

Options for a public health response to electronic cigarettes

Discussion Paper

12 June to 24 July 2015

Table of Contents

Invitation to comment	3
What is this paper about?	3
How do I provide feedback?	3
What's next?	3
Introduction	4
What are e-cigarettes?	4
Health effects	5
Consumer safety	5
Exposure to nicotine	5
Helping smokers quit	6
Public health concerns	7
Usage	7
Other Australian jurisdictions	8
E-cigarettes in Tasmania	9
Policy Options	10
Options to prevent uptake	11
Options to prevent renormalisation of smoking and protection from second hand vapour	13
Enforcement	14
Supporting Documents	14
References	15

Invitation to comment

What is this paper about?

The Department of Health and Human Services (DHHS) invites your feedback on the range of options that could be implemented in Tasmania on the use and availability of electronic cigarettes (e-cigarettes).

Some options include proposed amendments to the *Public Health Act 1997*.

The prospect of the legal sale of nicotine e-cigarettes, which would require amendments to the *Poisons Act 1971*, is not a principal consideration of this consultation. This is due to the absence of national regulation of the safety and quality of e-cigarettes that contain nicotine, and the lack of an established scientific basis for the safe use of such products.

How do I provide feedback?

Telephone queries can be directed to 1800 671 738.

Written submissions can be:

Emailed to public.health@dhhs.tas.gov.au

Posted to Senior Advisor Tobacco Policy
Public Health Services
Department of Health and
Human Services
GPO Box 125
HOBART TAS 7001

A response template is included with this discussion paper for your convenience however other written submissions are also welcome.

If you do not use the response template provided, in making your submission we ask you to focus on the options presented.

Anonymous submissions will not be accepted.

All responses must be received by 5pm on Friday 24 July 2015.

What's next?

Information gathered from the consultation process will contribute to the Department's advice to the Tasmanian Government and its decision-making process.

Submissions will be published on the DHHS website at www.dhhs.tas.gov.au unless clearly marked as confidential.

Introduction

The Tasmanian Government is seeking to examine options to address potential harms associated with the use of personal vaporisers, of which e-cigarettes are the most common type.

This discussion paper was commissioned by the Minister for Health, the Hon. Michael Ferguson MP, in April 2015. It seeks feedback on a range of options and responses will contribute to the Tasmanian Government's consideration of these issues.

The Tasmanian Government acknowledges and thanks the ACT Government for its permission to model this paper on the discussion paper it released in November 2014 – *Options to protect the community from potential harms associated with personal vaporisers (e-cigarettes)*.

What are e-cigarettes?

An e-cigarette replicates smoking behaviour without the use of tobacco.

It is a battery-operated device designed to heat a liquid (referred to as e-liquid or e-juice) to produce a vapour that a user inhales.

The liquid generally contains a base solution of propylene glycol and glycerine. Ingredients typically added to this solution include flavouring agents and a range of chemicals. They may or may not contain nicotine. E-cigarettes that contain nicotine are referred to as electronic nicotine delivery systems (ENDS).

All Australian jurisdictions ban the retail sale of e-cigarettes containing nicotine as it is classified as a Schedule 7 dangerous poison.

Most devices contain an electronic vaporisation system, a battery and a liquid cartridge. Some look like conventional cigarettes whilst others appear more like an electronic device or resemble everyday items such as lipsticks and pens. They can be disposable, re-chargeable and/or refillable.



Figure 1: Examples of personal vaporisers (or e-cigarettes)



Figure 2: Example of e-liquid with a personal vaporiser



Figure 3: Example of vaping

Health effects

Whilst e-cigarettes simulate the act of smoking and produce a vapour, they do not contain tobacco and appear to provide lower exposure to certain toxic chemicals found in combusted tobacco products.

