

Senior Advisor Tobacco Policy
Public Health Services
Department of Health and Human Services
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Email: public.health@dhhs.tas.gov.au

24 July 2015

Dear Senior Advisor

Re: Options for a public health response to electronic cigarettes

We thank the Department of Health and Human Services for the opportunity to provide comment on the options for a public health response to the use and availability of electronic cigarettes. We are however disappointed that the consultation process made it difficult to propose measures that would have the potential to be more beneficial to the health of Tasmanians. If we are to achieve the Government's goal of making Tasmania the healthiest population in Australia by 2025, the options provided in the options paper should have invited comments on the merits of a total ban on electronic cigarettes, until such a time that they have been assessed and deemed to be a safe and effective quitting aid by the Therapeutic Goods Administration (TGA).

The Heart Foundation Tasmania endorses the position statement of the Cancer Council Australia and the National Heart Foundation on electronic cigarettes, available here:
http://wiki.cancer.org.au/policy/Position_statement_-_Electronic_cigarettes

The position statement outlines three main concerns about electronic cigarettes:

- **Health of young people:** The principal concern is the way electronic cigarettes are being aggressively marketed to young people. In 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.

We have made great achievements in changing cigarette culture among 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 cigarettes could potentially renormalise smoking behaviour and re-glamorise the act of smoking more broadly.

- **Unsubstantiated quitting aid claims:** We are concerned about unsubstantiated claims that electronic cigarettes are a quitting device, and of reports that users have developed a stronger nicotine addiction. Moreover, electronic cigarettes deliver poisons and other chemicals directly to the lungs – and the long-term health effects of using these products are unknown.
- **Unproven for safety:** 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. Non-nicotine electronic cigarettes have not been tested for safety yet they can be lawfully sold to children and adults in Tasmania. This is a significant risk to long-term public health outcomes. The precautionary principle in public health should be adopted in respect to electronic cigarettes. That is:



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“... 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.”

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.

The discussion paper prepared for this consultation clearly outlines that whilst the short and long term health effects of electronic cigarettes are not known yet, there are real public health concerns around their potential harm. There is also solid evidence that non-nicotine e-cigarettes in Australia (unregulated) have been found to contain nicotine – and indeed other (unknown) substances. The discussion paper also clearly outlines the consumer safety risks posed by electronic cigarettes and e-liquids in the absence of TGA approval. The Tasmanian Government should therefore adopt the precautionary principle in public health – and the advice of the National Health and Medical Research Council, of not approving anything for which there is potential for harm.

The Heart Foundation therefore supports a ban on the promotion and sale of electronic cigarettes, until such a time that the product has been approved to be safe and effective by the TGA.

The precedence for an outright ban on electronic cigarettes has already been established in Western Australia. We believe that the Tasmanian Government should consider introducing legislation similar to that adopted in Western Australia.

In addition to this covering letter and the attached completed response template, we also wish to draw to the attention of the Tasmanian Government, the letter to the World Health Organisation (WHO), co-signed by 129 eminent global public health experts, including a number of Australian experts. The letter (attached) makes a number of important points. In particular, the letter states that WHO should be wary of the tobacco industry’s role moving into and driving the electronic cigarette market.

The letter states: “If the tobacco industry was committed to reducing the harm caused by tobacco use, it would announce target dates to stop manufacturing, marketing and selling its “more harmful” products rather than simply adding electronic cigarettes to its product mix and rapidly taking over the electronic cigarette market”.

This covering letter, the completed template and attached letter to the WHO, when combined form our submission from the Heart Foundation.

Sincerely

A handwritten signature in black ink, appearing to read 'Graeme Lynch', with a stylized flourish extending to the right.

