

Position statement - Electronic cigarettes



Overview

Research relevant to the potential impacts of electronic cigarettes on public health is continuing to evolve, including in areas such as safety of the product, cessation efficacy and trends in awareness and use. Cancer Council Australia and the Heart Foundation of Australia recommend that, based on past experience in tobacco control and early research on electronic cigarettes, there is sufficient information to act on three particular regulatory gaps in order to prevent uptake and use of electronic cigarettes by young people and other risks to public health. Areas in need of priority attention for this purpose include the proper regulation of: (a) non-nicotine electronic cigarettes; (b) use in smoke-free environments; and (c) advertising.

On 26 August 2014, the World Health Organisation released a report^[1] that makes a number of recommendations to governments worldwide, which are consistent with our position^[2].

Cancer Council Australia and the Heart Foundation of Australia will continue to monitor research on electronic cigarettes and will provide updated recommendations on other aspects of electronic cigarettes accordingly.

Key health concerns

The limited evidence available points to a risk that widespread electronic cigarette use could undo the decades of public policy work in Australia that has reduced the appeal of cigarette use in children. Already there are anecdotal reports of electronic cigarettes being confiscated in Australian schools.

The short and long term health effects of electronic cigarette use remain unknown. Products currently on the market in Australia have not been approved by the Therapeutic Goods Administration for safety, quality and efficacy, even though the products deliver substances to the lung. This is unfair and a significant risk to consumers, who may be under the false impression that electronic cigarettes available for sale have been proven safe to use.

Cancer Council and the Heart Foundation are also concerned about unsubstantiated claims that electronic cigarettes can assist smokers in quitting. The appropriate avenue for such claims is the Therapeutic Goods Administration, an agency that could independently analyse the evidence and ensure electronic cigarettes, if shown to be safe and effective, were manufactured and marketed according to strict therapeutic controls. While there are anecdotal claims of electronic cigarettes as an aid to quitting, there are also reports of users increasing their nicotine addiction, of dual use (electronic cigarettes and smoked tobacco) and of electronic cigarettes as a pathway for tobacco and nicotine addiction.

Major tobacco companies are investing heavily in electronic cigarettes as a product line and are deploying sophisticated marketing strategies mirroring those previously used to glamorise and promote smoking to young people. This marketing trend could normalise the use of an unproven product and, given electronic cigarettes are designed to simulate the act of smoking, risks re-normalising and re-glamorising the act of smoking more broadly.

The sale and possession or use of electronic cigarettes containing nicotine is unlawful in all Australian jurisdictions under poison control legislation. However, smoke-free laws do not apply to electronic cigarettes. They can therefore be readily used where smoking tobacco is prohibited - behaviour which could enhance their appeal to young people. Also of great concern is the fact that there are virtually no restrictions on electronic cigarettes without nicotine, which are clearly promoted to young people with their fruit, confectionery and energy drink flavours as well as varieties mimicking smoked tobacco.

Given the serious risks, Cancer Council and the National Heart Foundation are advising extreme caution on electronic cigarettes. As outlined in this document, there is a case for tighter controls on electronic cigarette use to help ensure young people are protected from the erosion of Australia's world-leading efforts in tobacco control.

Cancer Council Australia and the National Heart Foundation of Australia recommend the following public policy measures be considered to assist in protecting young Australians from the potential harms of widespread electronic cigarette use:

1. **Ban the retail sale of non-nicotine electronic cigarettes (unless the product has been approved by the TGA).** It is currently unlawful to sell electronic cigarettes that contain nicotine in any form. This is because nicotine is a scheduled poison and can only be lawfully sold in the form of legal tobacco products (a historical anomaly) and approved nicotine replacement products. This position could change in the future for individual nicotine electronic cigarette products that receive approval from the TGA. Similar restrictions should also apply to non-nicotine electronic cigarettes, which come in a variety of fruit, confectionery and other flavours that appeal to children. Laws in South Australia, Western Australia and Queensland prohibit the sale of products that resemble tobacco products. There are no such laws in other states and territories, meaning that non-nicotine electronic cigarettes (when marketed without therapeutic claims) can be lawfully sold, including to young people.
2. **Ensuring smoke-free laws in each state and territory cover electronic cigarette use.** The purchase, possession or use of electronic cigarettes containing nicotine is currently unlawful under state and territory poisons and public health laws. However, these laws are complicated and difficult to enforce. Prohibiting use of all electronic cigarettes under smoke-free laws would make the law clear for the community and ensure that both nicotine and non-nicotine electronic cigarettes are not used in places where smoking tobacco is prohibited.
3. **Prohibiting advertising and promotion of electronic cigarettes, consistent with tobacco advertising prohibitions.** Electronic cigarettes are being aggressively promoted, with young people and children clearly identified as a target market. Electronic cigarette advertising should be subject to similar restrictions as tobacco products.

Recommendation 1 – Ban the retail sale of non-nicotine electronic cigarettes (unless the product has been approved by the TGA)

It is currently unlawful to sell electronic cigarettes that contain nicotine in any form. This is because nicotine is a scheduled poison and can only be lawfully sold in the form of legal tobacco products (a historical anomaly) and approved nicotine replacement products. This position could change in the future for individual nicotine electronic cigarette products that receive approval from the TGA. Similar restrictions should also apply to non-nicotine electronic cigarettes, which come in a variety of fruit, confectionery and other flavours that appeal to children. Laws in South Australia, Western Australia and Queensland prohibit the sale of products that resemble tobacco products. There are no such laws in other states and territories, meaning that non-nicotine electronic cigarettes (when marketed without therapeutic claims) can be lawfully sold, including to young people.

Evidence and rationale

(a) The health effects of electronic cigarette use are currently unknown and should be subject to proper evaluation

While it is widely acknowledged that electronic cigarettes are likely to be less dangerous than tobacco products, the health effects of their use remain unknown^[3]. 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^[4]. A formal approval process also ensures that consumers are provided with specific guidance on safe and appropriate use^[4]. Electronic cigarettes currently on the market in Australia have not gone through these kinds of assessment processes.

Many electronic cigarette products differ in contents and manufacturing processes, so studies on individual varieties cannot be generalised across products^{[3][4][5]}. 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^{[4][6]}. Recent research (yet to be formally published) gives rise to concerns that

electronic cigarettes may cause or worsen acute respiratory diseases among youth. The study found that up to 40 per cent of particles emitted by an electronic 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^[7].

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 electronic cigarettes containing nicotine is currently unlawful^[8]. Research also demonstrates that a number of products are unlikely to meet basic consumer product safety standards (including around design features, packaging, accuracy and clarity of labelling and quality of instruction on use)^[9].

Given the tobacco industry's history of deceptively promoting "safer" tobacco products^[10], it is important to note that a number of major tobacco companies have recently entered the global electronic cigarette market. This includes Philip Morris with the brand 'Mark10'^[11], British American Tobacco with the brand 'Vype'^[12], Lorillard with the brand 'blu eCig'^[13], Reynolds American with the brand 'Vuse'^[14], Japan Tobacco International with the brand 'Ploom'^[15], and Imperial Tobacco with the brand 'Puritane' (and the purchase of patent rights and subsequent litigation to enforce those rights against multiple product competitors)^{[16][17]}. Both nicotine and non-nicotine electronic cigarette products are often promoted to be "safer" than tobacco products as well as fun recreational products that can be used 'anywhere'^{[18][19][20]}. 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 electronic cigarettes should be treated in a similar way to nicotine electronic 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 electronic 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^[21]. Care must be taken so that tobacco industry engagement in the electronic 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^[21].

(b) Non-nicotine electronic cigarettes have potentially high appeal and can be lawfully sold to young people, despite the health and social impacts remaining unknown

Children are at particular risk of the potential harms of electronic cigarettes, which are designed to be inhaled into the lung and have not been subject to appropriate safety assessment. Despite this, electronic cigarettes come in a variety of flavours including fruit, confectionery, chocolate, red bull and other flavours which appeal to children (they also come in tobacco and menthol flavours with broader appeal to smokers). Flavoured tobacco products are currently restricted in order to reduce their appeal to children; therefore, because most non-nicotine electronic cigarettes are flavoured, they should also be prohibited, consistent with the child-protective intention of restrictions on flavoured tobacco products^[22].