There is some preliminary evidence to support the view that e-cigarettes are less harmful than tobacco cigarettes, particularly in the short term.^{1 2} However, while they may contain a lower concentration of a range of constituents, there are other ingredients that remain unknown. Furthermore some studies have found e-cigarettes and tobacco cigarettes produce similar levels of formaldehyde.³ The actual level of risk for individuals using e-cigarettes, as opposed to tobacco cigarettes, can therefore not be determined at this stage.

Harms from long term use are also unknown. The World Health Organisation (WHO) states that conclusive evidence about the association of e-cigarettes with diseases of interest (such as cancer) will not be available for years, even decades.⁴

Evidence of the long term health effects of second hand exposure to emitted or exhaled vapour is also inconclusive. Some research evidence indicates there are short term risks relating to exposure to propylene glycol such as eye and respiratory irritation.⁵ There are also concerns that exposure to propylene glycol may form toxic or cancer-causing compounds when heated and vaporised and that products with nicotine may passively expose non-users to nicotine and other potentially harmful constituents. This includes flavoured chemicals which may be safe when ingested but unsafe when inhaled.⁶

Consumer safety

As outlined, all Australian jurisdictions ban the retail sale of e-cigarettes containing nicotine (ENDS).

Currently the WHO advises that consumers should not use e-cigarettes until they are deemed safe, effective and of acceptable quality by a national regulatory body. E-cigarettes and their cartridges have not been evaluated for quality, safety or performance nor approved by the Australian Therapeutic Goods Administration (TGA). This includes the contents of vapour emissions.

In the absence of TGA approval, potential risks include:

- High concentrations and variability in the amount and type of chemicals delivered.
- Leaking of chemicals from e-liquids with potential risk of nicotine poisoning.
- Inaccurate and inconsistent labelling.
- Marketing with implied health benefits and promotion as a safer option for smokers when their long-term health effects are unknown.
- Product manufacture affecting performance and safety. Some products contain interchangeable parts such as batteries and chargers for which there are no quality controls.
- Use of lithium batteries which have a risk of overheating, leading to fire and explosion increasing the risk of burns, blindness, car and house fires.⁷

Exposure to nicotine

Nicotine is a highly addictive and dangerous chemical that can be lethal in excessive amounts. High doses of nicotine can be absorbed through the skin as well as by the lungs (from smoking) and the gastrointestinal tract (from swallowing). Nicotine poisoning can result in a range of symptoms including abdominal cramps, agitation, changes in breathing and confusion.

Children, adolescents, pregnant and breastfeeding women, people with heart conditions and the elderly are particularly susceptible.

Again, to put this discussion in context, it must be emphasised that the retail sale of nicotine-containing e-cigarettes is illegal in Tasmania.

However, there remain potential risks for accidental or unknown exposure to nicotine in legally available e-cigarettes including:

- Users unknowingly ingesting nicotine through products that are labelled as nicotine-free or without listing nicotine as an ingredient. Tests in Tasmania in 2014 revealed e-liquid refills on the market with up to 18 mg/mL of nicotine even though they were labelled as nicotine-free.⁸ Similar tests conducted in New South Wales in 2013 revealed high levels of nicotine in 70% of products sampled.⁹
- Unreliable doses of nicotine being delivered due to the lack of standards and regulation around the manufacture and labelling of e-cigarette products.
- Risk of accidental poisoning to children due to there being no requirements for child-proof packaging or warnings about the risk of poisoning. Although nicotine has a bitter taste, some e-liquids contain fruit and confectionery flavouring that can be more enticing to children.
- At least one study supports the evidence that non-smokers passively exposed to e-cigarettes absorb nicotine.¹⁰

Other risks relating to nicotine exposure include:

- Lasting adverse effects on foetal and adolescent brain development.¹¹
- Nicotine acting as a “gateway drug” on the brain increasing the risk and potential for illicit drug use and addiction.¹²
- Studies that suggest it may be a tumour promoter, reduce sensitivity to insulin which could worsen or cause diabetes, and result in cardiovascular changes that could promote atherogenesis (hardening of the arteries) and precipitate acute ischaemic events.¹³

Helping smokers quit

Unlike nicotine replacement therapy products, which have been rigorously assessed for efficacy and safety, no model of e-cigarette has been approved by the Australian TGA as a smoking cessation aid.

