of significant human exposure and a high public interest.⁸

The claim is sometimes made that e-cigarette vapour is 'just like water vapour'. However, analyses of e-cigarette emissions have shown they include harmful substances such as nicotine, carbonyls, metals, organic volatile compounds and particulate matter.⁹ There is a need for further quality research in this area.

There is growing evidence concerning the risk that electronic cigarettes may serve to initiate young people into nicotine use and smoking. For example, the 2016 Office of the Surgeon General report, mentioned above, notes that e-cigarettes are now the most commonly used tobacco product among youth in the United States, and that this constitutes a major public health concern.

The Western Australian Government has concerns about a number of additional health impacts related to e-cigarettes. These include the dangers of nicotine poisoning (especially in children), and fires and burns generated by faulty equipment.¹⁰ The American Academy of Paediatrics has issued a policy statement highlighting concerns that reports of acute nicotine toxicity from US poison control centres have been increasing.¹¹

7. US Department of Health and Human Services. *E-cigarette Use Among Youth and Young Adults: A Report of the Surgeon General* Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health 2016. Available from: https://e-cigarettes.surgeongeneral.gov/documents/2016_sgr_full_report_non-508.pdf.

8. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Internal Report 14/002. Report of the Advisory Group to Recommend Priorities for IARC Monographs during 2015-2019. 7-9 April, 2014. Lyon: World Health Organization and International Agency for Research on Cancer, 2014.

9. Fernández E, Ballbè M, Sureda X, Fu M, Saltó E, Martínez-Sánchez JM. Particulate Matter from Electronic Cigarettes and Conventional Cigarettes: a Systematic Review and Observational Study. *Current Environmental Health Reports*. 2015;2(4):423-9.

10. U.S. Fire Administration. *Electronic cigarette fires and explosions 2014*. Available from: https://www.usfa.fema.gov/downloads/pdf/publications/electronic_cigarettes.pdf.

11. American Academy of Pediatrics. *Electronic Nicotine Delivery Systems Pediatrics*. 2015;136(5).

Finally, proponents of e-cigarette use have made much of a 2014 study, cited by Public Health England¹² and widely taken up by other sources, that claims that e-cigarettes are 95% less harmful than tobacco cigarettes. The study from which this figure is drawn has been discredited.¹³ In an editorial in *The Lancet* entitled *E-cigarettes: Public Health England's evidence-based confusion*¹⁴ major flaws are revealed, including that the figure of 95% was based on the views of a small number of invited attendees at a single meeting, with clear potential for conflicts of interest due to links of some members with the e-cigarette manufacturing industry. In contrast, the WHO states in its 2016 report, mentioned above, 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'.¹⁵

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

The Australian Government is a signatory to the WHO Framework Convention on Tobacco Control and the Western Australian Government looks to the FCTC, as referred to in the National Tobacco Strategy 2012 -2018,¹⁶ to guide approaches to legislating and regulating the use of e-cigarettes. In its October 2014 report to the sixth session of the Conference of the Parties to the FCTC, the WHO states that 'governments should consider that if their country has already achieved a very low prevalence of smoking and that prevalence continues to decrease steadily, use of electronic nicotine delivery systems (ENDS) will not significantly decrease smoking-attributable disease and mortality even if the full theoretical risk reduction potential of ENDS were to be realised.'¹⁷ Australia's approach to tobacco control has resulted in our having among the lowest smoking rates in the world.