(c) Electronic cigarette use is growing at significant rates, particularly among young people, giving rise to an urgent need for regulation

A topline research report (publication pending) prepared by the Centre for Behavioural Research in Cancer, *Electronic Cigarette Use in Victoria 2010 to 2013* (March 2014), found that 7.3% of Victorian adults had used electronic cigarettes in the past 12 months in 2013. This is a significant increase compared to 3.6% in 2012, 1.8% in 2011 and 0.7% in 2010 (landline data). Use was significantly more likely in younger age groups (compared to older adults aged 30-49 years and 50+ years), with 53.8% of current smokers, 30.5% of former smokers and 4.8% of never smokers aged 18-29 years having used an electronic cigarette in the past year (2013, dual frame).

In the US there is an alarming trend towards electronic cigarette use among children. A recent study showed experimentation and use doubled among US middle and high school students between 2011 (3.3%) and 2012 (6.8%). Among those who had tried electronic cigarettes, 9.3% reported never smoking tobacco cigarettes^[23].

A recently published study on electronic cigarette use among Korean adolescents found that in 2011, a total of 9.4% of Korean adolescents had ever used electronic cigarettes and 4.7% were current electronic cigarette users – more than 75% of whom were dual using with tobacco cigarettes. A previous study showed that 0.5% of Korean adolescents had ever used electronic cigarettes in 2008; therefore, the 2011 study demonstrated that ever use had increased almost 20 fold in three years. Those who had made an attempt to quit tobacco cigarettes were significantly more likely to use electronic cigarettes but much less likely to no longer smoke tobacco cigarettes. Further, electronic cigarette use was strongly associated with current and heavier smoking. The authors observed that the significant association between current electronic cigarette use and higher levels of tobacco cigarette consumption compared with ever and never electronic cigarette users "suggests that electronic cigarettes do not have a role in reducing harm among these teens, and in fact may be increasing harm"(p.3)^[24].

The above findings highlight the urgent need to prevent widespread uptake of electronic cigarettes among children and young adults in Australia.

(d) Nicotine and non-nicotine electronic cigarette products should only be available for use as cessation aids and only if proven effective for that purpose

The TGA is the appropriate body to determine whether specific nicotine or non-nicotine electronic cigarette products are effective as aids for tobacco cessation. To date, no electronic cigarette product has been shown in studies with adequate methodological design to be effective as a cessation aid; further clinical studies are needed to add to the evidence base around this issue. If the products are not effective as cessation aids, smokers using them to assist in quitting tobacco may not be successful and may maintain a tobacco addiction that might have been broken using other proven quitting methods^[4]. There is also the potential for electronic cigarettes to be used intermittently by tobacco smokers rather than as a means to quit smoking tobacco entirely; therefore, dual use is another potential barrier to tobacco smoking cessation^[22].

Marketing a product for purely recreational purposes on the basis that it is "safer" or more pleasant compared to tobacco use might turn out to have damaging public health impacts in the longer term in the event that use proves to be harmful and other effective cessation strategies are undermined^[25]. This is particularly the case where the marketing of recreational electronic cigarettes leads to use by tobacco smokers who would otherwise have quit altogether without switching to electronic cigarettes and use by non-smokers or ex-smokers^[25]. As noted above, the misleading promotion of tobacco products designed to be more attractive to smokers, such as "light" and "mild" cigarettes, turned out to be a highly damaging distraction to cessation efforts^{[10][26][27]}. For these reasons, nicotine and non-nicotine electronic cigarettes should be marketed as cessation aids, rather than recreational products, if proven effective for that purpose.

(e) There are concerns that electronic cigarette use could act as a gateway to tobacco use

This is particularly the case with respect to nicotine-based products^{[23][28]}, however, whether the use of non-nicotine electronic cigarettes could re-normalise smoking behaviour and encourage use of tobacco cigarettes, including among young people, requires further research. Further analysis of the data on US middle and high school student usage of electronic cigarettes (referred to at (c) above) led researchers to conclude that use of electronic cigarettes does not discourage, and may encourage, use of tobacco cigarettes among US adolescents^[29]. Data demonstrated that ever and current use of electronic cigarettes was associated with very high odds of experimentation with tobacco cigarette smoking as well as ever and current tobacco cigarette smoking. In 2011, 49.7% of current electronic cigarette users were current smokers of tobacco cigarettes with similar levels of 49.8% in 2012. Ever-use of electronic cigarettes was associated with planning to quit tobacco smoking; however, current electronic cigarette use was not. Neither ever or current electronic cigarette use was significantly associated with having made an attempt to quit tobacco cigarettes in the past 12 months^[29].

Recommendation 2 – Ensure smoke-free laws in each state and territory cover electronic cigarette use

The purchase, possession or use of electronic cigarettes containing nicotine is currently unlawful under state and territory poisons and public health laws. However, these laws are complicated, not well understood by the community and are difficult to enforce. Prohibiting use of all electronic cigarettes under smoke-free laws would make the law clear for the community and ensure that both nicotine and non-nicotine electronic cigarettes are not used in places where smoking tobacco is prohibited.

Evidence and rationale

(a) Public use could normalise smoking in school students

Smoking among Australian school students is at an unprecedented low, with only 4% of 12-15 year-olds and 13% of 16-17 year-olds identifying as smokers in 2011 – compared with 20% of 12-15 year-olds and 30% of 16-17 year-olds in 1984 (figures 3.4 and 3.5)^[30]. The reduction in smoking among Australian school students is one of the great public health successes of the past 30 years. Smoking as a behaviour has become "de-normalised" among this age group. It would be a retrograde outcome if this trend were to be reversed by the promotion of electronic cigarettes. By simulating the act of smoking, electronic cigarette use in smoke-free areas risks giving the impression to young people that the act of smoking is aspirational^[31]. Moreover, the use of electronic cigarettes in smoke-free places could confuse people into believing that smoking is permitted and make enforcement of smoke-free policies more difficult^[32]. Electronic cigarette manufacturers are actively promoting the use of their products in smoke-free areas^{[18][19]}, potentially accelerating the re-normalisation of smoking behaviour^[3]. This imposes serious risks on the health of young Australians.

(b) Public use and promotion could undermine quit attempts

There are potential risks that electronic cigarette use could elicit cravings and trigger tobacco smoking relapse among smokers who use them and for smokers seeking to quit, who are cued to smoke tobacco cigarettes by observing their use by others or through promotion^[33]. Electronic cigarettes could also delay a person's desire to quit because the nicotine-based products allow nicotine addiction to be maintained, including through use in places where tobacco use is prohibited^{[22][28][32][34][35]}. These issues require further research.

(c) The health impacts of exposure to second-hand vapour are unknown

There is limited research into whether electronic cigarette use impairs indoor air quality or causes passive exposure and negative health impacts in non-users. Early research concludes that indoor electronic cigarette use poses a new source of volatile organic compounds and ultrafine/fine particles in indoor environments, meaning that there is potential for passive inhalation by non-users. Researchers warn that these pollutants could be of health concern to both users and those exposed second-hand. These issues require further research^{[36][37]}.

(d) There is early evidence from Victoria that the community supports prohibiting use of electronic cigarette in smoke-free areas

The Topline Research Report asked Victorian adults whether they agreed or disagreed with banning electronic cigarette use in places where regular cigarettes are banned. More than two-thirds (69.0%) strongly agreed or agreed with the suggestion of a ban on electronic cigarettes in smoke-free areas. Majority support was found in all smoking categories with 72.5% of never smokers, 70.7% of former smokers and 52.9% of current smokers supporting bans.

Recommendation 3 – Prohibiting advertising and promotion of electronic cigarettes, consistent with tobacco advertising prohibitions

Electronic cigarettes are being aggressively promoted, with young people and children clearly identified as a target market. Electronic cigarette advertising should be subject to similar restrictions as tobacco products.