Anecdotally, many smokers have claimed e-cigarettes have helped them to quit smoking. On the other hand, there are also anecdotal reports of users increasing their nicotine addiction and of dual use (e-cigarettes and smoked tobacco which does not result in reduced harm). There are also concerns e-cigarettes undermine quit attempts and elicit cravings that trigger smoking relapse by ex-smokers.

A number of research studies have been conducted, with mixed results. Some indicate e-cigarettes may help smokers increase their chances of quitting long term or reduce consumption by at least half.¹⁴ Others indicate e-cigarettes reduce the likelihood of smokers quitting¹⁵ ¹⁶and that their effectiveness is similar to using nicotine replacement therapies such as a patch.¹⁷

The overall quality of evidence for the effectiveness of e-cigarettes as a smoking cessation aid is therefore currently low because it is based on only a small number of studies. More conclusive research is needed in this area which is underway both in Australia and internationally.¹⁸

Public health concerns

There is a risk that the increasing availability and use of e-cigarettes may undermine tobacco control efforts by reinforcing the normality and attractiveness of smoking behaviour. This has the potential to reverse the recent gains made to reduce smoking rates and tobacco related harm.

Identified concerns include:

- The visual cue and simulation of the hand-to-mouth action of cigarette smoking in smoke free public areas. This may risk renormalising smoking behaviour and increase the risk of uptake of cigarette smoking by non-smokers and relapse for some ex-smokers.
- That young people may be attracted to the glamorous packaging, youth oriented advertising and a wide range of enticing product flavours, which could lead them to inadvertently become addicted to nicotine (through accidental or unknown exposure) and/or take up tobacco smoking.
- Possible health effects of second hand exposure to vapour leading to an increased risk of disease.
- Reports of devices being used for covert cannabis, hallucinogens and heroin use.¹⁹

Usage

E-cigarettes entered the market ten years ago and are now sold by hundreds of companies, many of which are owned by tobacco companies. Market penetration has been lower in Australia compared to the UK or USA, most likely due to existing restrictions on access to nicotine.

Research on the use of e-cigarettes (both with nicotine and nicotine-free) found their prevalence in Australia has increased but is low. Of current and ex-smokers of tobacco cigarettes in 2013:

- 20% had tried e-cigarettes compared to 2% in 2010.
- 7% were current users of e-cigarettes compared to 2% in 2010.
- Among current e-cigarette users, 42% reported that their current brand contained nicotine.
- Among current smokers, 15% had recently used an e-cigarette in the last 12 months.²⁰

In Tasmania, Cancer Council Tasmania conducted the Smoking and Health Survey, a survey of 600 Tasmanian adults on smoking related topics including knowledge and use of e-cigarettes in 2013²¹ and 2014.

In 2013, approximately two thirds of respondents (67%) had an awareness of e-cigarettes with this knowledge more common among those aged 18-29 years, current smokers and those with a higher level of education. Advertising of e-cigarettes had most commonly been noticed on the internet, newspapers and magazines.

In the previous 12 months, 7% of respondents had tried an e-cigarette; this was higher for lower age groups, lower socio economic groups and current smokers. Of those who had tried an e-cigarette in the last 12 months, 26% reported regular use. Of all respondents, 2% reported regular use of an e-cigarette. It is noted the survey methodology excluded mobile phones and that this may affect survey results.

Of those who had tried an e-cigarette, two thirds were sure it did not contain nicotine and the remainder were unsure. Half reported the reason for trying an e-cigarette was the belief that “they help you quit”.

Three-quarters agreed e-cigarette usage should align with existing smoke free areas legislation. Agreement was higher among those in high socio economic areas, aged 50 and over and never-smokers.

Results from the 2014 survey have not yet been finalised.