12. McNeill A, Brose L, Calder R, Hitchman S, Hajek P, McRobbie H. E-cigarettes: an evidence update. A report commissioned by Public Health England. London: Public Health England, 2015.
13. McKee M, Capewell S. Evidence about electronic cigarettes: a foundation built on rock or sand? *BMJ*. 2015;351:h4863.
14. The Lancet. E-cigarettes: Public Health England's evidence-based confusion. *The Lancet*. 2015;386(9996):829.
15. World Health Organization. Conference of the Parties to the WHO Framework Convention on Tobacco Control, FCTC/COP/7/11. Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS). Seventh session, Delhi, India, 7-12 November 2016 Geneva: WHO, 2016.
16. Intergovernmental Committee on Drugs. National Tobacco Strategy 2012 - 2018 Canberra: Department of Health and Ageing, 2012. Available from: [http://www.nationaldrugstrategy.gov.au/internet/drugstrategy/publishing.nsf/Content/D4E3727950BDBAE4CA257AE70003730C/\\$File/National%20Tobacco%20Strategy%202012-2018.pdf](http://www.nationaldrugstrategy.gov.au/internet/drugstrategy/publishing.nsf/Content/D4E3727950BDBAE4CA257AE70003730C/$File/National%20Tobacco%20Strategy%202012-2018.pdf).
17. World Health Organization. Conference of the Parties to the WHO Framework Convention on Tobacco Control, FCTC/COP6(9). Decision. Electronic nicotine delivery systems and electronic non-nicotine delivery systems. Sixth session, Moscow, Russian Federation, 13-18 October 2014. Geneva: WHO, 2014.

This position is supported in a recent (April 2017) National Health and Medical Research Council (NHMRC) CEO Statement.¹⁸ This Statement emphasises the importance of protecting users, bystanders and vulnerable groups until evidence of the safety of e-cigarettes is produced.

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

The Western Australian Government strongly supports a precautionary approach to the regulation of e-cigarettes. Until there is clear and demonstrable evidence that these products are not harmful to the health of users and people around them, or alternatively, there is an accurate understanding of the extent of any harm which they may cause, it is not good public health policy to let these products into the market place. In other words, it is not good public health practice to embrace a potential 'solution' to a health issue when that solution may in itself have an unintended harmful impact.

The precautionary principle also places the burden of proof on the proponents of a particular activity (in this case, manufacturers/importers of e-cigarettes) to demonstrate the safety and utility of their product.

In Australia, the prevalence of usage of these products is low. In 2013, approximately 3.2% of the Australian general population aged 14 and over reported using e-cigarettes in the past twelve months.¹⁹ However in the current climate of sporadic media publicity and comparative ease of access in some jurisdictions, it is likely that experimentation and use of e-cigarettes will increase. It is prudent public health policy to restrict the availability of these products before their usage becomes more widespread. Interestingly, in countries without strict regulation, such as the United States, there has been an increasing trend of e-cigarette use amongst children and adolescents. For example, in Florida, prevalence of the use of e-cigarettes trebled between 2011 and 2014, with 20.5% of high school students reporting e-cigarette use in 2014.²⁰

While it is recognised that some jurisdictions have introduced partial restrictions on non-nicotine e-cigarettes, the Western Australian Government respectfully considers that effective monitoring and enforcement of any partial restriction would be extremely difficult. There is no visual means of determining the chemical nature of the inhalable matter contained in electronic cigarettes. Even if originally supplied as a nicotine-free device, they are easily modified to deliver nicotine or a range of illicit substances.

18. National Health and Medical Research Council. NHMRC CEO Statement: Electronic cigarettes (e-cigarettes) Canberra: NHMRC; 2015 [cited 4 December 2015]. Available from: <https://www.nhmrc.gov.au/guidelines-publications/ds13>.

19. Greenhalgh E, Scollo M. E-cigarette use by demographics and smoking status, 2013, citing NDSHS 2013 data analysed by Centre for Behavioural Research in Cancer. In: InDepth 18B: Electronic cigarettes (e-cigarettes). In: Scollo M, Winstanley M, editors. Tobacco in Australia: Facts and issues. Melbourne: Cancer Council Victoria; 2016.

20. Porter L, Duke J, Hennon M, et al. Electronic Cigarette and Traditional Cigarette Use among Middle and High School Students in Florida, 2011–2014. PLoS One. 2015;10(5).

The only way of determining whether an electronic cigarette contains nicotine or any other substance is by seizure and laboratory testing.