Evidence and rationale

(a) Current electronic cigarette marketing seeks to glamorise the products to young people^[38]

Young people are likely to be susceptible to the advertising techniques and new technology associated with electronic cigarettes^{[20][39]}. Given that electronic cigarettes resemble tobacco cigarettes and allow users to simulate the physical behaviour of smoking tobacco cigarettes, images of smoking behaviour in electronic cigarette advertisements could re-normalise smoking behaviour among young Australians and encourage children to use tobacco cigarettes^[39].

Significantly, electronic cigarette brands, including those owned by tobacco companies, are increasingly becoming involved in sophisticated promotional arrangements reminiscent of strategies previously used to glamorise tobacco^{[39][40][41]}. For example, 'Vuse', owned by tobacco company Reynolds American, has been announced as the official vapour product of the 2014 South by Southwest festival in Austin Texas^[42]. Blu eCigs, owned by tobacco company Lorillard, has various promotional activities. The Democrats US House of Representatives Committee on Energy and Commerce reports that "at the Bonnaroo Music Festival, blu eCigs ran a 'Vapor Lounge' where guests watched musical performances and sampled free e-cigarettes. Blu eCigs has also sponsored the popular Governors Ball Music Festival, SXSW, and the Sasquatch! Music Festival". The Committee also reports that blu eCigs, along with other electronic cigarette companies, Swisher, and Green Smoke "all have NASCAR sponsorships. Blu has sponsored numerous NASCAR races where it distributes e-cigarette samples, Green Smoke has sponsored stock car driver T.J. Bell and Swisher sponsors Reed Sorenson and the 'e-Swisher racing team'"^[40].

The aggressive marketing strategies of the electronic cigarette industry prompted the US National Association of Attorneys General to write to the FDA requesting urgent regulation of electronic cigarettes to prevent further marketing to young people^[43]. The promotion and glamorisation of electronic cigarettes has the potential to erode the strong social norms against smoking behaviour and risks normalising the use of a potentially harmful product^{[22][44]}. Urgent regulation is therefore needed to curb the emergence of similar promotional relationships in Australia.

(b) Current marketing strategies are highly inappropriate and potentially misleading

Current marketing of electronic cigarettes is designed to appeal to youth^[44], seeks to glamorise an addictive product^[20] and makes unsubstantiated and misleading claims about health impacts, safe use and tobacco cessation^{[4][45]}. It also encourages widespread recreational use and seeks to recruit new nicotine users^{[28][38][44]}. This form of marketing is occurring in retail outlets, on radio, on television and over the internet in Australia (and overseas). This is highly inappropriate for unproven products, particularly those containing an addictive and potentially toxic substance such as nicotine^{[4][44][46]}.

(c) Adults in Victoria recall of advertising of products

The Topline Research Report asked Victorian adults who had heard of electronic cigarettes about whether they had noticed any advertising for the products in the last six months. Electronic cigarette advertising was most commonly recalled on television (24.5%), inside shops (18.7%), on the internet (18.4%), in newspapers and magazines (14.9%) and also on radio (6.8%) and on posters or billboards (6.1%).

(d) Advertising/promotion should only be permitted if products are approved as therapeutic goods for smoking cessation

Nicotine replacement therapies and products inhaled to the lung should only be marketed in a manner that promotes safe and effective use, is socially responsible and does not mislead or deceive the consumer^[4]. This is consistent

with the principles underlying the Therapeutic Goods Advertising Code 2007^[47]. If electronic cigarette marketing were to be approved on this basis, advertising and promotion should also be consistent with the provisions of the *Tobacco Advertising Prohibition Act 1992* (Cth) to prevent the deliberate or inadvertent promotion of smoking.

Background: what are electronic cigarettes?

Electronic cigarettes are designed to deliver nicotine and/or other chemicals to the user via an aerosol vapour through devices designed to simulate the act of smoking tobacco cigarettes. The devices do not generally contain tobacco and products vary in terms of ingredients and designs. Non-nicotine products are also available and many brands (both nicotine and non-nicotine) come with fruit, confectionery and other flavours^{[4][48][49]}. The 'Ploom' product (part owned by Japan Tobacco International) differs from other brands in that it contains tobacco and is described as being designed to heat tobacco and release flavour and nicotine in the form of a vapour^[50]. Electronic cigarettes are often marketed (online and through television, radio and print) as recreational products that are safer alternatives to tobacco cigarette smoking as well as products that can be used in places where smoking tobacco is prohibited^{[18][19][20]}. In many instances, including for products marketed in Australia, it is claimed or at least strongly implied that electronic cigarettes can help with quitting smoking^[18].

Relevance of the WHO Framework Convention on Tobacco Control

The WHO Framework Convention on Tobacco Control (FCTC) was the first global health treaty negotiated under the auspices of the WHO and is one of the most widely embraced treaties in United Nations history, reflecting the drastic nature of the global tobacco epidemic^[51]. The FCTC was adopted on 21 May 2003 and entered into force on 27 February 2005^[51]. The treaty sets out key tobacco control measures to be implemented by the Parties with the overarching objective of protecting "present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke" (Article 3)^[52].

A WHO Convention Secretariat report outlines a number of grounds upon which the retail, promotion and use of electronic cigarettes may undermine the FCTC, including the following:

- Because electronic cigarettes are designed to resemble tobacco cigarettes, they could undermine the de-normalisation of tobacco smoking. The WHO report states that "Parties are therefore invited to consider that a ban of ENDS as already undertaken by some Parties would contribute to changing social norms regarding the consumption of tobacco products".
- The FCTC requires Parties to "adopt and implement effective...measures ...for preventing and reducing...nicotine addiction..." and therefore electronic cigarettes would contribute to maintaining nicotine addiction.
- The FCTC requires Parties to undertake a comprehensive ban on tobacco advertising, and because electronic cigarettes are designed to mimic tobacco cigarettes, they could be considered direct or indirect promotion of tobacco use.
- The FCTC requires parties to "...reduce continually and substantially the prevalence of tobacco use". Electronic cigarettes are new products resembling tobacco products that would maintain a nicotine addiction and "regulating them rather than banning them could grant these new products a level of legitimacy in terms of market access, even though they may be subject to the provisions of the WHO FCTC or to regulation as medical products".
- The FCTC requires parties to implement evidence-based treatment for tobacco dependence and cessation – which at present does not include electronic cigarettes (pp. 7-8)^[53].

Current regulation of electronic cigarettes in Australia

There are no laws specifically addressing the regulation of electronic cigarettes in Australia; instead, a number of existing laws relating to poisons, therapeutic goods and tobacco control apply to electronic cigarettes in some circumstances. This makes the regulation of electronic cigarettes complex. Below is a summary of key laws and regulations that impact. Some of these issues have yet to be clarified; therefore this summary may be updated as further information becomes available.

Commercial retail sale and personal possession/use of nicotine electronic cigarettes

The sale and personal possession or use (among other things) of nicotine electronic cigarettes is currently unlawful in every jurisdiction in Australia^{[54][55][56][57][58][59][60][61][62][63]}. This is due to controls on nicotine that apply in each state and territory by reason of it being classified as a 'Schedule 7- Dangerous Poison' under the Commonwealth Poisons Standard^[64]. This position could change in the future should an electronic cigarette product be registered by the Therapeutic Goods Administration (TGA) (discussed below).

Where a nicotine electronic cigarette is for therapeutic uses, such as smoking cessation or alleviation of nicotine withdrawal, the electronic cigarette must be registered by the TGA in order to be sold lawfully^[63]. This involves an assessment of elements including the safety, quality and efficacy of the liquid nicotine and an assessment of the design of the electronic cigarette to ensure it is safe to use^{[65][66]}. Liquid nicotine for inhalation for therapeutic uses is a 'Schedule 4 – Prescription only' medicine under the national Poisons Standard^[67], which means that any TGA registered nicotine electronic cigarette products would be available by prescription only. There are currently no TGA registered electronic cigarettes^[65] and importation, exportation, manufacture and supply of unregistered therapeutic goods is a criminal offence under the *Therapeutic Goods Act 1989* (Cth)^[63].

