Position Statement
Electronic cigarettes (e-cigarettes)

Key Messages and Recommendations

- Although smoking is in decline, tobacco use continues to have a major impact on public health and will continue to do so for many years to come¹;
- Smoking is a leading cause of preventable death and disease in Australia. It contributes to more drug-caused deaths than alcohol and illicit drugs combined². It has been estimated that smoking kills about one half of all persistent users³;
- Tobacco control requires a comprehensive, population wide approach which encompasses the regulation of products which may promote the uptake or continuation of smoking;
- Currently, in Australia, electronic cigarettes have not been approved by the Therapeutic Goods Administration as a smoking cessation aid.
- It is also an offence to sell e-cigarettes in Western Australia under the Tobacco Products Control Act 2006. In accordance with this Act, a person must not sell any food, toy or other product that is not a tobacco product but is designed to resemble a tobacco product or package. Although some products may not look like the usual appearance of cigarettes, a Western Australian Supreme Court decision in April 2014, deemed that e-cigarettes, resembled a tobacco product and the seller of these e-cigarettes was convicted of this offence. This decision highlights that products that resemble tobacco products, regardless of whether they contain nicotine or not, cannot be sold in WA and it is an offence under the Tobacco Products Control Act to do so.
- Hence, in line with the World Health Organisation’s report on electronic nicotine delivery systems⁴, Cancer Council Western Australia supports the continued prohibition of the promotion and sale of electronic cigarettes and discourages their use because:
  - Products claiming to help people quit smoking are classified as therapeutic goods and e-cigarettes have not been approved as being one of these;
  - The sale of products which resemble cigarettes is illegal in Western Australia;
  - There is limited evidence regarding the safety of long-term use of electronic cigarettes as well as inadequate long term data on contents and emissions as well as the health effects to both users and bystanders;
  - The product claims of electronic cigarettes as a smoking cessation aid are unsupported by firm clinical evidence, and there is some evidence demonstrating dual use of both electronic and traditional cigarettes;
  - Electronic cigarettes may contain nicotine and this use may lead to addiction. More research is required into the health implications of long-term nicotine use;
  - Other possible harms have been associated with their use such as poisoning and fires; and
  - There are concerns regarding the involvement of tobacco companies and the promotion and potential renormalisation of smoking.

E-Cigarettes- What Are They?

Electronic cigarettes are an alternative nicotine delivery device that are also termed ‘e-cigarettes’, ‘e-cigs’ or ‘electronic nicotine delivery systems’ (ENDS). Electronic cigarettes (to be referred to as e-cigarettes hereafter) initially emerged in China in 2003 and have since become widely available globally; particularly over the internet.5

E-cigarettes have been marketed as cheap and healthier alternatives to cigarettes as well as to look and feel like cigarettes for use in places where smoking is not permitted since they do not produce smoke. E-cigarettes are products operated by a single use or rechargeable battery that heats a liquid based solution (often containing nicotine) into a vapour. This is then inhaled by the user, simulating the effect of cigarette smoking.

A typical e-cigarette consists of three components: a battery, an atomiser and a cartridge containing nicotine. Most replacement cartridges contain nicotine suspended in propylene glycol or glycerine and water. The level of nicotine in the cartridges may vary and some also contain flavourings.6 Some e-cigarettes have an indicator light at the end that glows when the user sucks on the device; a sensor detects air flow and then heats the liquid in the cartridge. This causes the liquid to evaporate and form the vapour which then delivers the nicotine to the user. There is no side-stream smoke. However, some nicotine vapour is released into the air as the user is exhaling. Many e-cigarettes are designed to resemble traditional tobacco cigarettes and are designed to replicate smoking behaviour.

Background

Even though the sale of e-cigarettes is being more widely reported in Western Australia, e-cigarettes have not been approved by the Therapeutic Goods Administration (TGA) as a smoking cessation aid. Western Australia also has legislation that prohibits the sale of electronic cigarettes under the Tobacco Products Control Act 2006. A Supreme Court decision in April 2014, highlighted that products that resemble tobacco products, regardless of whether

they contain nicotine or not, cannot be sold in WA and it is an offence under the Tobacco Products Control Act to do so.

Unlike Nicotine Replacement Therapy (NRT) products which have been rigorously assessed for efficacy as well as safety, and approved by the TGA for use as aids in withdrawal from smoking, no assessment of e-cigarettes has been undertaken. Most e-cigarettes that are available in Australia are manufactured in China. Their manufacture is not regulated and few manufacturers disclose the ingredients of their products. They may deliver unreliable amounts of nicotine, or contain toxic chemicals, pesticides or carcinogens. Research has also suggested that some cartridges may leak nicotine which can be harmful or toxic to the user as well as to others around them, especially children. Studies measuring the contents of the cartridges used in e-cigarettes have found varying nicotine levels as well as unlisted dangerous ingredients. Quantitative and qualitative studies have identified a wide variety of chemical components in the cartridges, e-liquid and aerosol of e-cigarettes. There is also a growing body of evidence to demonstrate that e-cigarettes release some particles into the air, which are small enough to reach deep into the lungs. Czgola et al (2014) concluded that using an e-cigarette indoors may involuntarily expose non users to nicotine.

