Submission to South Australian House of Assembly

Select committee inquiry into e-cigarettes

August 2015

Terms of Reference
That this House establish a Select Committee to investigate and report on E-cigarettes and any legislative and regulatory controls that should be applied to the advertising, sale and use of personal vaporisers; and in particular –
(a) the potential for personal vaporisers to reduce tobacco smoking prevalence and harms;
(b) the potential risks of these products to individual and population health from vapour emissions, poisoning and the reduced impact of tobacco control measures;
(c) make recommendations on approaches to the regulation of personal vaporisers under the Tobacco Products Regulation Act 1997, including addressing the following areas –
i. availability and supply;
ii. sales to minors;
iii. advertising and promotion;
iv. use in smoke-free areas;
v. product safety and quality control; and
(d) any other relevant matters.

A public health response to electronic cigarettes

Addressed to:
The Secretary
Select Committee on E-Cigarettes
Parliament House
GPO Box 572
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From:
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The Heart Foundation SA, Asthma Foundation SA and AMA (SA) have formed an alliance to prepare this submission on the availability, use, promotion and harms of electronic cigarettes (also known as personal vaporisers), and to make recommendations for regulation.

We are very clear. We strongly call for:

- **A ban on the sale of electronic cigarettes and all vaporising devices and associated products** such as liquids, cartridges and mouthpieces as smoking products, including those devices that deliver nicotine and those that claim to be nicotine-free, in the absence of any approvals by the Therapeutic Goods Administration (TGA).
- **A ban on the use of electronic cigarettes in smoke-free areas.**
- **A ban on the advertising and promotion of electronic cigarettes, consistent with tobacco advertising prohibitions.**

Thank you for this opportunity to present the evidence.

The evidence presented addresses the Terms of Reference.
OUR POSITION


We refer to the definition of e-cigarettes as described by the NHMRC:

_E-cigarettes are battery operated devices that heat a liquid (called ‘e-liquid’ or ‘e-juice’) 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._

The position statement outlines the following concerns about electronic cigarettes:

- Unsubstantiated claims about reducing smoking prevalence
- Potential harm from vapour emissions and poisoning
- The potential risks to the health of young people

a) Unsubstantiated claims about reducing tobacco smoking prevalence and harm

We are concerned about unsubstantiated claims that electronic cigarettes are a quitting device, and of reports that users have developed a stronger nicotine addiction. The available evidence for effectiveness of electronic cigarettes as an aid to quit smoking is mostly inconclusive. The dual use of electronic cigarettes and regular cigarettes is shown to be the main pattern of use, and might be associated with an increase in nicotine dependence, and therefore reduce the likelihood of quitting.

E-cigarettes should not be confused with the various forms of Nicotine Replacement Therapies (NRT), including inhalers, which may appear similar but do not produce any ‘vapor’. NRT products have been assessed for safety and efficacy and approved as a therapeutic product by the TGA for use in smoking cessation. At this point in time, e-cigarettes have not been assessed as a therapeutic product. Comprehensive smoking cessation programs rely on a host of measures to suit the needs of the individual, including support from a GP.

In the US electronic cigarettes have not been approved by the FDA as a smoking cessation device. In Australia, an NHMRC statement of March 2015 on e-cigarettes indicated:

_There is currently insufficient evidence to conclude whether e-cigarettes can benefit smokers in quitting, or about the extent of their potential harms. It is recommended that health authorities act to minimise harm until evidence of safety, quality and efficacy can be produced. NHMRC is currently funding research into the safety and efficacy of e-cigarettes for smoking cessation._

The World Medical Association’s 2012 statement indicates that:

_Manufacturers and distributors mislead people into believing these devices are acceptable alternatives to scientifically proven cessation techniques, thus delaying actual smoking cessation. E-cigarettes are not comparable to scientifically-proven methods of smoking cessation. Their dosage, manufacture, and ingredients are not consistent or clearly labelled._
The Australian Council on Smoking and Health (ACOSH) in its 2015 National Tobacco Scoreboard recommended that in the absence of any approvals by the TGA, South Australia ban all e-cigarette sale, promotion and marketing, and ban use in places where cigarette smoking is prohibited. This action is recommended by ACOSH for all states bar Western Australia, which is commended in the Scoreboard for banning sales of e-cigarettes with or without nicotine, to all people, including minors.

It is currently unlawful to sell electronic cigarettes containing nicotine, as nicotine is a scheduled poison, and can only lawfully be sold in legal tobacco products. Laws in South Australia prohibit the sales of products resembling tobacco products (Tobacco Products Regulation Act 1997) and the Controlled Substances Act 1984 makes it an offence to sell liquid nicotine without a permit, which is not provided for e-cigarette products.

b) Potential harm from vapour emissions and poisoning

Products containing dangerous poisons and involving the inhalation of chemicals directly to the lung are ordinarily only approved after extensive evaluation of safety and efficacy. In addition, as liquid nicotine is illegal to sell in Australia, consumers are relying on the largely unregulated sale of nicotine liquid from online sellers, which leaves Australians vulnerable and unaware of the content of the products bought.