Where the nicotine electronic cigarette is represented as being for recreational purposes only (that is, not for therapeutic use), the nicotine is classified as a 'Schedule 7 - Dangerous Poison' under the national Poisons Standard^[67]. This means that the manufacture, sale and possession of this kind of recreational product is unlawful in all states and territories (unless a licence/ authority/ approval (as the case may be) can be sought and is granted by the relevant state or territory authority)^{[54][55][56][57][58][59][60][61][62][63]}.

Even if a specific electronic cigarette product were to receive TGA registration in the future, it is possible that its sale would still be banned in states and territories that specifically prohibit the retail sale of products that resemble tobacco products (i.e. SA^[68], WA^[69] and QLD^[70]).

Commercial importation and retail sale of non-nicotine electronic cigarettes

Importation for commercial purposes and retail sale of non-nicotine electronic cigarettes that are marketed with therapeutic claims is unlawful across Australia unless the product is registered by the TGA^[63]. There are currently no TGA registered electronic cigarettes^[65].

Importation and retail sale of non-nicotine electronic cigarettes that do not make therapeutic claims is not covered by laws relevant to therapeutic goods, meaning that they can be imported and sold by retailers without needing to comply with laws relevant to therapeutic goods.

As noted above, SA^[68], WA^[69] and QLD^[70] laws prohibit retail sale of products that resemble tobacco products. Therefore, even if non-nicotine electronic cigarette products make no therapeutic claims, the retail sale of particular models in those jurisdictions may still be an offence.

Importation of nicotine electronic cigarettes for personal use

Importation of nicotine electronic cigarettes for personal therapeutic use (e.g. use as a quitting aid) is exempt from registration requirements (but other conditions apply, noted below). This exemption arises under the personal importation scheme provided for under the *Therapeutic Goods Regulations 1991*. It is therefore possible to lawfully import nicotine electronic cigarettes for personal use if the importer is able to comply with the requirements of the TGA's personal importation scheme. Under this scheme^{[71][72][73]}:

- As the goods are listed in Schedule 4 of the Poisons Standard (Prescription only), the importer must have a prescription from a medical practitioner registered in the relevant state or territory (unless the importer carries the goods as a passenger on a ship or plane).
- The goods must be imported for use in the treatment of the importer or the importer's immediate family.
- The quantity imported in one importation must not be more than three months' supply at the maximum dose recommended by the manufacturer.
- The total quantity of the goods imported in a 12 month period must not exceed 15 months' supply.

The existence of the medical prescription would mean that, the nicotine is supplied in compliance with Schedule 4 of the Poisons Standard ('Prescription Only') and is therefore no longer prohibited as a Schedule 7- Dangerous Poison under state and territory laws and can be lawfully used. However, the requirement for a medical prescription may pose practical barriers for people in Australia wishing to order nicotine electronic cigarettes online in the event that medical practitioners are unwilling or unable (for legal reasons) to provide a prescription for a product that has not been approved by the TGA.

Importation of nicotine electronic cigarettes not for therapeutic use (i.e. for recreational use) is not directly covered by the TGA personal importation scheme and does not breach customs laws^{[74][75]}. However, possession and/or use of any nicotine electronic cigarette product without a medical prescription is prohibited under state and territory poisons laws (as such a product would be considered a Schedule 7 - Dangerous Poison in the absence of a medical prescription)^{[54][55][56][57][58][59][60][61][62]}. Therefore, a person importing nicotine electronic cigarettes that are not registered by the TGA or without a medical prescription, even just for personal use, will be in breach of state and territory laws (unless approval for personal use can be sought and is granted by the relevant state or territory authority)^{[54][55][56][57][58][59][60][61][62][63]}.

Importation of non-nicotine electronic cigarettes for personal use

Importation of non-nicotine electronic cigarettes that are marketed with therapeutic claims is covered by therapeutic goods laws and regulations and it is lawful to import these products for personal use or use by an immediate family member under the personal importation scheme (described above). Because the products do not contain a prescription only medicine (i.e. nicotine), no medical prescription is required, but the other conditions outlined above (regarding personal/family use, three months' supply and 15 months' supply within 12 months) all apply.

Importation of non-nicotine electronic cigarettes that do not make therapeutic claims is not covered by laws relevant to therapeutic goods, meaning that they can be imported for personal use and commercial purposes without needing to comply with laws relevant to therapeutic goods.

Applicability of tobacco control laws

There may be a case that certain promotions of electronic cigarettes are in breach of the *Tobacco Advertising Prohibition Act 1992* (Cth) (TAP Act); however, there are currently no legislative provisions in the TAP Act that specifically refer to electronic cigarettes.

It is unlikely that electronic cigarettes fall within laws regarding smoke-free areas in each state and territory; however, individual businesses and the public sector can develop their own policies on use of electronic cigarettes in their organisations.

International context

In considering the international context, it is important to note that Australia is a unique case: we have among the world's lowest smoking rates, especially among our young people; we are a recognised world leader through plain packaging, which is expected to further reduce smoking uptake in young people; and, on current trends, the successive annual increases in tobacco tax in Australia up to 2016 are expected to further reduce smoking prevalence (price is a key smoking deterrent for young people). So, while a number of countries are exploring options to reduce potential electronic cigarette harms, it should be noted that:

- Electronic cigarette use is not as prevalent in Australia as it is in many other countries; and
- Australia's relative success in protecting its younger age groups from smoking-related harms puts us in a strong position to protect Australian school children from exposure to electronic cigarettes before their use becomes more widespread, and to build on our track record of de-normalising smoking behaviour among Australian youth.

Following is a snapshot of developments overseas (based on academic commentary publicly available).

United States

Electronic cigarettes (both nicotine and non-nicotine) are currently only subject to regulation by the Food and Drug Administration (FDA) if therapeutic claims are made^[76]. This means that products containing nicotine that are not marketed with therapeutic claims can be lawfully promoted and sold with minimal regulatory oversight. In April 2014 the FDA issued proposed regulations that at the time of preparing this paper, were open for community consultation^[76].

Sales to minors

There is currently no federal regulation on selling electronic cigarettes to minors in the US. Unpublished data shows that as at mid-November 2013, youth access laws in 22 US states included electronic cigarettes^[22]. California, Utah and New Jersey are among the places where the sale of electronic cigarettes to minors is prohibited^[20]. The City of Chicago recently passed an ordinance regulating electronic cigarettes including by prohibiting sales to minors, requiring retailers to keep the products behind the counter and prohibiting use in smoke-free areas^[77]. Ohio and Iowa legislatures are set to pass laws that prohibit sales of electronic cigarettes to minors; however, these bills are reported to have had close input from tobacco company Lorillard, owners of blu eCigs, and do not prohibit smoking in public places^{[78][78][79]}.

Smoke-free laws and policies

Unpublished data shows that as at mid-November 2013, 11 US states explicitly addressed electronic cigarette use under smoke-free air policies as did 108 communities at January 2014^[22]. The US States, cities and local councils that have moved to prohibit electronic cigarette use in smoke-free areas include North Dakota, New Jersey, Utah, New York, Chicago and Los Angeles. A number of other States and cities have prohibited their use in specific places (such as schools and state buildings)^{[77][80][81][82]}.

Advertising and promotion

There are currently no specific advertising restrictions on electronic cigarettes and since 2007 products have been subject to increasingly sophisticated marketing campaigns that use celebrity endorsements to glamorise product use^{[20][31]}. While marketing claims vary across manufacturers and vendors, electronic cigarettes are frequently promoted as a "safe" alternative to cigarettes^[20]; a fashionable and tech savvy alternative that can be "smoked anywhere" and therefore used to avoid tobacco smoking restrictions^{[18][19][28]} and in some instances, as a cessation aid^{[35][45][83]}. Electronic cigarettes have started to appear in popular entertainment through movies, television and on-air advocacy by celebrities^[20]. In 2010, actor Katherine Heigl appeared on the Late Show with David Letterman where she used an electronic cigarette along with the program host, and endorsed the product as a "fun addiction" because "it is not bad for you"^[20]. A US TV show titled The Doctors featured electronic cigarettes among a list of top ten health innovations as well as non-smoking medical doctors using the product^[20]. Other prominent promotional strategies have included distributing electronic cigarettes "bedazzled" with Swarovski crystals in gift bags at the 2011 Academy awards^[20] and broadcasts have occurred at Super Bowl games, reaching millions of viewers^[39]. These types of aggressive marketing strategies prompted the National Association of Attorneys General to write to the FDA requesting urgent regulation of electronic cigarettes to prevent further marketing to young people^[43]. Many other public health experts and groups are calling for regulation, including the Campaign for Tobacco Free Kids^{[22][23][28][39][84]}.