The use of these kinds of devices should be prohibited in smoke-free areas because:

- The health impacts of exposure to second hand vapour are unknown, and require further research;
- Their use in smoke-free places could give the impression that smoking is permitted, undermine smoke-free legislation, and make enforcement of smoke-free policies more difficult; and
- Their use could undermine efforts to de-normalise smoking.

The Western Australian Government supports a total ban on nicotine and non-nicotine containing electronic cigarettes, until such time as evidence of their safety, quality and efficacy as a therapeutic good can be produced and appropriately assessed.

It is submitted that appropriate infrastructure and a regulatory framework currently exists to carry out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard.

The Western Australian Government supports the current regulatory framework through the TGA at the Commonwealth level of government, and under the *Medicines and Poisons Act 2014* at a State level.

5. Any other related matter

Additional public health concerns about e-cigarettes include whether:

- Their use could sustain nicotine dependence, delay motivation to quit, and encourage relapse among quitters;
- Their use of fruit and confectionary flavours could appeal to new users, especially children, and lead to tobacco use; and
- The marketing and advertising of these products could undermine long-standing tobacco control strategies.

The Western Australian Government supports the development of a broad set of guiding principles to inform the regulation of electronic cigarettes and personal vaporisers. It is suggested that these principles should:

- Be consistent with the aims of the National Tobacco Strategy and jurisdictional regulatory frameworks;
- Encourage a precautionary approach to minimise any potential risks and harm;
- Advocate for decisions to be made based on a strong evidence base;
- Protect the significant gains that have been made in reducing smoking rates in Australia; and
- Provide clarity for the public, retailers and users about the legal obligations related to these products.



**The Hon Roger Cook MLA
Deputy Premier
Minister for Health; Mental Health**

Our Ref: 4-105102

Senator Jonathon Duniam
Chair, Senate Community Affairs Legislation Committee
PO Box 6100
Parliament House
CANBERRA ACT 2600

Dear Senator Duniam

**GOVERNMENT OF WESTERN AUSTRALIA – SUBMISSION RE: SENATE
COMMUNITY AFFAIRS LEGISLATION COMMITTEE INQUIRY INTO THE
VAPORISED NICOTINE PRODUCTS BILL 2017**

Thank you for your email of 28 June 2017 addressed to the Premier of Western Australia regarding the Senate Community Affairs Legislation Committee inquiry into the Vaporised Nicotine Products Bill 2017. The Premier has asked me to respond as Minister for Health on behalf of the Government of Western Australia.

The Western Australian Government is committed to protecting and promoting the health of the Western Australian population by applying primary preventive health measures, promoting healthy behaviours and environments, and intervening to reduce hazards to health.

The Western Australian Legislative Assembly's Education and Health Standing Committee recently tabled a report titled "Clearing the air on e-cigarettes: Factors regarding regulation that require consideration" (the Report). The Report reviews Western Australian laws governing electronic cigarettes and highlights areas for consideration for regulating electronic cigarettes in the future.

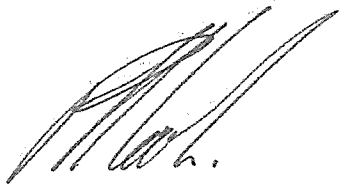
While the work of this Parliamentary Committee looks at regulatory arrangements, the Western Australian Department of Health (DoH) is also taking population-wide steps to develop, coordinate and deliver a range of state-wide public health policies and programs pertinent to electronic cigarettes.

DoH continues to monitor evidence about electronic cigarettes as it emerges. It is not legal to sell electronic cigarettes containing nicotine anywhere in Australia, and Western Australian legislation also bans the sale of these and other products designed to resemble tobacco products.

The enclosed submission is forwarded on behalf of the Government of Western Australia to the Community Affairs Legislation Committee with regard to the inquiry into the Vaporised Nicotine Products Bill 2017.

Thank you for your consideration of our submission.

Yours sincerely

A handwritten signature in black ink, appearing to read 'R. Cook', written in a cursive style.