Graeme Lynch
CEO, Heart Foundation

Options for a public health response to electronic cigarettes

Response Template for Discussion Paper

12 June to 24 July 2015

Response Template

Options for a public health response to electronic cigarettes discussion paper
Submissions must be received by **5pm on Friday 24 July 2015**

1. Contact Details

Name: Graeme Lynch

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Organisation: Heart Foundation

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Email: graeme.lynch@heartfoundation.org.au

2. Do you currently smoke cigarettes or use an electronic cigarette?

- Yes – I smoke cigarettes
- Yes – I use electronic cigarettes
- Yes – I smoke cigarettes and use an electronic cigarette
- No – I do not smoke cigarettes or use an electronic cigarette
- Not applicable - this submission is provided on behalf of the Heart Foundation

3. Have you previously smoked cigarettes?

- Yes
- No
- Not applicable - this submission is provided on behalf of the Heart Foundation

4. Have you ever used an electronic cigarette?

- Yes
- No – but I would be interested to try
- No – I have no interest
- Not applicable - this submission is provided on behalf of the Heart Foundation

Options to prevent uptake

NON-REGULATION

Option 1.1: Continue with the status quo

- a) Do you support maintaining the current arrangements governing the promotion and sale of electronic cigarettes in Tasmania?

Yes No Don't know

- b) What do you see as the benefits of maintaining the current arrangements?

There are no benefits - only potential hazards, of maintaining the current arrangements.

The promotion and sale of electronic cigarettes should be banned in Tasmania, unless the product has been approved by the Therapeutic Goods Association (TGA).

- c) What do you see as the costs of maintaining the current arrangements?

Until further evidence comes to hand regarding the potential deleterious health effects caused by electronic cigarettes, it is not possible to determine the costs for treating these health effects that may result from the use of electronic cigarettes.

Option 1.2: Public education

a) Do you support public education activities to inform the community about the potential health and safety risks associated with using nicotine-free electronic cigarettes?

Yes No Don't know Please see comment below

b) Do you think community education and awareness raising activities would be sufficient to prevent electronic cigarette uptake by non-smokers, ex-smokers and young people?

Yes – in isolation of other measures to restrict the sale and promotion of electronic cigarettes

Yes – with other regulatory options such as restrictions on the sale and promotion of electronic cigarettes

No – education is not effective

Don't know

Please see comment below

Comments:

As stated previously, **the promotion and sale of electronic cigarettes should be banned in Tasmania, unless the product has been approved 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. In the event that electronic cigarettes are not banned in Tasmania, then an ongoing public education program to inform the community about the potential health and safety risks associated with using electronic cigarettes would be required. IN ADDITION to the education campaign (as an education campaign on it's own is not sufficient), other regulatory options would be required, as is in place for tobacco, to restrict the promotion and sale of electronic cigarettes, and ensuring they are not used in smoke-free areas.

PART-REGULATION

Option 1.3: Restrictions on sale and advertising

- a) Do you support the introduction of restrictions on the sale and promotion of electronic cigarettes in Tasmania?

Yes No Don't know

- b) What do you see as the benefits of this?

The Heart Foundation supports **full** restriction - i.e. **banning the promotion and sale of electronic cigarettes in Tasmania, unless the product has been approved by the TGA**. The long-term health consequences of inhaling the chemicals in electronic cigarettes are unknown. Such products should only be made available for smoking cessation purposes if proven safe and effective for that purpose. If a total ban is not enacted, the same restrictions would need to be imposed on the promotion and sale of electronic cigarettes as currently exist for tobacco.

- c) What do you see as the costs of this?

This is unknown - however a precedent of banning the promotion and sale of electronic cigarettes has been established in Western Australia.

- d) What do you see as the risks or implementation issues that could be associated with this?

It would be easier to implement a total ban on electronic cigarettes than to perpetuate the difficulties in enforcing similar restrictions as they exist for tobacco products. However, if a total ban is not enacted, the same restrictions would need to be imposed on electronic cigarettes as currently exists for tobacco.

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

- a) Do you support extending existing restrictions on the sale of tobacco to children to include electronic cigarettes?

Yes No Don't know

- b) What do you see as the benefits of this?