Other Australian Jurisdictions

All Australian jurisdictions ban the retail sale of e-cigarettes containing nicotine as it is a classified Schedule 7 dangerous poison, including purchase over the internet and importation.

At the time of writing, all jurisdictions allow the sale of nicotine free e-cigarettes except for South Australia and Western Australia, where a product cannot be sold if it resembles a tobacco product (such as a cigarette or cigar).

Queensland has passed legislation which means 'personal vaporisers,' including e-cigarettes, have been subject to the same laws as tobacco products from 1 January 2015. This means e-cigarettes cannot be used in existing smoke free areas, sold to children or advertised and displayed in retail outlets.

The ACT is considering a range of options detailed in a consultation process that was held between 12 November and 24 December 2014.

New South Wales and South Australia have announced bans on the sale of e-cigarettes to children.

The Commonwealth Department of Health is conducting a National ENDS project to review Australia's response to electronic nicotine delivery systems and to identify and analyse policy considerations by governments in Australia. The project is expected to be completed by the end of 2015.

E-cigarettes in Tasmania

Because e-cigarettes do not contain tobacco leaf, the current restrictions in the *Public Health Act 1997* for tobacco products do not apply. This means a retailer does not require a licence to sell nicotine-free e-cigarettes and there are no restrictions on sale to children, displays in retail stores, location or storage, range of flavours offered and place of use.

Legal Requirements

The sale of e-cigarettes with cartridges that contain nicotine is a breach of the *Poisons Act 1971*. This is because nicotine is a prescribed dangerous poison and it is an offence to manufacture, obtain, possess, sell or supply nicotine or products containing nicotine unless a permit has been issued by a state authority.

Only e-cigarettes with liquid cartridges that are nicotine-free can presently be sold in Tasmania.

Retail Environment

E-cigarettes sold in Tasmania are currently available from a range of retail settings such as service stations, markets and corner stores. Tasmanians can also purchase e-cigarettes online from local and national websites. The majority of products are sold individually with refills available in packs or individually.

Promotional advertising in retail shops appears to rely heavily on displays on service counters and there is at least one outlet that retails as a “vape” shop. There is also promotion via social media.

Although nicotine liquid cartridges are banned in Tasmania, there are anecdotal reports of users being able to buy it online from overseas in small “personal use” quantities. This is despite Tasmanian law banning the possession of liquid nicotine.²²

Access by Children

There is no restriction on the sale of nicotine free e-cigarettes to people under the age of 18 years.

Place of Use

There are no restrictions on where e-cigarettes can be used in Tasmania. This has created uncertainty in some existing smoke free areas, particularly health care facilities and hospitality venues.

Public Education

Public Health Services has a fact sheet which is available on the DHHS website. It is noted the fact sheet is currently being reviewed.

The Director of Public Health released a public health alert in February 2014 following testing of products found to contain nicotine but were labelled as nicotine-free.²³

Policy Options

Some health experts welcome nicotine free e-cigarettes as an option to help with smoking cessation and the reduction of smoking rates, while others argue that e-cigarettes only work to undermine tobacco control efforts by re-normalising smoking.

The National Health and Medical Research Council (NHMRC) has advised because there is currently insufficient evidence about the extent of the potential harms of nicotine free e-cigarettes, health authorities should act to manage the risk of potential harms until evidence of safety, quality and efficacy can be produced.²⁴

Policy responses, therefore, need to remain adaptable to new scientific evidence, particularly if evidence is produced to support e-cigarettes working as an effective quitting aid.

With this in mind and guided by the recommendations of the WHO and NHMRC, the intent of this paper is to canvass whether and how the Tasmanian Government should take action to ensure potential harms to the community are minimised by:

- Preventing uptake of e-cigarettes by young people, non-smokers and ex-smokers.
- Preventing re-normalisation of smoking behaviour.
- Protection from possible harms from exposure to second hand vapour.