HON ROGER COOK MLA
DEPUTY PREMIER
MINISTER FOR HEALTH; MENTAL HEALTH

14 AUG 2017

Att:



Government of Western Australia

SUBMISSION TO THE SENATE COMMUNITY AFFAIRS LEGISLATION COMMITTEE

Inquiry into Vaporised Nicotine Products Bill 2017

Response

In response to the Inquiry, the Western Australian Government submits the following.

The Western Australian Government does not support the proposed Bill for an Act to make provision in relation to vaporised nicotine products and to distinguish vaping from smoking, and for related purposes. The reasons for the Western Australian Government's position are detailed under the headings below.

Existing national and international frameworks

There are well established national and international frameworks and processes to guide decisions regarding the legislation of vaporised nicotine products. The Government of Australia is a signatory to the World Health Organization (WHO) *Framework Convention on Tobacco Control* (FCTC) and the WA Government looks to the FCTC, as referred to in the *National Tobacco Strategy 2012 -2018*,¹ to guide approaches to legislating and regulating the use of vaporised nicotine products. In its October 2014 report to the sixth session of the Conference of the Parties to the FCTC, the WHO states that 'governments should consider that if their country has already achieved a very low prevalence of smoking and that prevalence continues to decrease steadily, use of electronic nicotine delivery systems (ENDS) will not significantly decrease smoking-attributable disease and mortality even if the full theoretical risk reduction potential of ENDS were to be realised.'² This position is supported in a recent (April 2017) National Health and Medical Research Council

1. Intergovernmental Committee on Drugs. *National Tobacco Strategy 2012 - 2018* Canberra: Department of Health and Ageing, 2012 [Available from: [http://www.nationaldrugstrategy.gov.au/internet/drugstrategy/publishing.nsf/Content/D4E3727950BDBAE4CA257AE70003730C/\\$File/National%20Tobacco%20Strategy%202012-2018.pdf](http://www.nationaldrugstrategy.gov.au/internet/drugstrategy/publishing.nsf/Content/D4E3727950BDBAE4CA257AE70003730C/$File/National%20Tobacco%20Strategy%202012-2018.pdf)].
2. World Health Organization. *Conference of the Parties to the WHO Framework Convention on Tobacco Control, FCTC/COP6(9). Decision. Electronic nicotine delivery systems and electronic non-nicotine delivery systems. Sixth session, Moscow, Russian Federation, 13–18 October 2014.* Geneva: WHO; 2014.

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(NHMRC) CEO Statement.³ This Statement emphasises the importance of protecting users, bystanders and vulnerable groups until evidence of the safety of ENDS is produced.

In Australia, the Therapeutic Goods Administration's (TGA) regulation process provides a well-established pathway for manufacturers of e-cigarettes to obtain approval to sell their products as smoking cessation products. To date, the TGA has not approved any application to sponsor importation or supply of e-cigarettes as an aid to reducing cigarette use.⁴ Sales of e-cigarettes containing nicotine are not legal anywhere in Australia. Nicotine is a dangerous (Schedule 7) poison, even in small quantities, and in Western Australia it is strictly regulated under the *Medicines and Poisons Act 2014*.

In Western Australia, products that resemble tobacco products, regardless of whether they contain nicotine or not, cannot be sold: it is an offence under the *Tobacco Products Control Act 2006* (Section 106) to sell such products. In a 2016 Supreme Court of WA decision⁵, e-cigarettes were found to resemble a tobacco product.

Nicotine and other substances in vaporised products

It is not uncommon to hear from promoters of e-cigarettes that the disease-causing element of conventional cigarettes is the tar; and that nicotine itself is not harmful. This is not the case. The 2016 report of the US Surgeon General *E-cigarette Use Among Youth and Young Adults* states that, 'the use of products containing nicotine poses dangers to youth, pregnant women, and fetuses. The use of products containing nicotine in any form among youth, including in e-cigarettes, is unsafe'.⁶