As stated previously, the Heart Foundation supports **full** restriction - i.e. **banning the promotion and sale of electronic cigarettes in Tasmania**, unless the product has been approved by the TGA. If a total ban is not enacted, the existing restrictions on the sale of tobacco to children would need to be imposed on the sale of electronic cigarettes.

We need to ensure that we protect our children, so that electronic cigarettes do not re-normalise smoking behaviour and re-glamorise the act of smoking more broadly. See comments regarding the health of young people in the covering letter.

- c) What do you see as the costs of this?

It would be easier to implement a total ban on electronic cigarettes than to perpetuate the difficulties in enforcing similar restrictions as they exist for tobacco products. If a total ban is not enacted, and that electronic cigarettes become restricted for sale only to those 18+, presumably the cost will be the same as enforcing the current restrictions for tobacco sales.

- d) What do you see as the risks or implementation issues that could be associated with this?

It would be easier to implement a total ban on electronic cigarettes than to perpetuate the difficulties in enforcing similar restrictions as they exist for tobacco products. However, if a total ban is not enacted, the same restrictions would need to be imposed on electronic cigarettes as currently exists for tobacco, presumably with no additional risk or implementation issues.

FULL-REGULATION

Option I.6 Regulate electronic cigarettes and tobacco in the same way

a) Do you support electronic cigarettes being fully regulated in the same way as tobacco?

Yes No Don't know Please see comments at b)

b) What do you see as the benefits of full-regulation?

As stated previously, the Heart Foundation supports full restriction - i.e. **banning the promotion and sale of electronic cigarettes in Tasmania, unless the product has been approved by the TGA.** If a full ban is not implemented there should be a minimum requirement to regulate electronic cigarettes and tobacco in the same way.

c) What do you see as the costs of full-regulation?

The only foreseeable costs are to those businesses who are currently selling these products who may have current stock that they are no longer able to sell after a full ban is implemented, or the sale is restricted in a similar way to tobacco.

d) What do you see as the risks or implementation issues of full-regulation?

It would be easier to implement a total ban on electronic cigarettes than to perpetuate the difficulties in enforcing similar restrictions as they exist for tobacco products. However, if a total ban is not enacted, the same restrictions would need to be imposed on electronic cigarettes as currently exists for tobacco, presumably with no additional risk or implementation issues.

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

Option 2.1: Continue with the status quo

a) Do you support permitting electronic cigarette use in smoke free areas?

Yes No Don't know

b) What do you see as the benefits of permitting electronic cigarette use in smoke free areas?

The Heart Foundation supports **full** restriction - i.e. **banning the promotion and sale of electronic cigarettes in Tasmania, unless the product has been approved by the TGA**. If banned, they would not be available for use.

However, if not banned, and to protect others from second hand vapour from electronic cigarettes purchased outside of Tasmania, their use should be prohibited in smoke free areas. There are no benefits of permitting electronic cigarette use in smoke free areas.

c) What do you see as the costs?

Minimal costs in signage and education to businesses and the public that you cannot use electronic cigarettes in smoke free areas.

d) What do you see as the risks or implementation issues of permitting electronic cigarette use in smoke free areas?

There is limited research into whether electronic cigarette use impairs indoor air quality or causes passive exposure and negative health impacts in non-users. Researchers warn that pollutants from electronic cigarettes could be of health concern to both users and those exposed second-hand. These issues require further research¹.

Public use could renormalise smoking, particularly among young people. Electronic cigarette manufacturers are actively promoting the use of their products in smoke free areas, potentially accelerating the renormalisation of smoking behaviour².

¹Schripp T, Markewitz D, Uhde E, Salthammer T

²Benowitz N, Goniewicz M

Option 2.2: Prohibit use in existing smoke free public places

a) Do you support prohibiting electronic cigarette use in existing smoke free areas?

Yes No Don't know

b) What do you see as the benefits of prohibiting electronic cigarette use in smoke free areas?