New research suggests nicotine is genotoxic, promotes tumours and is linked to the onset and growth of head and neck, gastric, pancreatic, gallbladder, liver, colon, breast, cervical, urinary bladder and kidney cancers, as well as small-cell and other lung carcinomas. There are also potential implications for immune response.

Nicotine is highly addictive and the AMA view is that there is no good reason to ingest it in any form. While there is sufficient evidence for nicotine replacement therapy (NRT) to be made available to people smoking more than 10-15 cigarettes a day, e-cigarettes should not be confused with nicotine replacement therapy.

The number of cases of accidental nicotine poisoning caused by swallowing e-cigarette liquids is on the rise in the UK and the US.

While it is widely acknowledged that electronic cigarettes are likely to be less dangerous than tobacco products, the health effects of their use remains unknown. The World Health Organization is concerned about the safety of the chemical combinations used across the variety of electronic cigarette products that are available. The American Thoracic Society has also reported recent research indicating health risks and ineffectiveness for long-term smoking cessation.

The World Medical Association has indicated in 2012 that quality control processes used to manufacture these products are “substandard or non-existent” and that few studies had been done to analyse the level of nicotine delivered to the user and the composition of the vapor produced. It indicated that clinical testing; large population studies and full analyses of e-cigarette ingredients and manufacturing processes need to be conducted before their safety, viability and impacts can be determined as either clinical tools or as widely available effective alternatives to tobacco use.

Researchers warn that flavourings are a largely unrecognised potential hazard of electronic cigarettes. While flavours and other chemicals used in many electronic cigarette products have
been assessed for safety in food (for ingestion), inhalation has not be similarly assessed and cannot be described as safe. Chemicals found in a range of electronic cigarettes products, such as diacetyl, have been linked to serious respiratory conditions when inhaled in workplace environments. Recent research also suggests that high levels of formaldehyde, a chemical known to cause cancer, might be inhaled when ‘vaping’ at high voltages. Other research continues to emerge on potential health impacts, including, for example on respiratory system and immune system impacts. There is little known about their long-term health effects but adverse short term effects on diastolic blood pressure, heart rate and airway resistance have been measured.

Little is known about the effects of passive exposure. Little is known about the effects on pregnancy.

The precautionary principle in public health should be adopted in respect to electronic cigarettes. That is:

"... that lack of scientific certainty must not be used as a reason to ignore or postpone preventive or remedial action when there are other good reasons to do so, as has happened many times in the past. The prescription to err on the side of caution, the “better safe than sorry” approach, may seem little more than common sense. Indeed it is implied by the principles of clinical medicine, in particular by the principle of non maleficence, more familiar to the public health profession. The concept of precaution is deeply rooted in the history of public health, and environmental health is no exception."

c) The potential risks to the health of young people: The principal concern is the way electronic cigarettes are being aggressively marketed to young people.

Electronic cigarettes are purely recreational products designed to deliver nicotine into the body in a way that mimics smoking. As such, e-cigarettes may be a gateway to smoking. ‘Starter packs’ are promoted to new users. The wide variety of sweet fruit, candy, alcohol and chocolate flavored nicotine solutions for use with electronic cigarettes could appeal to children and young people.

In South Australia, cigarette use and acceptability among children and young adults is at an all-time low. Nationally only 2.5% of children aged 12 to 17 smoke daily - a dramatic reduction on previous figures.

In addition to health risks to individuals related to use and second-hand exposure, key concerns include potential public health impacts arising from the widespread availability and use of electronic cigarette products. Potential public health impacts include:

- the renomalisation of smoking behaviour
- the glamorisation and normalisation of products with unknown health impacts
- rapid uptake by young people
- use by non-smokers and ex-smokers
- dual use by smokers and the undermining of quit attempts.

Concerns about these issues continue to grow internationally in light of electronic cigarette use trends. Research demonstrates alarming trends in use of nicotine electronic cigarettes overseas, including rapid uptake by young people, use by non-smokers and dual use with tobacco by
smokers, although still less than tobacco usage. In the US regulation around marketing and promotion is only now being finalised, but meanwhile aggressive television and print advertising continues, particularly aimed at the youth market.\textsuperscript{xvii} Primary and secondary school students are increasingly using electronic cigarettes in the US.