The International Agency for Research on Cancer (IARC) Advisory Group has flagged nicotine as a 'high priority' for assessment due to increasing population exposure via e-cigarettes and existing mechanistic data suggestive of an association between nicotine exposure and DNA damage and other pathways of carcinogenesis. The IARC applies specific, stringent criteria to inform priority for substance assessment. Nicotine is considered a 'high priority' by the IARC because it has a potential for direct impact on public health; there is sufficient scientific literature to support suspicion of carcinogenicity; there is evidence of significant human exposure; and a high public interest in the matter.⁷

3. National Health and Medical Research Council. NHMRC CEO Statement: Electronic cigarettes (e-cigarettes) Canberra: NHMRC; 2015 [Available from: <https://www.nhmrc.gov.au/guidelines-publications/ds13>].
4. Therapeutic Goods Administration. Electronic cigarettes Canberra: Department of Health; 2013 [Available from: <http://www.tga.gov.au/consumers/ecigarettes.htm>].
5. Supreme Court of Western Australia (Court of Appeal). Decision: Van Heerden v Hawkins 2016 WASCA 42.
6. US Department of Health and Human Services. E-cigarette Use Among Youth and Young Adults: A Report of the Surgeon General Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health 2016 [Available from: https://e-cigarettes.surgeongeneral.gov/documents/2016_sgr_full_report_non-508.pdf].
7. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Internal Report 14/002. Report of the Advisory Group to Recommend Priorities for IARC Monographs

The toxicity profile of nicotine is not altered in vaporised nicotine products, and its potential ready availability in the community is concerning. There is a serious danger of acute poisoning for children which can occur through ingestion of products containing nicotine or by absorption of nicotine through the skin. The risk of poisoning can be increased with e-liquids as they often contain flavouring (for example bubble gum, fruit and confectionary) which is likely to be appealing to children.

While some of the chemicals in e-liquid are also used in food production and are generally considered safe when ingested, this does not constitute reliable evidence that these chemicals are safe when inhaled, as a vapour, directly into the lungs. The limited available evidence shows that the safety of e-liquids and their aerosols cannot be guaranteed for users and other people who are exposed to them. Studies have shown that ENDS vapour can worsen existing illnesses, or increase the risk of developing cardiovascular or respiratory disease.⁸

Advertising of vaporised nicotine products

The Bill proposes to amend the *Tobacco Advertising Prohibition Act 1992* so that it only relates to smoking 'using a combustion process'. The Western Australian Government is concerned that the advertising of vaporised nicotine products, and tobacco prepared and packed for heating, would undermine long standing tobacco control measures and increase the attractiveness of these products, especially to young people. ENDS advertising is largely unregulated in countries such as the United States and there are many examples of advertisements that are obviously targeting young people. Research commissioned by Cancer Research UK in 2013 reports that e-cigarette companies use packaging, fruit and confectionary flavouring, celebrity endorsements, online competitions and sponsorship of events to market their products in a way that could be particularly appealing to young people.⁹

Another concern is that even with the current restrictions on advertising in Australia, some e-cigarette retailers have been shown to make misleading claims. In May 2017, following independent testing and legal action by the Australian Competition and Consumer Commission (ACCC), the Australian Federal Court ordered three online e-cigarette retailers to pay penalties for making false and misleading claims about the lack of exposure to harmful chemicals when smoking e-cigarettes.¹⁰

during 2015-2019. 7-9 April, 2014. Lyon: World Health Organization and International Agency for Research on Cancer; 2014.

8. National Health and Medical Research Council. NHMRC CEO Statement: Electronic Cigarettes (E-cigarettes) Canberra: Australian Government 3 April 2017 [Available from: https://www.nhmrc.gov.au/_files_nhmrc/file/publications/17072_nhmrc_-_electronic_cigarettes-web_final.pdf].
9. de Antrade, G. Hastings, K. Angus, D. Dixon, Purves R. The marketing of electronic cigarettes in the UK. A report commissioned by Cancer Research UK. November 2013 [Available from: http://www.cancerresearchuk.org/prod_consump/groups/cr_common/@nre/@pol/document/s/generalcontent/cr_115991.pdf].
10. Australian Competition and Consumer Commission. E-cigarette companies to pay penalties. ACCC Media Release Number MR 61/17 Canberra: ACCC; 8 May 2017 [16 June 2017]. Available from: <https://www.accc.gov.au/media-release/e-cigarette-companies-to-pay-penalties>.

