



Australian Government

Department of Health

Policy and regulatory approach to electronic cigarettes (e-cigarettes) in Australia

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Principles that underpin the current policy and regulatory approach:

Protecting the health of children and young people

The evidence is clear that e-cigarettes in Australia are increasingly marketed to appeal to children and young Australians.

The widespread marketing and use of e-cigarettes cause harms to the health of children and young people, including:

- e-cigarettes can provide a gateway/pathway to a lifetime of nicotine addiction and dependency;
- e-cigarettes can lead to an increased uptake of smoking among young people;
- e-cigarettes cause direct harms to users from inhalation of a range of chemicals;
- e-cigarettes also provide health risks to bystanders from exposure to exhaled aerosol from e-cigarette users; and
- the liquid nicotine in e-cigarettes is a poison and children and adults can be harmed by swallowing, breathing or absorbing e-cigarette liquid.

Australia's successful approach to tobacco control over many decades has seen substantial declines in tobacco use among young Australians, with current tobacco use among secondary school students aged 12-15 declining from 17% in 1996 to 3% in 2017. E-cigarettes expose a new generation of young Australians to an unacceptable risk to their current and future health.

Any change to regulation of e-cigarettes in Australia will have protecting children and young people as its primary focus and goal.

Protecting the health of current adult cigarette smokers

E-cigarettes have been marketed by the e-cigarette and tobacco industries to existing smokers as both a smoking cessation tool and as a less harmful alternative to cigarettes and tobacco smoking.

This marketing has been effective as surveys of adult cigarette smokers indicate quitting or reducing smoking as reasons for using e-cigarettes. However, at the population level there is no strong evidence that e-cigarettes assist smoking cessation and some evidence suggests the opposite effect: that overall they may be depressing smoking cessation.

E-cigarettes pose a range of harms to human health. Many e-cigarettes contain nicotine at higher concentrations than in cigarettes so may contribute to increasing rather than decreasing nicotine dependence. No studies have yet demonstrated the safety of e-cigarettes or efficacy of e-cigarettes as an effective smoking cessation tool at a population level. Governments continue to support a range of measures and services to help people quit smoking.

Any change to regulation of e-cigarettes in Australia will place protecting the health of existing adult cigarette smokers as its second key goal.

Evidence-based

The current evidence base supports maintaining and, where appropriate, strengthening the current controls that apply to the marketing and use of e-cigarettes in Australia.

Decisions should take into account the conclusions reached by credible health and scientific agencies in relation to the interpretation and advice about that evidence, including for example the WHO, the NHMRC and the US Surgeon General.¹

A notable example is the Therapeutic Goods Administration's (TGA's) scheduling legislation and underlying decision making processes which are informed by relevant evidence and provide a robust mechanism to balance potential risks and benefits of substances such as nicotine for use in e-cigarettes.

The [TGA's consideration and final decision](#) on an application to allow nicotine for use in e-cigarettes to be commercially sold in Australia during 2016 and early 2017, provides a valuable analysis to guide action (Scheduling delegate's final decisions, March 2017).

Health claims for e-cigarettes, such as that they are effective smoking cessation aids or safe alternatives to conventional tobacco products, should be rejected by health authorities in the absence of robust supporting scientific evidence to substantiate these claims.

Relevant to Australia's national circumstances

The appropriate policy and regulatory response to e-cigarettes should take into account Australia's national circumstances, including in the context of the existing approaches taken by the Australian and state and territory governments to reduce tobacco smoking prevalence and its associated harms and costs. Australia's favourable progress in tobacco control to date is also an important factor.

Current and future approaches taken by other countries to e-cigarettes are relevant to the formulation of potential national policy and regulatory responses to these products. At present, there is no international consensus on the most appropriate policy response or regulatory framework for e-cigarettes. Current and planned regulatory approaches vary considerably and across countries, ranging from treatment as tobacco products, poisons, medicines (including medical devices), and consumer products. Additionally, in some countries, the sale of e-cigarettes is prohibited, while in many developing countries, it is likely that minimal or no regulatory controls apply.

¹ In November 2016, the seventh session of the Conference of the Parties to the WHO Framework Convention on Tobacco Control (WHO FCTC) invited Parties to consider applying regulatory measures to 'prohibit or restrict the manufacture, importation, distribution, presentation, sale and use of ENDS/ENNDS, as appropriate to their national laws and public health objectives'. Read the statement about [Electronic nicotine delivery systems and electronic non-nicotine delivery systems](#) on WHO's website.