Europe

In December 2012 the European Commission (EC) released a draft Tobacco Products Directive that if passed by the European Parliament, would have required electronic cigarettes with nicotine levels exceeding 2 mg; nicotine concentrations exceeding 4 mg/ml; or whose intended use resulted in a maximum peak plasma concentration exceeding 4 ng/ml to be regulated as medicinal products.

Low level nicotine products with nicotine below these levels would not have required medicines regulation provided they carried a modified health warning^[85] (see 3.7 and Art 18). However, after extensive lobbying from the electronic cigarette industry and other stakeholders^{[86][87]}, in February 2014 the European Parliament voted in favour of an updated draft directive^[88] that when operable (from May 2014 with a two year transition period) will provide for the following with respect to electronic cigarettes:

- Categories of electronic cigarettes to be sold as consumer products: Products with levels of nicotine of up to 20 mg/ml can be sold as a consumer product (without medicines regulation). This is the case so long as the products are not marketed with therapeutic claims^[89]. 20 mg/ml is typically the strength of nicotine used by a regular smoker^[90]. Various new requirements will apply to products falling within this category, including with respect to:
 - Safety and quality: for example, making the nicotine containers child and tamper proof and protected against leakage; use of ingredients of high purity; and requirements that products deliver nicotine doses at consistent levels under normal conditions of use^{[91][92]}.
 - Informing consumers: for example, through mandatory health warnings, instructions on use, information on addictiveness and toxicity, a list of all ingredients and information on nicotine content along with a prohibition on promotional materials on packs^{[91][92]}.
 - Protection of consumers: for example, Member States and the Commission will be able to act in cases of justified safety concerns with respect to specific products. Authorities will monitor the market for evidence that the products lead to nicotine addiction or tobacco consumption, particularly among young people and non-smokers^{[91][92]}.
 - Increased reporting requirements: electronic cigarette manufacturers will be required to report on a number of issues including by providing notification prior to placing new products on the market (including on information of the manufacturer, ingredients, emissions, nicotine dose and uptake, production processes and a declaration that the manufacturer takes full responsibility for quality and safety under normal use). Other

reporting obligations include the provision of annual reports to Member States on sales, types of users and user preferences and trends^{[91][92]}.

- Restrictions on advertising: Promotion of nicotine electronic cigarettes in this category will be prohibited in various cross-border contexts including in print, radio, at events and in audio-visual commercial communications^[93]. The directive does not generally cover domestic forms of advertising which do not cross borders (for example, point of sale and billboard advertising), but Member States can elect to regulate or prohibit advertising in these areas^[91] (see Art 20.5 and paragraph 43, page 25 and paragraph 48, p.28 of the explanatory materials).
- Categories of electronic cigarettes to be sold under medicines frameworks: All products containing more than 20 mg/ml of nicotine are to be regulated under a medicines framework (and subject to other applicable EU directives)^[89]. Any products marketed with therapeutic claims are also to be regulated under a medicines framework, regardless of nicotine content. Electronic cigarette manufacturers can opt in to a medicines framework even if their products are not caught by the directive in the event they wish to market a product with less than 20 mg/ml of nicotine on the basis that it can be used for therapeutic purposes.
- Smoke-free and sales to minors: There are no provisions requiring Member States to prohibit sales to minors or use in smoke-free areas. However, the explanatory materials to the directive note that "Member States are free to regulate such matters within the remit of their own jurisdiction and are encouraged to do so"^[94].

United Kingdom

In the UK, electronic cigarettes (both nicotine and non-nicotine) are currently only subject to regulation by the Medicines and Healthcare Products Regulatory Agency if therapeutic claims are made^{[53][95]}. Like in the US, this means that products containing nicotine that are not marketed with therapeutic claims can be lawfully promoted and sold with minimal regulatory oversight. In light of the original 2012 draft terms of the proposed EU Tobacco Directive, the UK Government announced its intention to regulate all nicotine containing electronic cigarettes as medicinal products from 2016, regardless of whether therapeutic claims were made^[96]. However, since the updated EU Tobacco Directive now allows products containing up to 20 mg/ml of nicotine to be regulated and sold as general consumer products, recent comments made in the UK Parliament indicate that products that do not make medicinal claims will not be regulated as medicines in the UK (as originally proposed)^[97]. The Health Minister for Wales recently expressed serious concerns about electronic cigarettes, including their potential to re-normalise tobacco smoking^[98].

Sales to minors

A law was recently passed in the UK empowering the relevant Minister to make regulations that prohibit sales of electronic cigarettes to minors (clause 122)^[99]. Such regulations (when created) will also apply in Wales^[100].

Smoke-free laws and policies

Electronic cigarettes are not currently regulated by smoke-free laws and users are generally allowed to use them in most public places, including bars, restaurants and public transport but there are reports that managers of particular premises have banned their use^{[101][102]}. A recent news investigation found that electronic cigarette use is banned in the majority of Scottish hospitals, schools and council buildings and it has also been announced that electronic cigarette use will be prohibited in and around Commonwealth Games venues in Scotland for the 2014 Commonwealth Games^{[103][104]}. The head teachers Union in the UK has called for use of electronic cigarettes to be prohibited on school grounds, particularly by parents, due to concerns about the example being set for young people^[105].

Advertising and promotion

TV campaigns were launched in early 2013^[106] and sport related sponsorship deals are emerging, including a football ground being named "Cigg-E Stadium"^{[44][107][108][109]}. Singer Lily Allen recently entered into a product placement deal for an electronic cigarette brand to appear in a music video clip^[110]. An academic review of news

media representations of electronic cigarettes found that between 2007 and 2012, UK news coverage of electronic cigarette products grew substantially, with the top two themes emerging as (a) presenting electronic cigarettes as a "healthier choice" and (b) using electronic cigarettes to "get around smoke-free legislation"^[46]. Recent advertisements have been the subject of complaints and subsequent inquiries including for being highly sexualised as well as failing to disclose that the products contained nicotine (which is now required by the advertising authority)^{[111][112]}. Bars dedicated to electronic cigarette use are also emerging.

New Zealand and Canada

Electronic cigarettes containing nicotine are regulated as medicines regardless of whether therapeutic claims are made^{[113][114]}. With respect to non-nicotine electronic cigarettes:

- Sales to minors: There are no restrictions on sales to minors in Canada^[115]. In New Zealand, it is unlawful to sell a product that looks like a tobacco product or smokers' pipe to people under 18 except where that product's primary purpose is to help people quit smoking^{[113][116]}.
- Smoke-free laws and policies: For both Canada and New Zealand there is no national legislative framework on use in public places.
- Advertising and promotion: For both Canada and New Zealand there are no specific laws regulating the advertisement of electronic cigarettes; however, like under Australian laws, arguments could be put that tobacco advertising prohibitions could apply to electronic cigarettes in some circumstances (for example, where an advertisement promotes "smoking behaviour" (New Zealand^[117]) or "evokes a tobacco product" (Canada^{[39][118]})).