There is growing evidence concerning the risk that electronic cigarettes may serve to initiate young people into nicotine use and smoking. For example, the 2016 US Surgeon General's report¹¹, notes that e-cigarettes are now the most commonly used tobacco product among youth in the United States, and that this constitutes a major public health concern. In addition, a recent systematic review and meta-analysis found that 'e-cigarette use was associated with a greater risk for subsequent cigarette smoking initiation and past-30 day cigarette smoking'.¹²

Evidence regarding the harm associated with e-cigarettes

There is limited and highly contested evidence regarding the potential public benefit for harm reduction from a more widespread use of e-cigarettes, while there are known and quantifiable risks of poisoning related to the use of nicotine that could reasonably be expected to increase significantly if nicotine were exempted as proposed. If removed from scheduling, there would be no alternative standards or regulatory schemes that would address compliance with appropriate standards for formulation, packaging, labelling, or quality. Without regulation and accurate labelling it is impossible to determine exactly how much nicotine these products will contain; and there would be no controls in place to ensure that products are sold or used for the proposed purpose. Some e-liquids that do not list nicotine on the label have been found, upon scientific testing by State and Territory health authorities, to contain nicotine.

The explanatory memorandum relating to the Bill makes reference to a 2014 study, cited by Public Health England¹³ and widely taken up by other sources, that claims that e-cigarettes are 95% less harmful than tobacco cigarettes. The study from which this figure is drawn has been discredited.¹⁴ In an editorial in *The Lancet* entitled *E-cigarettes: Public Health England's evidence-based confusion*¹⁵ major flaws are revealed, including that the figure of 95% was based on the views of a small number of invited attendees at a single meeting, with clear potential for conflicts of interest due to links of some members with the e-cigarette manufacturing industry. In contrast, multiple statements issued by authoritative national and international health agencies agree that there is currently insufficient evidence to confirm that ENDS assist smokers in quitting, do not cause some level of physical harm, and will not serve to undermine

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11. US Department of Health and Human Services. E-cigarette Use Among Youth and Young Adults: A Report of the Surgeon General Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health 2016 [Available from: https://e-cigarettes.surgeongeneral.gov/documents/2016_sgr_full_report_non-508.pdf].
 12. Soneji S, Barrington-Trimis JL, Wills TA, et al. Association between initial use of e-cigarettes and subsequent cigarette smoking among adolescents and young adults: A systematic review and meta-analysis. *JAMA Pediatrics*. 2017.
 13. McNeill A, Brose L, Calder R, Hitchman S, Hajek P, McRobbie H. E-cigarettes: an evidence update. A report commissioned by Public Health England. London: Public Health England; 2015.
 14. McKee M, Capewell S. Evidence about electronic cigarettes: a foundation built on rock or sand? *BMJ*. 2015;351:h4863.
 15. The Lancet. E-cigarettes: Public Health England's evidence-based confusion. *The Lancet*. 2015;386(9996):829.

long-standing and effective tobacco control measures.^{16,17,18,19} For example, in its 2016 report to the Seventh Session of the Conference of the Parties to the WHO FCTC, the WHO states 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'.²⁰

Vaping in non-smoking areas

The amendments also propose to allow the use of e-cigarettes, and tobacco prepared and packed for heating at airports. The Western Australian Government does not support this proposal as the risks of passive exposure to e-cigarettes and heat-not-burn cigarettes are still not known. The claim is sometimes made that e-cigarette vapour is 'just like water vapour'. However, analyses of e-cigarette emissions have shown they include harmful substances such as nicotine, carbonyls, metals, organic volatile compounds and particulate matter.²¹ The use of these kinds of devices should be prohibited in smoke-free areas, including airports, because:

- The health impacts of exposure to second hand vapour and heat-not-burn tobacco product emissions are unknown, and require further research²²;
- Their use in smoke-free places could give the impression that smoking is permitted, undermine smoke-free legislation, and make enforcement of smoke-free policies more difficult; and
- Their use could undermine efforts to de-normalise smoking.