Campaigners argue that the growing popularity of e-cigarettes could undermine years of anti-smoking efforts. The tobacco industry has moved into the market of e-cigarettes. For example, Lorillard purchased the leading e-cigarette maker ‘Blu’ in 2012; Reynolds America is increasingly marketing its VUSE digital technology e-cigarette as exclusively designed and made in the US; Altria’s subsidiary, Nu Mark, has entered the e-vapour category by introducing MarkTen™ e-cigarettes in 2013; Imperial Tobacco launched its own product in 2014 through the Fontenr Ventures unit and British American Tobacco has launched its first e-cigarette in the UK-Vype. E-cigarettes are also being promoted through social media by popular figures from film and music (You Tube http://bit.ly/19799LC; http://bit.ly/10phvaU and http://www.youtube.com/watch?v=OeihRcsprvg). Furthermore, there is at this stage no research about the impact of e-cigarettes promotion on children and young people’s attitudes to smoking.

With the involvement of tobacco companies in the e-cigarette market, there is growing concern that “Big Tobacco” will have a renewed presence in a declining marketplace. There is also concern that tobacco companies will use marketing tactics for e-cigarettes similar to those that have been used for traditional cigarettes such as sponsorship and advertising. E-cigarettes may be a potential gateway to new smokers, particularly among children and young people.

The Medicines and Healthcare Products Regulatory Agency in the United Kingdom reported that it planned to regulate e-cigarettes as medicines from 2016 when new European tobacco laws come into force. Proper regulation would ensure the safety and quality of the products, and prohibit promotion of e-cigarettes to children.

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or non-smokers\textsuperscript{13}. However, the European Parliament voted against imposing these stringent regulations on e-cigarettes. The National Institute for Health Care and Excellence (NICE) has published public health guidelines backing the use of licensed nicotine products to help people cut down as well as stop smoking. However, these guidelines have not covered e-cigarettes.

Proponents of their use claim that e-cigarettes are a useful harm reduction tool to aid smoking cessation. E-cigarettes are also seen by some as a safer alternative to burnt tobacco being free of the tar and ingredients of traditional cigarettes. It is also claimed that e-cigarettes do not provide second hand smoke and can assist smokers to cope with their addiction in situations where they are required to be smokefree such as on aeroplanes.

The Evidence Concerning E-Cigarettes

Currently, it is difficult to quantify the sale and use of e-cigarettes in Western Australia, although there are more reported incidents of e-cigarettes being sold in shopping centres and market places as well as being sold or used in schools. Some advocates of harm reduction have described e-cigarettes as viable substitutes for cigarettes because they produce fewer toxins in the vapour delivered to the user\textsuperscript{14,15,16} and may assist smokers to reduce cigarette consumption. However, there are concerns regarding the unknown long term safety of e-cigarettes, inadequate data on the contents and emissions in particular with long term use, and unsupported product claims that they are a smoking cessation aid\textsuperscript{17,18}. There is sufficient evidence to caution children, adolescents and women who are pregnant or of reproductive age about the use of e-cigarettes because of the possibility for nicotine exposure to have long-term consequences on brain development\textsuperscript{4}. Other unintended consequences of e-cigarette use include the potential to induce nicotine addiction in non-smokers or maintain addiction in current smokers who might otherwise quit. Furthermore, concerns have been raised that e-cigarettes may undermine the comprehensive indoor smoking restrictions and smokefree air policies\textsuperscript{19} as well as increased reporting of nicotine poisoning\textsuperscript{20}.

The main benefits of e-cigarette use that are most widely perceived by smokers are the degree to which they satisfy the desire to smoke, helping to reduce consumption of cigarettes, helping to eradicate the smell of stale smoke\textsuperscript{21,5}, helping to quit traditional cigarettes and to reduce the harm of traditional cigarettes\textsuperscript{4}. Research has shown that the effectiveness of e-cigarettes varies between products, between users and according to their

\textsuperscript{13}Briggs H. retrieved 13 June 2013 E-cigarettes face new restrictions. www.bbc.co.uk/news/health-22870301
\textsuperscript{17}Trichounian A. and Talbot P. Variability among electronic cigarettes nicotine delivery systems: is there a need for regulation? Tobacco Control, 20, 47-52.
\textsuperscript{19}Heningfield J. and Zaatar G. 2010 (Electronic nicotine delivery systems: emerging science foundation for policy. Tobacco Control, 19 (2), 89-90.
experience in use\textsuperscript{14}. Some experienced e-cigarette users using their own products for example have been found to have nicotine absorption at similar levels to that found in traditional cigarettes\textsuperscript{22}.

To date, four longitudinal studies\textsuperscript{23, 24, 25, 26} and two cross sectional studies\textsuperscript{27, 28} have been conducted examining the association between e-cigarette use and cessation of traditional cigarettes. When the results of these studies are combined in a random effects meta-analysis, they indicate that e-cigarette use in the real world is associated with significantly lower odds of quitting smoking traditional cigarettes\textsuperscript{11}.