References

- [1] http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10-en.pdf?ua=1
- [2] World Health Organization. *Electronic nicotine delivery systems*. Geneva, Switzerland: WHO; 2014 Aug Available from: http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10-en.pdf?ua=1.
- [3] 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>].
- [4] 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.
- [5] US Food and Drug Administration. *Summary of Results: Laboratory Analysis of Electronic Cigarettes Conducted By FDA*. Silver Spring, Maryland: Department of Health and Human Services; 2009 Available from: <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm173146.htm>.
- [6] Avdalovic MV, Murin S. *Electronic cigarettes: no such thing as a free lunch...Or puff*. Chest 2012 Jun;141(6):1371-2 [Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/22670013>].
- [7] 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>.
- [8] New South Wales Department of Health. *NSW Health Alert - Warning on e-liquids*. Sydney: NSW Government; 2013 Oct Available from: http://www.health.nsw.gov.au/campaigns/quitting_smoking/Pages/e-liquid.aspx.
- [9] Trtchounian A, Talbot P. *Electronic nicotine delivery systems: is there a need for regulation?* Tob Control 2011 Jan;20(1):47-52 [Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/21139013>].
- [10] Anderson SJ, Ling PM, Glantz SA. *Implications of the federal court order banning the terms "light" and "mild": what difference could it make?* Tob Control 2007 Aug;16(4):275-9 [Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/17652244>].
- [11] Altria. *Press Release: Altria Holds Investor Day; Revises 2013 Full-Year Reported EPS Guidance and Reaffirms 2013 Full-Year Adjusted EPS Guidance*. Richmond, Virginia: Altria; 2013 Jun 11 Available from: <http://investor.altria.com/phoenix.zhtml?c=80855&p=irol-newsArticle&ID=1828778&highlight=>.
- [12] British American Tobacco. *News Release: British American Tobacco launches e-cigarette in the UK*. British American Tobacco; 2013 Jul 29 Available from: http://www.bat.com/group/sites/UK_9D9KCY.nsf/vwPagesWebLive/DO9A3D5G?opendocument&SKN=1.
- [13] Lorillard. *Lorillard Inc. reports first quarter 2012 results and acquisition of blu ecigs*. Lorillard Inc; 2012 Apr 25 Available from: <http://investors.lorillard.com/phoenix.zhtml?c=134955&p=irol-newsArticle&ID=1687024&highlight=>.
- [14] R.J. Reynolds Vapor Company. *R.J. Reynolds Vapor Company bringing 'VUSE' Digital Vapor Cigarette to Colorado*. R.J. Reynolds Vapor Company; 2013 Dec 16 Available from: http://files.shareholder.com/downloads/RAI/3065693894x0x713880/959029b5-96f5-4c93-b0ef-ff6e8147996d/2013-02_Release-R.J.

- _Reynolds_Vapor_Company_to_showcase_VUSE_Digital_Vapor_Cigarette_at_2014_Consumer_Electronics_Show.pdf.
- [15] Ploom, Japan Tobacco International. *Innovative partnership for Ploom and Japan Tobacco International: JTI to take minority share in Ploom*. Ploom, JTI; 2011 Dec 8 Available from: <http://www.jti.com/media/news-releases/jti-macdonald-corp-reaches-an-agreement-regarding-illicit-trade-of-cigarettes-in-canada-2/>.
 - [16] Fletcher N. *Imperial Tobacco shares lifted by deal to sell its e-cigarettes in Boots*. The Guardian; 2014 Feb 21 Available from: <http://www.theguardian.com/business/marketforceslive/2014/feb/21/imperial-tobacco-e-cigarettes-boots>.
 - [17] Chellel K. *Imperial Tobacco unit sparks e-cig patent dispute in US suits*. Bloomberg; 2014 Mar 11 Available from: <http://www.bloomberg.com/news/2014-03-11/imperial-tobacco-unit-sparks-e-cig-patent-dispute-in-u-s-suits.html>.
 - [18] Ayers JW, Ribisl KM, Brownstein JS. *Tracking the rise in popularity of electronic nicotine delivery systems (electronic cigarettes) using search query surveillance*. Am J Prev Med 2011 Apr;40(4):448-53 [Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/21406279>].
 - [19] Stanford School of Medicine. *Smoke Anywhere*. Stanford School of Medicine; 2014 Apr 7 Available from: http://tobacco.stanford.edu/tobacco_main/images_ecigs.php?token2=fm_ecigs_st379.php&token1=fm_ecigs_img16990.php&theme_file=fm_ecigs_mt025.php&theme_name=Freedom&subtheme_name=SmokeAnywhere.
 - [20] Grana RA, Glantz SA, Ling PM. *Electronic nicotine delivery systems in the hands of Hollywood*. Tob Control 2011 Nov;20(6):425-6 [Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/21659450>].
 - [21] 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 Jan 22 [Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/24457543>].
 - [22] Chaloupka FJ. *Tobacco Control Policy and Electronic Cigarettes*. JAMA Pediatr 2014 Mar 6 [Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/24603982>].
 - [23] Centers for Disease Control and Prevention (CDC). *Notes from the field: electronic cigarette use among middle and high school students - United States, 2011-2012*. MMWR Morb Mortal Wkly Rep 2013 Sep 6;62(35):729-30 [Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/24005229>].
 - [24] Lee S, Grana RA, Glantz SA. *Electronic Cigarette Use Among Korean Adolescents: A Cross-Sectional Study of Market Penetration, Dual Use, and Relationship to Quit Attempts and Former Smoking*. J Adolesc Health 2013 Nov 22 [Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/24274973>].
 - [25] Scollo M. *Recreational nicotine: uncertain benefits and several major risks [comment]*. Tob Control 2000 Jun;9(2):240-1 [Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/10841864>].
 - [26] Anderson SJ. *Marketing of menthol cigarettes and consumer perceptions: a review of tobacco industry documents*. Tob Control 2011 May;20 Suppl 2:i20-8 [Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/21504928>].
 - [27] Non-smokers' Rights Association. *The 'light' and 'mild' consumer fraud*. Toronto, Ontario: Smoking and Health Action Foundation; 2002 Available from: https://www.nsra-adnf.ca/cms/index.cfm?group_id=1306.
 - [28] Grana RA. *Electronic cigarettes: a new nicotine gateway?* J Adolesc Health 2013 Feb;52(2):135-6 [Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/23332475>].
 - [29] Dutra LM, Glantz SA. *Electronic Cigarettes and Conventional Cigarette Use Among US Adolescents: A Cross-sectional Study*. JAMA Pediatr 2014 Mar 6 [Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/24604023>].
 - [30] White V, Bariola E. *Australian secondary school students' use of tobacco, alcohol, and over-the-counter and illicit substances in 2011*. Melbourne: Centre for Behavioural Research in Cancer, Cancer Council Victoria; 2012 Dec. Sponsored by Drug Strategy Branch Australian Government Department of Health and Ageing.
 - [31] McKee M. *E-cigarettes and the marketing push that surprised everyone*. BMJ 2013 Sep 26;347:f5780 [Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/24070876>].
 - [32] Regan AK, Promoff G, Dube SR, Arrazola R. *Electronic nicotine delivery systems: adult use and awareness of the 'e-cigarette' in the USA*. Tob Control 2013 Jan;22(1):19-23 [Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/22034071>].
 - [33] Kim AE, Lee YO, Shafer P, Nonnemaker J, Makarenko O. *Adult smokers' receptivity to a television advert for electronic nicotine delivery systems*. Tob Control 2013 Oct 3 [Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/24092599>].
 - [34] Odum LE, O'Dell KA, Schepers JS. *Electronic cigarettes: do they have a role in smoking cessation?* J Pharm Pract 2012 Dec;25(6):611-4 [Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/22797832>].
 - [35] Adkison SE, O'Connor RJ, Bansal-Travers M, Hyland A, Borland R, Yong HH, et al. *Electronic nicotine delivery systems: international tobacco control four-country survey*. Am J Prev Med 2013 Mar;44(3):207-15 [Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/23415116>].
 - [36] Schripp T, Markewitz D, Uhde E, Salthammer T. *Does e-cigarette consumption cause passive vaping?* Indoor Air 2013 Feb;23(1):25-31 [Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/22672560>].
 - [37] Schober W, Szendrei K, Matzen W, Osiander-Fuchs H, Heitmann D, Schettgen T, et al. *Use of electronic cigarettes (e-cigarettes) impairs indoor air quality and increases FeNO levels of e-cigarette consumers*. Int J Hyg Environ Health 2013 Dec 6 [Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/24373737>].
 - [38] Taleb ZB, Maziak W. *Harm reduction and e-cigarettes: not evidence-based*. Lancet Oncol 2014 Mar;15(3):e104 [Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/24599927>].
 - [39] Hodge JG Jr, Collmer V, Orenstein DG, Millea C, Van Buren L. *Reconsidering the legality of cigarette smoking advertisements on television public health and the law*. J Law Med Ethics 2013;41(1):369-73 [Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/>]