It should be noted that in Western Australia the regulation of use of e-cigarettes, both indoors and outdoors, is currently managed under policies administered by airport operators.

16. Therapeutic Goods Administration. Electronic cigarettes Canberra: Department of Health; 2013 [Available from: <http://www.tga.gov.au/consumers/ecigarettes.htm>].

17. National Health and Medical Research Council. NHMRC CEO Statement: Electronic Cigarettes (E-cigarettes) Canberra: Australian Government 3 April 2017 [Available from: https://www.nhmrc.gov.au/_files_nhmrc/file/publications/17072_nhmrc_-_electronic_cigarettes-web_final.pdf].

18. Cancer Council Australia, Heart Foundation. Position statement - electronic cigarettes: Cancer Council Australia; 2015 [Available from: http://wiki.cancer.org.au/policy/Position_statement_-_Electronic_cigarettes].

19. World Federation of Public Health Associations. Statement by the World Federation of Public Health Associations on electronic cigarettes Geneva: World Federation of Public Health Associations; 2015 [Available from: http://www.wfpha.org/images/events/141218_WFPHA_ECig_Statement_FINAL.pdf].

20. World Health Organization. Conference of the Parties to the WHO Framework Convention on Tobacco Control, FCTC/COP/7/11. Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDs). Seventh session, Delhi, India, 7-12 November 2016 Geneva: WHO; 2016.

21. Fernández E, Ballbè M, Sureda X, Fu M, Saltó E, Martínez-Sánchez JM. Particulate Matter from Electronic Cigarettes and Conventional Cigarettes: a Systematic Review and Observational Study. *Current Environmental Health Reports*. 2015;2(4):423-9.

22. World Health Organization. Conference of the Parties to the WHO Framework Convention on Tobacco Control, FCTC/COP/7/11. Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDs). Seventh session, Delhi, India, 7-12 November 2016 Geneva: WHO; 2016.

Human rights implications

The Explanatory Memorandum to the Vaporised Nicotine Products Bill states that 'the Bill promotes the right to do what you want as long as it does not harm anyone else.' However it should be noted, as outlined above, emissions have been shown to include harmful substances.

Concluding remarks

The Western Australian Government strongly supports a precautionary approach to the regulation of vaporised nicotine products. Until there is clear and demonstrable evidence that these products are not harmful to the health of users and people around them, or alternatively, there is an accurate understanding of the extent of any harm which they may cause, it is not good public health policy to let these products into the market place. In other words, it is not good public health practice to embrace a potential 'solution' to a health issue when that solution may in itself have an unintended harmful impact.

The precautionary principle also places the burden of proof on the proponents of a particular activity (in this case, manufacturers/importers of e-cigarettes) to demonstrate the safety and utility of their product.

In Australia, the prevalence of usage of these products is low. In 2013, approximately 3.2% of the Australian general population aged 14 and over reported using e-cigarettes in the past twelve months.²³ However, in the current climate of sporadic media publicity and comparative ease of access in some jurisdictions, it is likely that experimentation and use of e-cigarettes will increase. It is prudent public health policy to restrict the availability of these products before their usage becomes more widespread.

The Western Australian Government supports a total ban on nicotine and non-nicotine containing electronic cigarettes, until such time as evidence of their safety, quality and efficacy as a therapeutic good can be produced and appropriately assessed. It is submitted that appropriate infrastructure and a regulatory framework currently exists to carry out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard.

23. Greenhalgh E, Scollo M. E-cigarette use by demographics and smoking status, 2013, citing NDSHS 2013 data analysed by Centre for Behavioural Research in Cancer. In: InDepth 18B: Electronic cigarettes (e-cigarettes). In: Scollo M, Winstanley M, editors. Tobacco in Australia: Facts and issues. Melbourne: Cancer Council Victoria; 2016.