Possible policy responses are presented under two headings:

1. Options to prevent uptake

Non-regulation:

- 1.1 Continue with the status quo
- 1.2 Public education

Part-regulation:

- 1.3 Restrictions on sale and advertising
- 1.4 Prohibit sale to people under 18 years of age
- 1.5 Prohibit sale of flavoured e-liquids

Full-regulation:

- 1.6 Regulate e-cigarettes in the same way as tobacco

2. Options to prevent renormalisation of smoking and protection from second-hand vapour

- 2.1 Continue with the status quo
- 2.2 Prohibit use in existing smoke free public places

Options to prevent uptake

Possible options to prevent the uptake of e-cigarettes in Tasmania include:

NON-REGULATION

Option 1.1: Continue with the status quo

This would see no change to the current arrangements governing the promotion and sale of e-cigarettes in Tasmania. This means nicotine-free devices could continue to be sold through retail outlets with no restrictions on display, marketing and age of purchase or a licence to sell.

- a. Do you support maintaining the current arrangements governing the promotion and sale of e-cigarettes in Tasmania?
- b. What do you see as the benefits of maintaining the current arrangements?
- c. What do you see as the costs of maintaining the current arrangements?

Option 1.2: Public education

This would also see the current arrangements around the promotion and sale of e-cigarettes continue but with community education and awareness raising activities to inform the public about the potential health and safety risks associated with using nicotine free e-cigarettes. Examples could include education materials such as fact sheets, flyers and web content.

- a. Do you support public education activities to inform the community about the potential health and safety risks associated with using nicotine free e-cigarettes?
- b. Do you think public education and awareness raising activities would be sufficient to prevent e-cigarette uptake by non-smokers, ex-smokers and young people?

PART-REGULATION

This would see changes made to the *Public Health Act 1997* with direct amendment to individual provisions for some or all of the following options:

Option 1.3: Restrictions on sale and advertising

This would extend current restrictions on tobacco product displays and advertisements inside and outside retail shops and vending machines. It includes shopper loyalty schemes, sponsorship and product giveaways and marketing. It would mean e-cigarettes could not be displayed and price information would only be permitted on a price board. If this option were implemented, it is also possible that tobacco licensing could be extended to include e-cigarettes. This would support DHHS in monitoring retailer compliance.

- a. Do you support the introduction of restrictions on the sale and promotion of e-cigarettes in Tasmania?
- b. What do you see as the benefits of this?
- c. What do you see as the costs of this?
- d. What do you see as risks or implementation issues that could be associated with this?

Option 1.4: Prohibit sale to people under 18 years of age

This would involve extending current restrictions on the sale of tobacco to people under 18 years of age to e-cigarettes. It includes the capacity to conduct controlled purchase operations to test retailer compliance.

- a. Do you support extending existing restrictions on the sale of tobacco to children to include e-cigarettes?
- b. What do you see as the benefits of this?
- c. What do you see as the costs of this?
- d. What do you see as risks or implementation issues that could be associated with this?

Option 1.5: Prohibit sale of flavoured e-liquids

Although nicotine has a bitter taste, some e-cigarette cartridges are flavoured that can result in them being more enticing and palatable to young people. This option would make it unlawful to sell flavoured e-liquids to adults or children, regardless of whether the product contains nicotine. This could only be a temporary arrangement pending agreement between Australian jurisdictions and New Zealand under mutual recognition arrangements.²⁵

- a. Do you support prohibiting the sale of flavoured e-liquids in Tasmania?
- b. What do you see as the benefits of this?
- c. What do you see as the costs of this?
- d. What do you see as risks or implementation issues that could be associated with this?