- 23581678].
- [40] Democrats Committee for Energy and Commerce. *E-Cigarettes Flashbacks*. Washington DC: US House of Representatives; 2014 Apr 7 Available from: http://democrats.energycommerce.house.gov/index.php?q=page/e-cigarette-flashbacks#_=1396498603146&count=horizontal&id=twitter-widget-0&lang=en&original_referer=http%3A%2F%2Fwww.strikingly.com%2Fecigflashbacks&size=m&text=Saw%20an%20awesome%20one%20pager.%20Check%20it%20out%20%23strikingly&url=http%3A%2F%2Fwww.strikingly.com%2Fecigflashbacks.
- [41] Stanford School of Medicine. *Ecigs vs. Cigs*. [homepage on the internet] Stanford School of Medicine; 2015 Aug 21 Available from: http://tobacco.stanford.edu/tobacco_main/images-ecig.php?token2=fm_tn_st286.php&token1=fm_tn_img9656.php&theme_file=fm_tn_mt001.php&theme_name=E-Cigs&subtheme_name=Ecigs%20vs.%20Cigs.
- [42] RJ Reynolds Vapor. *VUSE makes South by Southwest debut as official e-cigarette sponsor*. Reynolds American Inc.; 2014 Mar 3 Available from: <http://reynoldsameric.com/releases.cfm?ReleasesType=&Year=>.
- [43] National Association of Attorneys General. *FDA should regulate sales and advertising of e-Cigarettes*. NAAG; 2013 Sep 24 Available from: <http://www.naag.org/fda-should-regulate-sales-and-advertising-of-e-cigarettes1.php>.
- [44] The Lancet Oncology. *Time for e-cigarette regulation*. Lancet Oncol 2013 Oct;14(11):1027 [Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/24079859>].
- [45] Cobb NK, Brookover J, Cobb CO. *Forensic analysis of online marketing for electronic nicotine delivery systems*. Tob Control 2013 Sep 13 [Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/24038037>].
- [46] Rooke C, Amos A. *News media representations of electronic cigarettes: an analysis of newspaper coverage in the UK and Scotland*. Tob Control 2013 Jul 24 [Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/23884011>].
- [47] Therapeutic Goods Administration. *Therapeutic Goods Advertising Code 2007*. Canberra: TGA; 2007 Available from: <http://www.tga.gov.au/industry/legislation-tgac.htm>.
- [48] Trtchounian A, Williams M, Talbot P. *Conventional and electronic cigarettes (e-cigarettes) have different smoking characteristics*. Nicotine Tob Res 2010 Sep;12(9):905-12 [Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/20644205>].
- [49] Cobb NK, Abrams DB. *E-cigarette or drug-delivery device? Regulating novel nicotine products*. N Engl J Med 2011 Jul 21;365(3):193-5 [Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/21774706>].
- [50] Ploom. *The Ploom*. [homepage on the internet] Ploom; 2015 Aug 21 [cited 2014 Apr 8]. Available from: <http://www.ploom.com/modeltwo/>.
- [51] World Health Organization. *The History of the WHO Framework Convention on Tobacco Control*. France: WHO; 2009.
- [52] World Health Organization. *WHO Framework Convention on Tobacco Control*. Geneva, Switzerland: WHO; 2005.
- [53] World Health Organization Convention Secretariat. *Electronic nicotine delivery systems, including electronic cigarettes*. Seoul, Republic of Korea: Conference of the Parties to the WHO Framework Convention on Tobacco Control, fifth session; 2012. Report No.: FCTC/COP/5/13.
- [54] *Drugs, Poisons and Controlled Substances Regulations. 2006* (Vic) r 65.
- [55] *Poisons and Therapeutic Goods Regulation. 2008* (NSW) r 20.
- [56] *Health (Drugs and Poisons) Regulation. 1996* (Qld) r 271.
- [57] *Controlled Substances (Poisons) Regulations. 2011* (SA) r 30.
- [58] *Poisons Act. 1964* (WA) s 25(1); s 62; s 24(1)(d).
- [59] *Poisons Act. 1971* (Tas) s 37(2).
- [60] *Poisons Regulations. 2008* (Tas) r 74(11).
- [61] *Medicines, Poisons and Therapeutic Goods Act. 2012* (NT) ss 42-44.
- [62] *Medicines, Poisons and Therapeutic Goods Act. 2008* (ACT) s 36; s 35(1); s 26(1).
- [63] *Therapeutic Goods Act. 1989* (Cth) s 19B.
- [64] *Standard for the Uniform Scheduling of Medicines and Poisons, commonly referred to as the 'Poisons Standard'. 2012* (Cth).
- [65] Therapeutic Goods Administration. *Electronic cigarettes*. Canberra: Australian Government Department of Health and Ageing; 2013 Available from: <http://www.tga.gov.au/consumers/ecigarettes.htm>.
- [66] National Coordinating Committee on Therapeutic Goods. *Scheduling Policy Framework for Medicines and Chemicals*. Canberra: Department of Health; 2010.
- [67] *Poisons Standard. 2013* (Cth).
- [68] *Tobacco Products Regulation Act. 1997* (SA) s 36.
- [69] *Tobacco Products Control Act. 2006* (WA) s 106.
- [70] *Tobacco and Other Smoking Products Act. 1998* (Qld) s 26ZS.
- [71] *Therapeutic Goods Act. 1989* (Cth) s 18(1).
- [72] *Therapeutic Goods Regulations. 1990* (Cth) reg 12(1) and Schedule 5, item 1(d).
- [73] Therapeutic Goods Administration. *Personal Importation Scheme*. Canberra: Australian Government Department of Health; 2013 Available from: <http://www.tga.gov.au/consumers/personal-importation-scheme.htm>.
- [74] *Customs Act. 1901* (Cth) s 51(1).
- [75] *Customs (Prohibited Imports) Regulations. 1956* (Cth) reg 5, Schedule 4.
- [76] US Food and Drug Administration. *Electronic Cigarettes (e-Cigarettes)*. Silver Spring, Maryland: Department of Health and Human Services; 2013 Available from: <http://www.fda.gov/newsevents/publichealthfocus/ucm172906.htm>.

