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Submission to Drug and Alcohol SA

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A public health response to proposed amendments to the *Tobacco Products Regulation Act 1997* to regulate e-cigarettes in South Australia

The *Heart Foundation SA*, *Asthma Foundation SA* and *Australian Medical Association (SA)* have formed an alliance (SA Health Alliance) to prepare this submission on the availability, promotion and use of e-cigarettes and to restate our position for regulation.

The SA Health Alliance welcome the opportunity to respond to proposed amendments to the *Tobacco Products Regulation Act 1997* to regulate e-cigarettes in South Australia.

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 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.**

We support a ban on the sale of e-cigarettes for all ages. Not limited to minors. The SA Health Alliance is satisfied that there is insufficient evidence to recommend e-cigarettes as a cessation advice. We need to be cautious in regard to the health risks of passive exposure and the potential adverse effects on pregnancy.

The body of evidence supporting the damaging health effects of e-cigarettes is growing, and early observations show cardiovascular risk increased, respiratory disease progression, safety issues with nicotine poisoning, and worryingly, a number of thermal injuries associated with e-cigarettes in young adults who sustained mixed partial and full thickness thermal burn injuries as a result of e-cigarette-related explosions.

This is the opportunity to ban their use. We do not need to wait for long term studies to take action.

The precautionary principle in public health should be adopted in respect to e-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.”ⁱ

Evidence: Potential harm from vapour emissions and poisoning

Nicotine containing products

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.ⁱⁱ There are also potential implications for immune response.

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

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

E-cigarette use

While it is widely acknowledged that e-cigarettes are likely to be less dangerous than tobacco products, the health effects of their use remain unknown.^{vi} Products inhaled directly to the lung are normally only approved after extensive safety and efficacy evaluation due to the serious issues that can potentially arise with this form of substance delivery.^{vii} A formal approval process also ensures that consumers are provided with specific guidance on safe and appropriate use. E-cigarettes currently on the market in Australia have not gone through these kinds of assessment processes.

Many e-cigarette products differ in contents and manufacturing processes, so studies on individual varieties cannot be generalised across products. The World Health Organization (WHO) and other researchers are concerned about the safety of the chemical combinations used across the variety of products available. These chemical combinations have not been evaluated for either short-term or long-term safety; and manufacturers have not fully disclosed the chemicals used. Recent research gives rise to concerns that e-cigarettes may cause or worsen acute respiratory diseases among youth. The study found that up to 40 per cent of particles emitted by an e-cigarette can deposit in the deepest areas of youth's lungs, and that chemicals contained in these particles may irritate airways or worsen pre-existing respiratory conditions such as asthma and bronchitis.^{viii}

Early observations show oxidative stress in e-cigarette users that further substantiates cardiovascular injury owing to e-cigarette use.^{ix} These findings are in agreement with the results of a study by Carnevale *et al*^x showing that smoking e-cigarettes decreases the bioavailability of nitric oxide and the levels of the antioxidant vitamin E while at the same time increasing the levels of the oxidant-generating enzyme nicotinamide adenine dinucleotide phosphate oxidase as well as the levels of 8-iso-prostaglandin F2 α , an indicator of lipid peroxidation.

E-cigarettes are not a safe alternative

In addition, testing conducted by New South Wales Health found 70% of e-liquids sampled contained high levels of nicotine despite the fact that the retail sale of e-cigarettes containing nicotine is currently unlawful.^{xi} Consumers, and worryingly young consumers, of these products are unwittingly being exposed to nicotine, and potential addiction, as well as normalising smoking once again. Research also demonstrates that a number of products are unlikely to meet basic consumer product safety standards.^{xii}

Given the tobacco industry's history of deceptively promoting "safer" tobacco products, it is important to note that a number of major tobacco companies have

recently entered the global e-cigarette market. Both nicotine and non-nicotine e-cigarette products are often promoted to be "safer" than tobacco products as well as fun recreational products that can be used 'anywhere'. This is the case, even though the products have not passed through the kinds of formal safety assessment processes that are normally undertaken with lung delivery products.

In light of these issues, non-nicotine e-cigarettes should be treated in a similar way to nicotine e-cigarettes and banned from retail sale unless their use has been approved by the Therapeutic Goods Administration (TGA). At the same time, government regulators should be cautious of the possibility that tobacco industry engagement in the e-cigarette market is part of a broader attempt to re-normalise its community standing so that it can re-establish engagement with policy makers, researchers and other public health stakeholders.^{xiii} Care must be taken so that tobacco industry engagement in the e-cigarette market in Australia, including under a medicines framework, does not allow the tobacco industry to re-enter the policy space and consumer market in a way that offends Article 5.3 of the WHO Framework Convention on Tobacco Control, which aims to protect public health from the commercial and other vested interests of the tobacco industry.

Time for Action

South Australia has the opportunity to demonstrate strong leadership and foresight, and demonstrate nationally and globally that e-cigarettes are a public health threat, and that the health of our community is a priority for our state. Now is the time to act.

We acknowledge that DASSA have addressed our calls to action around use of e-cigarettes in smoke-free areas, and marketing and promotion. However, this does not go far enough.

To access the Cancer Council of Australia and National Heart Foundation of Australia's full position statement on e-cigarettes, with evidence and references, please go to: [\[http://wiki.cancer.org.au/policy/Position_statement_-_Electronic_cigarettes\]](http://wiki.cancer.org.au/policy/Position_statement_-_Electronic_cigarettes)

We look forward to further discussions on this important issue.

Yours sincerely

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- ⁱ Commission of the European Communities, Communication from the Commission on the precautionary principle. Brussels, 2000 (COM(2000) 1).
- ⁱⁱ Grando, Connections of nicotine to cancer. *Nature Reviews*. 2014
- ⁱⁱⁱ AMA, E-Cigarette Statement <https://ama.com.au/article/e-cigarette-statement>
- ^{iv} AMA, Position Statement on Tobacco Smoking (20015) <https://ama.com.au/position-statement/tobacco-smoking-2005>
- ^v National poison information service. <http://www.npis.org/>
- ^{vi} Benowitz NL, Goniewicz ML. *The regulatory challenge of electronic cigarettes*. *JAMA* 2013 Aug 21;310(7):685-6 [Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/23856948>].
- ^{vii} World Health Organization Study Group on Tobacco Product Regulation. *Report on the scientific basis of tobacco product regulation: third report of a WHO study group*. Geneva, Switzerland: WHO; 2009. Report No.: WHO Technical Report Series 955
- ^{viii} RTI International. *Electronic cigarettes may cause, worsen respiratory diseases, among youth, study finds*. New York, NY: RTI International; 2014 Apr 29 Available from: <http://www.rti.org/newsroom/news.cfm?obj=C6EFA34B-0757-4185-CE29DB92E8231C67>
- ^{ix} Bhatnagar A, Are Electronic Cigarette Users at Increased Risk for Cardiovascular Disease? *JAMA Cardiol* 2017
- ^x Carnevale, R et al. Acute Impact of Tobacco vs Electronic Cigarette Smoking on Oxidative Stress and Vascular Function. 2016
- ^{xi} New South Wales Department of Health. *NSW Health Alert - Warning on e-liquids*. Sydney: NSW Government; 2013.
- ^{xii} Trtchounian A, Talbot P. *Electronic nicotine delivery systems: is there a need for regulation?* *Tob Control* 2011 Jan;20(1):47-52
- ^{xiii} Peeters S, Gilmore AB. *Understanding the emergence of the tobacco industry's use of the term tobacco harm reduction in order to inform public health policy*. *Tob Control* 2014