Precautionary approach

This acknowledges the potential risks associated with the marketing and use of e-cigarettes.

The precautionary approach encourages action to prevent harm when there is scientific uncertainty and until a body of evidence establishes the requirement for alternative regulation. This includes the lack of conclusive evidence around the safety risks posed to users by the unknown inhalation toxicity of nicotine and other chemicals used with e-cigarettes, passive exposure to e-cigarette vapour, risks associated with child poisoning, and issues around quality control and efficacy.

The precautionary approach also takes into account the broader risks that e-cigarettes may pose to population health, namely their potential to disrupt the decline in tobacco use in Australia.

Protecting public health gains

While there have been significant gains made in reducing smoking rates and reducing exposure to tobacco smoke and smoking culture in Australia, an increase in e-cigarette marketing and use may undermine tobacco control success by establishing new cohorts with nicotine dependence, renormalising smoking, encouraging dual use of tobacco and e-cigarettes, and discouraging quitting.

Policy and regulatory decisions on e-cigarettes should aim to minimise the proliferation of e-cigarette marketing and use, particularly among young people while maximising the impact of effective tobacco control measures.

Policy and regulation for e-cigarettes should aim to protect public health gains in relation to smoking prevalence as well as smoke-free culture, including smoke-free areas and other measures that have contributed to the continued denormalisation of smoking in Australia.

Protecting public health policy from all commercial and other vested interests related to e-cigarettes, including interests of the tobacco industry

This acknowledges Australia's obligations under [Article 5.3 of the WHO Framework Convention on Tobacco Control \(FCTC\)](#), to which Australia is a party. Under Article 5.3 of the WHO FCTC, parties are obliged to act to protect their public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry, in accordance with national law.

Legal clarity to the public

Information from a range of sources highlights that there may be some confusion to users, retailers, employers and the general public about the legality of e-cigarettes and/or nicotine, especially in terms of the regulations that apply to their importation, marketing (including sale) and use.

It is important that Governments provide clarity to the public about their legal obligations in relation to these products.

The commercial supply of nicotine for use in e-cigarettes is prohibited under all state and territory poisons legislation.

Complementary with jurisdictional regulation and existing health and social policy frameworks

National policy and regulation of e-cigarettes and nicotine should aim to complement jurisdictional legislation, to the greatest degree possible.

It is also important that any action taken at a national or jurisdictional level for e-cigarettes and nicotine supports existing health and social policy frameworks. These include but are not limited to the [WHO FCTC](#) (and also including recent decisions of the Conference of the Parties to the WHO FCTC as noted above) the [National Drug Strategy 2017–2026](#), the [National Tobacco Strategy 2012-2018](#) and the [Scheduling Policy Framework](#).

Note: This document supersedes the previous version endorsed by the Ministerial Drug and Alcohol Forum in 2017.

Evidence statement to accompany the national guiding principles for e-cigarettes

Updated to 11 November 2019

Summary

There is growing evidence linking the marketing and use of e-cigarettes to nicotine addiction, tobacco use and a range of other public health harms.

Recent developments suggest that Australia's existing regulatory controls that govern the marketing and use of e-cigarettes may not be providing adequate protection to the Australian community, particularly children and youth.

E-cigarette use among children and youth leading to nicotine addiction and smoking initiation

In the United States (U.S.), the largest e-cigarette market globally, rates of current² e-cigarette use among U.S high school students have surged to 27.5% in 2019, up from 20.8% in 2018 and 11.7% in 2017.⁽¹⁾ Rates of e-cigarette use among youth have also increased in other countries in recent years although there is variation across different markets and cohorts.^(2, 3, 4)

Most e-cigarettes marketed globally contain nicotine⁽⁵⁾, and there is evidence that children and youth who are exposed to nicotine can become addicted at lower or more intermittent levels of consumption compared to adults.⁽⁶⁾ Nicotine is highly addictive and exposure during adolescence can have damaging effects on brain development.⁽⁷⁾

Unlike countries with more established markets for e-cigarettes, the commercial supply of nicotine is prohibited in Australia under state and territory poisons legislation. However, testing conducted by the New South Wales Ministry of Health in the course of compliance activity since late 2015 found that of 929 samples of e-liquids tested, 567 (61%) contained nicotine.³ The samples tested were a mix of those labelled as containing nicotine and those labelled as containing no nicotine; 54% of the positive samples returned a nicotine concentration greater than or equal to 2,500 mg/L.