The Heart Foundation supports **full** restriction - i.e. **banning the promotion and sale of electronic cigarettes in Tasmania, unless the product has been approved by the TGA**. If banned, they would not be available for use.

However, if not banned (and also to protect others from the potential harms of second hand vapour from electronic cigarettes purchased outside of Tasmania) and to not renormalise the act of using cigarettes whether tobacco or electronic, their use should be prohibited in smoke free areas.

c) What do you see as the costs?

Minimal costs in signage and education to businesses and the public that you cannot use electronic cigarettes in smoke free areas.

d) What do you see as the likely risks or implementation issues?

Nil known.

e) Do you believe electronic cigarette use should not be permitted in all smoke free areas or only some?

- All smoke free areas
- Some smoke free areas
- No smoke free areas
- Don't know

If some, in which areas do you believe the use of electronic cigarettes should be permitted and why?

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.....
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.....

Do you have any other comments?

Further comments can be found in the covering letter that accompanies this submission.

All submissions will be published on the DHHS website at www.dhhs.tas.gov.au/publichealth/tobacco_control/electronic-cigarettes unless clearly marked as confidential.

Anonymous submissions will not be accepted.

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

Thank you for your participation in this consultation

June 16, 2014 (updated)

Dr. Margaret Chan
Director General
World Health Organization
Geneva

Dear Dr. Chan,

We, the 129 signatories to this letter, are writing to express our support for WHO's evidence-based approach to determine the best way forward for public health to respond to Electronic Nicotine Delivery Systems (ENDS), as expressed in WHO's June 3, 2014 statement.¹

Recently, media attention was focused on a statement by a group of "specialists in nicotine science and public health policy."² Unfortunately, the statement makes several assertions about ENDS' marketing, emissions, harms, and use that are either contradicted by available evidence or for which no evidence is currently available. (Indeed, the statement does not cite a single scientific study.)

The statement also included several policy recommendations, including effectively exempting ENDS from FCTC Articles 8 and 13 and ignoring Article 5.3.

It is fundamental that WHO and other public health authorities not buy into the tobacco industry's well-documented strategy of presenting itself as a "partner."³ If the tobacco industry was committed to reducing the harm caused by tobacco use, it would announce target dates to stop manufacturing, marketing and selling its "more harmful" products rather than simply adding e-cigarettes to its product mix and rapidly taking over the e-cigarette market.⁴⁻⁵ It would also immediately desist from its aggressive opposition to tobacco control policies such as tax increases, graphic health warnings and plain packaging.

By moving into the e-cigarette market, the tobacco industry is only maintaining its predatory practices and increasing profits. As stated in the guidelines for Article 5.3 of the WHO FCTC, there is a "fundamental and irreconcilable conflict of interest" between the tobacco industry's interests and public health's interests."⁶

Public health embraced cigarette filters and "low tar" cigarettes as harm reduction strategies before manufacturers provided evidence and at a time when the manufacturers were well aware that these technologies did not actually reduce harm but were designed to promote cigarette sales by reassuring a concerned public that the new products were safer.⁷⁻⁸ The negative consequences of these acts remain in cancer and heart disease hospital wards throughout the world. Ignoring the link between ENDS and the tobacco industry is overlooking

the WHO FCTC Parties' legal obligation to protect government policies against tobacco industry interference.

The aggressive marketing and promotion of e-cigarettes to youth is well-documented⁹⁻¹⁰⁻¹¹⁻¹² and evidence from the US¹³⁻¹⁴ and Korea¹⁵ shows rapid growth in youth e-cigarette use, including disturbing rates among youth who have never smoked a cigarette. One e-cigarette manufacturer warns parents that "kids may be particularly vulnerable" to the flavoring in its products.¹⁶