- [77] City of Chicago. *City Council approves ordinance to regulate e-cigarettes as tobacco products*. Chicago, Illinois: City of Chicago; 2014 Jan 15 Available from: <http://www.cityofchicago.org/city/en/depts/cdph/provdrs/boh/news/2014/jan/city-council-approves-ordinance-to-regulate-e-cigarettes-as-toba.html>.
- [78] Siegel J. *E-cig bill moves despite anti-smoking concerns*. The Columbus Dispatch; 2014 Feb 11 Available from: <http://dispatchpolitics.dispatch.com/content/blogs/the-daily-briefing/2014/02/2-11-14-ecig-bill.html>.
- [79] Ngo M. *Legislators focus on e-cigarettes*. Iowa: The Daily Iowan; 2014 Feb 6 Available from: <http://www.dailyiowan.com/2014/02/06/Metro/36491.html>.
- [80] The New York City Council. *City votes to prohibit the use of electronic cigarettes in places where smoking is banned*. New York, New York: The New York City Council; 2013 Dec 19 Available from: <http://www.council.nyc.gov/html/pr/121913stated.shtml>.
- [81] Phend C. *FDA: No Surprises Planned for E-Cigarette Regs*. MedPage Today; 2013 Oct 27 Available from: <http://www.medpagetoday.com/PublicHealthPolicy/FDAGeneral/42506>.
- [82] Whitcomb D, Gorman S. *Los Angeles moves to ban e-cigarettes, joining NY, others*. Reuters; 2014 Mar 4 Available from: <http://www.reuters.com/article/2014/03/05/us-usa-ecigarettes-california-idUSBREA2324920140305>.
- [83] Stanford School of Medicine. *Helps you quit*. [homepage on the internet] Stanford School of Medicine; 2015 Aug 21 Available from: http://tobacco.stanford.edu/tobacco_main/subtheme_ecigs.php?token=fm_ecigs_mt043.php.
- [84] Campaign for Tobacco-Free Kids. *FDA and the States Must Regulate E-Cigarettes To Protect Public Health*. Washington, DC: Campaign for Tobacco-Free Kids; 2013.
- [85] European Commission. *Proposal for a directive of the European Parliament and of the Council*. Brussels, Belgium: European Commission; 2012. Report No.: 2012/0366 (COD).
- [86] Information Daily. *EU Parliament rejects regulation of e-cigarette as medical device*. Information Daily; 2013 Oct 15 Available from: <http://www.theinformationdaily.com/2013/10/08/eu-parliament-rejects-regulation-of-e-cigarettes-as-medical-devices>.
- [87] Keating D. *Battle over electronic cigarettes dominates negotiations on tobacco legislation*. European Voice; 2013 Nov 28 Available from: <https://www.europeanvoice.com/article/imported/battle-over-e-cigarettes-dominates-negotiations-on-tobacco-legislation/78896.aspx>.
- [88] Keating D. *Parliament adopts new EU tobacco rules*. European Voice; 2014 Feb 26 Available from: <http://www.europeanvoice.com/article/2014/february/parliament-adopts-new-eu-tobacco-rules/79824.aspx>.
- [89] European Parliament. *Texts Adopted Part III at the sitting of Wednesday 26 February 2014*. European Parliament; 2014. Report No.: P7_TA-PROV (2014) 0160 Art 20.1; Art 20.3(b).
- [90] European Parliament. *Texts Adopted Part III at the sitting of Wednesday 26 February 2014*. European Parliament; 2014. Report No.: P7_TA-PROV (2014) 0160, paragraph 38, page 24.
- [91] European Parliament. *Texts Adopted Part III at the sitting of Wednesday 26 February 2014*. European Parliament; 2014. Report No.: P7_TA-PROV (2014) 0160, Art 20.
- [92] European Commission. *Questions & Answers: New rules for tobacco products*. [homepage on the internet] European Commission; 2015 Aug 21 Available from: http://europa.eu/rapid/press-release_MEMO-14-134_en.htm.
- [93] European Parliament. *Texts Adopted Part III at the sitting of Wednesday 26 February 2014*. European Parliament; 2014. Report No.: P7_TA-PROV (2014) 0160, Art 20.5.
- [94] European Parliament. *Texts Adopted Part III at the sitting of Wednesday 26 February 2014*. European Parliament; 2014. Report No.: P7_TA-PROV (2014) 0160 paragraph 48, page 28.
- [95] Gornall J. *Electronic cigarettes: medical device or consumer product?* BMJ 2012 Sep 25;345:e6417 [Abstract available at <http://www.ncbi.nlm.nih.gov/pubmed/23014904>].
- [96] Medicines and Healthcare Products Regulatory Agency. *The Regulation of Nicotine Containing Products (NCPs)*. London, United Kingdom: Medicines and Healthcare Products Regulatory Agency; 2013.
- [97] UK Parliament. *Written answers to questions 28 February 2014*. [homepage on the internet] UK Parliament; 2014 Available from: http://www.publications.parliament.uk/pa/cm201314/cmhansrd/cm140228/text/140228w0003.htm#140228w0003.htm_spnew43.
- [98] BBC News Wales. *Mark Drakeford: E-Cigarettes 're-normalising' smoking*. BBC News Wales; 2014 Feb 2 Available from: <http://www.bbc.co.uk/news/uk-wales-26008454>.
- [99] House of Commons. *Lords Amendments to the Children and Families Bill*. London: House of Commons; 2014 Available from: <http://www.publications.parliament.uk/pa/bills/cbill/2013-2014/0171/14171.pdf>.
- [100] BBC News. *E-Cigarettes ban for under 18s to apply to Wales*. BBC News; 2014 Feb 4 Available from: <http://www.bbc.co.uk/news/uk-wales-politics-26031708>.
- [101] Medicines and Healthcare Products Regulatory Agency. *The Regulation of Nicotine Containing Products: Questions and Answers*. London, United Kingdom: Medicines and Healthcare Products Regulatory Agency; 2013.
- [102] Moyo L. *E-Cigarette smoking indoors – a grey area in Manchester nightlife*. Manchester Evening News; 2014 Mar 12 Available from: <http://www.manchestereveningnews.co.uk/whats-on/music-nightlife-news/e-cigarette-smoking-indoors-grey-6808101>.
- [103] Aitken M. *Electronic cigarettes banned from the majority of Scotland's hospitals, schools and council buildings*. Daily Record; 2014 Jan 19 Available from: <http://www.dailyrecord.co.uk/news/scottish-news/electronic-cigarettes-banned-majority-scotlands-3037859>.
- [104] Lindsay B. *Glasgow 2014: E-Cigarettes banned from all venues*. The Scotsman; 2014 Jan 29 Available from: <http://www.scotsman.com/news/health/glasgow-2014-e-cigarettes-banned-from-all-venues-1-3285053>.
- [105] Hannah R. *Ban E-Cigarettes from school premises, heads say*. BBC News; 2014 Jan 27 Available from: <http://www.bbc.co.uk/news/education-25913518>.

- [106] Sweney M. *E-cigarette company to launch TV advertising campaign*. The Guardian; 2013 Jan 15 Available from: <http://www.theguardian.com/media/2013/jan/15/ecigarette-advertising-campaign-uk-ban-smoking>.
- [107] Talking Retail. *E-Lites announces partnership with MCE British Superbike Championship*. Talking Retail; 2013 Mar 25 Available from: <http://www.talkingretail.com/products/product-news/e-lites-announces-partnership-with-mce-british-superbike-championship>.
- [108] Hertfordshire Mercury. *Buntingford racer gets sponsorship from e-cigarette company*. Hertfordshire Mercury; 2013 Available from: <http://www.hertfordshiremercury.co.uk/Business/Buntingford-racer-gets-sponsorship-from-e-cigarette-company-20130628102757.htm>.
- [109] Hawkes S. *Football ground becomes the 'Cigg-E' stadium in controversial sponsorship deal*. The Telegraph; 2013 Apr 21 Available from: <http://www.telegraph.co.uk/news/uknews/10257883/Football-ground-becomes-the-Cigg-E-stadium-in-controversial-sponsorship-deal.html>.
- [110] Chapman M. *E-Lites secures product placement 'first' in Lily Allen's 'Hard Out Here' video*. Brand Republic; 2013 Nov 13 Available from: <http://www.brandrepublic.com/news/1220802/e-lites-secures-product-placement-first-lily-allens-hard-here-video/>.
- [111] Bond B. *Ad watchdog warns e-cigarette brands over 'unclear' ads*. Marketing; 2013 Oct 25 Available from: <http://www.marketingmagazine.co.uk/article/1213256/ad-watchdog-warns-e-cigarette-brands-unclear-ads>.
- [112] Sherwin A. *Sexually suggestive e-cigarette advert banished to the late-night TV hinterlands after more than 100 viewers complain*. The Independent; 2014 Feb 26 Available from: <http://www.independent.co.uk/news/media/advertising/sexually-suggestive-ecigarette-advert-banished-to-the-latenight-tv-hinterlands-after-more-than-100-viewers-complain-9152162.html>.
- [113] Ministry of Health. *Electronic Nicotine Delivery Systems (ENDs), including E-cigarettes*. Wellington, New Zealand: Ministry of Health; 2013 Available from: <http://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/electronic-nicotine-delivery-systems-ends-including-e-cigarettes>.
- [114] Health Canada. *Notice To All Persons Interested in Importing, Advertising or Selling Electronic Smoking Products in Canada*. Health Canada; 2009 Mar 27 Available from: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/pol/notice_avis_e-cig-eng.php.
- [115] Canadian Lung Association. *News and Announcements*. [homepage on the internet] Canadian Lung Association; 2013 Available from: <https://www.on.lung.ca/document.doc?id=1583>.
- [116] *Smoke-free Environments Act. 1990* (NZ) s 36A.
- [117] *Smoke-free Environments Act. 1990* (NZ) s 22.
- [118] *Tobacco Act. 1997* (S.C.) c.13.