Recent Australian data indicates that a significant number of existing smokers - particularly younger smokers – have used electronic cigarettes. Australian data on daily electronic cigarettes use are unavailable, but a 2013 national survey found that 15.4% of smokers aged 14 years or over had used them at least once in the past 12 months\textsuperscript{xviii}, despite sales of nicotine liquid being illegal here.

We have made great achievements in changing cigarette culture amongst young people. Much of that is the result of reduced smoking rates in the adult population – the group younger people seek to mimic. Widespread use of electronic cigarettes could see a return to the bad old days of cigarette use being an aspirational activity for young people. Electronic cigarette use could potentially renormalise smoking behaviour and re-glamorise the act of smoking more broadly. It is likely that electronic cigarettes will fuel and promote nicotine addiction, especially in children, and potentially serve as a gateway to other drugs and harmful substances.\textsuperscript{xix}

If electronic cigarettes became commonplace, decades of effective tobacco control could unravel – and we would face new challenges to reduce the harms of cigarette use.

There is also a dangerous opportunity for the tobacco industry to now begin to circumnavigate advertising restrictions at precisely the moment when Australia has removed package branding and point-of-sale displays.
RECOMMENDATIONS ON CHANGES TO LEGISLATION

We urge the committee to ensure that the definition of a personal vaporiser captures all devices; even those that don’t contain nicotine [see notes section for Queensland’s amendment to the Act].

We recommend that the promotion and sale of electronic cigarettes be banned in South Australia, unless the product has been approved by the TGA, and on the basis of conditions required by the TGA. If electronic cigarettes were banned, it would not be necessary to provide any ongoing public education regarding their potential health and safety risks.

The Heart Foundation SA, Asthma Foundation SA and the AMA (SA) strongly recommend the following laws be implemented:

1. **Ban the retail sale of non-nicotine electronic cigarettes** because they are currently available unregulated for everyone to purchase as they don’t contain tobacco leaf and are not automatically covered by tobacco laws. There are no restrictions relating to their sale and supply, promotion, use or enforcement.

2. **Ensure smoke-free laws cover electronic cigarette use.** Electronic cigarettes need to be brought under smoke-free laws to ensure that both nicotine and non-nicotine e-cigarettes are not used in places where smoking tobacco is prohibited. Unrestricted use of e-cigarettes undermines South Australia’s excellent smoke-free laws.

   There are absolutely no benefits of permitting electronic cigarette use in smoke-free areas.

3. **Ban advertising and promotion of electronic cigarettes, consistent with tobacco advertising prohibitions** to limit the aggressive promotion of electronic cigarettes currently being directed at young people and children. Electronic cigarette advertising should be subject to similar restrictions as other tobacco products.

   Our Alliance supports amendments to the Tobacco Products Regulation Act 1997 that achieve the above recommendations with the intention to capture all vaporising devices and associated products such as liquids, cartridges and mouthpieces as smoking products, including those devices that deliver nicotine and those that claim to be nicotine-free.
NOTES

Queensland legislation
Amendment of *Tobacco and Other Smoking Products Act 1998*
Clause 52 Act amended.

Meaning of *personal vaporiser* and *personal vaporiser related product*

(1) A **personal vaporiser** is a device that—
   (a) is capable of being used to deliver nicotine into an individual’s body when the individual inhales through the device; and
   (b) has 1 or more of the following parts—
      (i) a battery;
      (ii) a cartridge or container to store a liquid, vapour or gas;
      (iii) an electric heating element.

(2) A **personal vaporiser related product** means any of the following—
(a) a device or other product that—
   (i) is apparently intended to be part of a personal vaporiser; and
   (ii) is not capable of being used to deliver nicotine into an individual’s body without an adjustment, modification or addition;

*Examples for paragraph (a)*—
• an atomiser, battery, cartridge, container or mouthpiece
• a product that combines an atomiser and cartridge in a single unit

(b) a device or other product to which paragraph (a) does not apply that is apparently intended to be used in connection with a personal vaporiser;

*Example for paragraph (b)*—
a liquid that is to be used in a personal vaporiser, whether or not the liquid is in a cartridge or container

(c) any other product, prescribed by regulation, that is used primarily to smoke with a personal vaporiser.
REFERENCES


viii WMA Statement on Electronic Cigarettes and Other Electronic Nicotine Delivery Systems, Adopted by the 63rd WMA General Assembly, Bangkok, Thailand, October 2012 http://www.wma.net/en/30publications/10policies/e19/


xvi WMA Statement on Electronic Cigarettes and Other Electronic Nicotine Delivery Systems, Adopted by the 63rd WMA General Assembly, Bangkok, Thailand, October 2012 http://www.wma.net/en/30publications/10policies/e19/


xxvii AIHW, Online tables. National Drug strategy Household Survey. 2013