In addition to the public health harms specific to nicotine, the evidence is also consistent in suggesting that use of e-cigarettes by non-smoking youth predicts future smoking.⁽⁸⁾

E-cigarette advertising and promotion

The e-cigarette industry in Australia continues to employ a wide range of strategies and channels to advertise and promote e-cigarettes, often using the same themes and tactics that have been shown to increase youth initiation of tobacco products.⁽⁵⁾ For example, the wide range of e-cigarette flavours are a key reason youth report for using e-cigarettes. Children and youth have also reported using e-cigarettes out of curiosity, and based on an unproven belief that they are relatively harmless compared to tobacco products.

² 'Current' refers to e-cigarette use once or more in the preceding 30 days of being surveyed.

³ Note: Sampling was not conducted randomly, but undertaken if a NSW Health inspector suspected the presence of nicotine in the e-liquid.

Poisoning from e-cigarette liquids (including nicotine)

The number of calls to Australian Poisons Information Centres regarding exposure of children and adults to e-cigarettes and their refills, rose from less than 5 in 2012 to approximately 70 in 2016.⁽⁹⁾

Children and adults have been poisoned by swallowing, breathing or absorbing e-cigarette liquid through their skin or eyes and in 2018, a young child in Victoria died from poisoning after consuming an e-liquid containing nicotine.⁽¹⁰⁾

Outbreak of lung disease following e-cigarette exposures in the United States⁽¹¹⁾

On 13 September 2019, the Commonwealth Government Chief Medical Officer and state and territory Chief Health Officers issued a joint statement on e-cigarettes following emerging evidence linking their use to lung disease. The joint statement follows the publication of updated guidance issued by the United States Centres for Disease Control and Prevention (CDC) regarding a '*...multistate outbreak of lung disease associated with e-cigarette product use.*' As of 5 November 2019, 2,051 cases of lung injury and 39 deaths associated with e-cigarette use have been reported to the CDC:

- Of the 1,379 cases of lung injury with data on age, the median age of patients is 24 years (age range 13 to 75 years), with 14% of patients aged under 18 years, 40% of patients aged 18-24 years and 79% of patients under 35 years.
- Of the 39 confirmed deaths, the median age of patients was 53 years (age range 17 to 75 years).

The CDC has also indicated that:

- Although most patients have reported a history of using e-cigarettes containing tetrahydrocannabinol (THC), the only commonality among all cases is that patients report the use of e-cigarettes.
- Since the specific compound or ingredient causing lung injury are not yet known, the only way to assure that users are not at risk while the investigation continues is to refrain from use of all e-cigarettes. It may be that there is more than one cause of this outbreak.
- All types of e-cigarettes carry a risk.

To date, the majority of case reports of lung disease following e-cigarette exposures have been reported in the U.S, and no case reports following e-cigarette exposures have been identified in Australia. However, as similar case reports have been identified in countries outside of the U.S.^(12,13), the possibility of similar case reports in Australia in future cannot be ruled out at this time.

Additional health risks associated with e-cigarette exposure and use

Aside from the case reports of lung disease following e-cigarette exposures that have been predominantly reported in the U.S. to date, other evidence from observational and experimental studies has implicated the use of e-cigarettes in a range of harms to the heart and lungs.^(14,15)

Aside from nicotine, the e-cigarette aerosol that users inhale from the device and exhale can contain a range of harmful and potentially harmful substances. These include but may not be limited to: ultrafine particles, flavourings, volatile organic compounds, cancer-causing chemicals, heavy metals, propylene glycol, vegetable glycerin and tetrahydrocannabinols (THC) and vitamin E acetate.⁽⁵⁾

E-cigarettes also provide health risks to bystanders from exposure to exhaled aerosol from e-cigarette users. A recent systematic review of the health risks from second-hand e-cigarette aerosol concluded

that “*the absolute impact from passive exposure to electronic cigarette vapour has the potential to lead to adverse health effects*”.⁽¹⁶⁾

E-cigarettes for smoking cessation and harm reduction

The use of e-cigarettes to quit smoking is a common reason for their reported use among adults.⁽¹⁷⁾ However, at a population level, there continues to be insufficient evidence to promote the use of e-cigarettes for smoking cessation.⁽¹⁸⁾

E-cigarettes may also be used based on a belief that they are much less harmful than conventional tobacco products. However, as no long term vaping safety studies have been done in humans, these claims are not based on credible evidence.⁽¹⁵⁾

There is evidence that concurrent (dual) use of e-cigarettes and conventional tobacco products is common.⁽⁸⁾ This is problematic as in addition to any independent health risks introduced by e-cigarettes, even light smoking still poses serious health risks.⁽¹⁹⁾

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