Manufacturers of ENDS are making a range of false and unproven claims,¹⁷⁻¹⁸⁻¹⁹ misleading the public into thinking these products are harmless (they are not) and effective cessation aids (unknown). Most ENDS users are "dual users" who continue to smoke cigarettes.²⁰ Reviews of evidence about reducing smoking (instead of quitting) show that dual users are unlikely to see any health benefit in terms of cardiovascular disease.²¹⁻²² Population studies of all smokers consistently show that smokers who use ENDS are *less* likely to stop smoking.²³⁻²⁴⁻²⁵⁻²⁶⁻²⁷⁻²⁸

The evidence is insufficient to accept the assertions that ENDS are effective as a smoking cessation device. There is a single randomized controlled trial of early generation e-cigarettes that found no difference between ENDS delivered directly to experimental subjects compared with mailing subjects a voucher that they could take to a pharmacy to obtain nicotine replacement therapy.²⁹ One population-based cross-sectional study found that highly motivated smokers using ENDS to quit were less likely to be still smoking than smokers making unassisted quit attempts with over-the-counter NRT.³⁰ However, this cross-sectional study³¹ showed a point prevalence of 80% of smokers using ENDS in a cessation attempt having failed, compared to 84.6% of those who tried to quit unassisted. Significantly, the former study is biased against conventional therapy (because of the additional barrier to getting the NRT) and the latter did not report a comparison with well-supervised approved cessation therapies.

There is already good evidence that ENDS emissions release several toxic substances into the environment that cause harm to health. These substances include ultrafine particles, propylene glycol, tobacco-specific nitrosamines; nicotine; volatile organic compounds (VOCs), and carcinogens and reproductive toxins, including benzene, lead, nickel, and others.³²⁻³³⁻³⁴⁻³⁵⁻³⁶⁻³⁷⁻³⁸⁻³⁹⁻⁴⁰ Proposals to allow ENDS use in indoor spaces like workplaces, bars and transportation could see significant exposure to these substances.

It is important to note that nicotine itself is not harmless, which is why strict regulatory measures are in place to control the marketing of Nicotine Replacement Therapy for smoking cessation. The 2014 U.S. Surgeon General Report includes an extensive review of acute and long-term effects of nicotine exposure. It concludes, among other things, that nicotine exposure has adverse effects on fetal growth and development, including fetal brain development.⁴¹ The manufacturer of one electronic cigarette in the U.S. acknowledges in its product labeling that nicotine is not harmless.⁴² Acute poisoning from nicotine is well established, and there has been an increase in documented cases of children being accidentally poisoned by ingesting the liquid content of ENDS cartridges.⁴³

Remaining unregulated, risk profiles and potential harms these products may pose to the public are unknown. The absence of detailed evidence on adverse health effects is not evidence that no effect exists. Rather, insufficient time has elapsed to determine what effects exist and their magnitude on a population level.

Manufacturers have not secured regulatory approval for claims that ENDS are effective products for smoking cessation or harm reduction from regulatory authorities in any country. From a population perspective, it is important to know what new risks a consumer product may introduce in the market.

We applaud WHO's commitment to listen to the experience from Member States that have successfully implemented tobacco control and regulated sales, marketing and use of ENDS. Implementation of the WHO FCTC by its 178 parties demonstrates great progress in decreasing the harm caused by tobacco use and decreasing the burden from NCDs.

There is evidence of success from many countries, including Australia, Brazil and Turkey. The former prohibits import and sales of cartridges containing nicotine, the latter two banned import, sales and marketing of e-cigarettes until, and unless, manufacturers present safety information.

Both scientific evidence and best practices are available to support a regulatory framework that will best prevent initiation of use among youth and other non-tobacco users, protect bystanders in public areas from involuntary exposure, regulate marketing, and prohibit unsubstantiated claims.

Such a regulatory framework would require manufacturers to present safety and efficacy data. In this case, the use of these products as cessation aids (if the evidence supports such use) would operate under the supervision of a health authority that could control manufacturers' claims, impose health warnings about risks, require disclosure of ingredients and safety data and regulate product engineering as well as mandate surveillance.

This is the path that the WHO has been pursuing and encouraging. We urge you to continue doing so.

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