A number of clinical trials of have also been conducted examining the efficacy of e-cigarettes for smoking cessation\textsuperscript{29, 30, 31, 32}. Three of these studies did not have a control group who were not using e-cigarettes\textsuperscript{29-31}. For example, study by Polosa et al. (2011)\textsuperscript{29} assessed e-cigarettes as a harm reduction and cessation aid. Significant smoking reduction and smoking abstinence were observed, with an overall smoking reduction and abstinence shown in 55% of participants. However, it was a small, uncontrolled study. In another Italian study\textsuperscript{30}, a prospective 12-month randomized, controlled trial was used that evaluated smoking reduction/abstinence in smokers not intending to quit. Two different nicotine strengths of a popular Italian e-cigarette model were compared to its non-nicotine choice. The use of e-cigarettes, with or without nicotine, decreased cigarette consumption and elicited enduring tobacco abstinence without causing significant side effects\textsuperscript{3}. This research has been criticized for its funding sources, design and analysis flaws (http://tobacco.ucsf.edu/italian-e-cig-study-does-not-support-conclusion-e-cigarettes-stimulate-smoking-cessation#comment-569). In the absence of independent clinical randomised controlled trials to evaluate the efficacy of an e-cigarette as a stop-smoking aid, it is difficult to judge claims about the effectiveness and safety of these products as treatments for nicotine addiction\textsuperscript{4}.

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\textsuperscript{25} Vickerman K, Carpenter K, Altman T, Nash C and Zbikowski S (201) Use of electronic cigarettes among state tobacco cessation quitline callers. Nicotine and Tobacco research, 15, 1787- 1791.
\textsuperscript{26} Choi K and Forster J (201)
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A study by Bullen et al (2013) used a pragmatic randomised control superiority trial with adults wanting to quit smoking using nicotine e-cigarettes, nicotine patches and placebo e-cigarettes. At six months, verified abstinence of nicotine e-cigarettes was 7.3%, 5.8% with patches and 4.1% with placebo e-cigarettes. Thus, there was insufficient statistical power to conclude the superiority of nicotine e-cigarettes to patches or placebo e-cigarettes. There were also no significant differences in adverse events between groups. E-cigarettes with or without nicotine, were modestly effective in helping smokers to quit, but achieved similar abstinence as with nicotine patches. More research is urgently needed to clearly establish the benefits and harms of e-cigarettes at both an individual and population level.

There is little objective information concerning the safety, abuse potential and efficacy of these products. Other concerns have been expressed, including that some flavours may appeal to children, that e-cigarettes may become a gateway to smoking or to nicotine addiction, that they undermine smokefree laws and policy, delay a smoker’s decision to quit or might be used in conjunction with drug misuse. Although smoking cessation and harm reduction motivated many e-cigarette users there were no differences in smoking quit rates between e-cigarette users and non users. Moreover, cutting down cigarettes rather than quitting confers little if any health benefit.

The lack of certainty regarding the variants of capsule contents is worrisome, given that the testing of cartridges has revealed poor quality control and marked manufacturer variability in nicotine content, as well as large deviations from the content claimed on the label. Testing of the vapour from the device has revealed similar variability, including marked ‘puff-to-puff’ variation. The positive effect of e-cigarette use that has been documented may be due to its capacity to provide a coping mechanism for conditioned smoking cues by replacing some of the rituals associated with smoking gestures (eg. hand to mouth action of smoking). Besides, nicotine free inhalers can only improve quit rates in those smokers whom handling and manipulation of their cigarette play an important role in their ritual of smoking. A nicotine replacement inhaler that has been approved by the Therapeutic Goods Administration may be a suitable alternative.

With long term firm evidence of both safety and smoking cessation lacking, there is cause for concern that e-cigarettes will become products for use in places where smoking is prohibited, or as starter products to children and ex-smokers. Trcchounian and Talbot (2011) found that print and internet material relating to e-cigarettes often contained information or made claims for which there is currently little or no scientific support. It was also found that it was difficult to avoid touching the nicotine-containing reservoir fluid when handling cartridges, which presents health risks to both e-cigarette users and non-users. Nicotine can be absorbed through the skin and cause harm if amounts are large. Nicotine can be converted into carcinogens, as shown with third hand

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smoke\textsuperscript{39}. A recent experimental study concluded that nicotine exposure can adversely affect genes by inducing mutations, and over a period of significant exposure, it may contribute to increased cancer incidence\textsuperscript{40}.

Conclusion

E-cigarettes are currently not legally sold in Australia and are highly variable in safety and efficacy. There is a lack of research concerning the effectiveness of the product as well as significant concerns regarding the involvement of the tobacco companies in the promotion of e-cigarettes and smoking. Thus, Cancer Council WA supports the legislation prohibiting the promotion and sale of electronic cigarettes as well as discouraging their use.

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\textsuperscript{40} Bavarva J, Hongseok T, McIver L and Garner H (2014) Nicotine and oxidative stess induced exomix variations are concordant and overrepresented in cancer-associated genes. Oncotarget, 5.