FULL-REGULATION

Option 1.6: Regulate e-cigarettes in the same way as tobacco

This would involve changes being made to the *Public Health Act 1997* to have e-cigarettes fully regulated in the same way as tobacco. One way to do this would be to extend the definition of a tobacco product to include a 'personal vaporiser'.²⁶ This would involve the implementation of options 1.3, 1.4 and the following:

- A child would not be able to use an e-cigarette (section 63).
- A child would not be able to possess an e-cigarette (section 63).
- Retailers would need to provide information to employees about sale and supply to children (section 64).
- Other employees would be committing an offence if they permitted an employee to supply to a child within 100 metres of the premises (section 64(3)).
- Specialist tobacconists would be permitted to sell e-cigarettes, which they are currently prevented from doing. However, like general retailers they would be unable to display e-cigarettes (section 72A).
- Retailers would be prevented from providing incorrect information relating to the legislation and health effects of e-cigarettes (sections 74 and 74AA).

- a. Do you support e-cigarettes being fully regulated in the same way as tobacco?
- b. What do you see as the benefits of full-regulation?
- c. What do you see as the costs of full-regulation?
- d. What do you see as the risks or implementation issues of full-regulation?

Options to prevent renormalisation of smoking and protection from second hand vapour

Possible options to prevent the renormalisation of smoking and protect the public from second-hand vapour include:

Option 2.1: Continue with the status quo

This would see no change to the current arrangements whereby there are no restrictions on where e-cigarettes can be used in indoor and outdoor public areas that are currently smoke free.

- a. Do you support permitting e-cigarette use in smoke free areas?
- b. What do you see as the benefits of permitting e-cigarette use in smoke free areas?
- c. What do you see as the costs?
- d. What do you see as likely risks of continuing to permit e-cigarette use in smoke free areas?

Option 2.2: Prohibit use in existing smoke free public places

This would extend current provisions under the *Public Health Act 1997* to capture e-cigarettes. This means e-cigarettes would not be able to be used in:

- Enclosed public places including licensed bars and pubs.
- Enclosed workplaces.
- Entrances and exits to public buildings (within three metres).
- Air conditioning intakes to public buildings (within 10 metres).
- Cars where children are present.
- Cars used in employment if another person is present.
- Outdoor dining areas.
- Public swimming pools.
- Seating and competition areas of sporting grounds (within 20 metres).
- Children's playgrounds (within 10 metres).
- Patrolled beaches (between the flags).
- A range of public events declared by the Director of Public Health to be smoke free.
- Any area declared by the occupier as smoke free, examples include state government facilities such as schools, prisons and hospitals.

It would also mean:

- It would be an offence for occupiers of smoke free areas to permit use of e-cigarettes in that area unless a defence applies (section 67D).
- Occupiers of a smoke free area would need to display signage (section 67E).
- Occupiers of an outdoor dining area would need to ensure it is not of inferior amenity to any outdoor smoking area (section 67F).
- Procedures to minimise risks to health would need to be developed and implemented if use is permitted in personal living areas where a person works (section 67G).

- a. Do you support prohibiting e-cigarette use in existing smoke free areas?
- b. What do you see as the benefits of prohibiting e-cigarette use in smoke free areas?
- c. What do you see as the costs?
- d. What do you see as likely risks or implementation issues?
- e. Do you believe e-cigarette use should not be permitted in all smoke free areas or only some? If some, in which areas do you believe the use of e-cigarettes should be permitted and why?

Enforcement

DHHS staff and nominated officers empowered under the *Public Health Act 1997* are responsible for enforcing tobacco control provisions. This would extend to e-cigarettes if part or full regulatory options were implemented. Enforcement can include verbal or written warnings, infringement notices or prosecution.

Supporting Documents

ACT Government. Discussion Paper: *Options to protect the community from potential harms associated with personal vaporisers (e-cigarettes)*, November 2014.

National Health and Medical Research Council. *CEO Statement: Electronic Cigarettes*, March 2015.

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²² <http://www.tga.gov.au/behind-news/liquid-nicotine-and-personal-importation-use-electronic-cigarettes>

²³ http://www.dhhs.tas.gov.au/news/2014/warning_on_e-cigarettes

²⁴ National Health and Medical Research Council. *CEO Statement: Electronic cigarettes*, March 2015.

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