

Position Paper on Electronic Cigarettes

December 2014

Summary

- According to research commissioned by the Irish Cancer Society, there are approximately 134,000 ecigarette users in Ireland.
- Research into the long-term effects of their using e-cigarettes is not yet available.
- The Irish Cancer Society cannot recommend the use of e-cigarettes without guarantees on their longterm safety.
- In the absence of proven safety and efficacy, the Society wants the Department of Health to regulate e-cigarettes as medicinal product.
- The Irish Cancer Society is committed to a reduction in the rate of smoking in Ireland and has been a tireless advocate of the Government's goal of a Tobacco Free Ireland by 2025. We recommend that smokers seeking to quit do so by giving up immediately and permanently.
- The Irish Cancer Society wants to ensure marketing of e-cigarettes 'denormalises' smoking rather than renormalise it.
- The Irish Cancer Society believes the workplace smoking ban should not be undermined and therefore supports employers who keep their workplaces free of e-cigarette use.

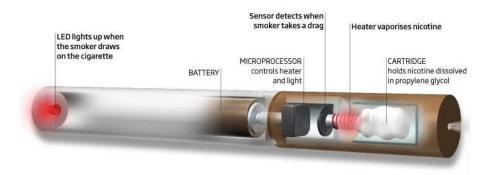
Background

Electronic cigarettes, also known as 'vaporisers' or Electronic Nicotine Delivery Systems (ENDS), are mechanical devices that are marketed as a less harmful alternative to cigarettes. While conventional cigarettes contain thousands of toxic chemicals, an e-cigarette is designed to deliver nicotine, a highly addictive substance that is poisonous in high concentrations.

There are three types of e-cigarette currently on the market in Ireland:

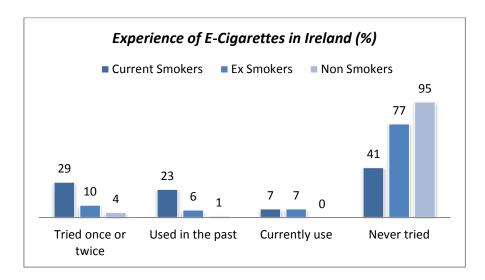
- Disposable, non-rechargeable devices that provide a certain number of 'puffs'
- Rechargeable devices using pre-filled replaceable liquid cartridges
- Rechargeable devices containing a tank or reservoir that is filled with liquid manually

E-cigarettes allow the inhalation of vaporised nicotine dissolved in propylene glycol or glycerine and are designed around a battery, an atomizer and a cartridge of liquid. The level of nicotine in an e-cigarette has been found to vary widely. When the user sucks on an e-cigarette, a sensor detects air flow and heats the liquid in the cartridge so that it evaporates. The majority of devices have a tip that lights up when used.



E-Cigarettes in Ireland

According to research commissioned by the Irish Cancer Society, there are approximately 134,000 e-cigarette users in Ireland. The vast majority of these are either current tobacco smokers or former tobacco smokers and there is little evidence that the devices are used by people who have never smoked tobacco.²



The primary motivation for e-cigarette users is to stop smoking (62%) but just over half (55%) were successful in achieving that aim. The second most popular motivation was to cut down the number of cigarettes they smoke and a similar number (59%) believed the devices helped them to do so. The research has also shown that upwards of one-third of current e-cigarette users continue to smoke tobacco cigarettes simultaneously.

Almost 8 in 10 Irish people acknowledge that not enough is known about the health effects of e-cigarettes but despite this 45% agree that the devices are not as harmful as tobacco cigarettes. 44% of Irish people say they would have 'no problem' with people using e-cigarettes in places where smoking is banned but it should be noted that a resistance to such a proposal is highest among ex-smokers as well as non-smokers. ³

Safety

Compared to smoking tobacco, e-cigarettes are deemed to be safer; however, there is no research into the long-term effects of their usage. The Irish Cancer Society cannot recommend the use of e-cigarettes without guarantees of their long-term safety.

In the absence of regulation, the quality and safety of e-cigarettes varies by brand. There have been recent media reports in Ireland and the UK of devices exploding⁴ and of an increase in incidences of nicotine

poisoning caused by e-cigarettes.⁵ In Ireland, there were as many incidents of nicotine poisoning in the first three months of 2014 as in the whole of 2013. 11 of these cases involved children less than six years of age.⁶ All were allegedly caused by the ingestion of liquid for e-cigarettes.

Nicotine affects the peripheral and central nervous systems, and has been shown to increase heart rate and blood pressure while constricting cutaneous and coronary blood vessels. Some studies suggest that nicotine may promote tumour growth in human cells. The WHO have also cautioned children and adolescents, pregnant women and women of reproductive age against using e-cigarettes because of the potential for foetal and adolescent nicotine exposure to have long-term consequences for brain development.

Do they help smokers to quit?

81 per cent of smokers in Ireland plan to quit smoking. ¹⁰ The Irish Cancer Society recommends that smokers give up immediately and permanently. Professional smoking cessation services, along with the use of traditional Nicotine Replacement Therapies (NRT) increase the chances of success in quitting up to four times. ¹¹ Yet, there is evidence to suggest that smokers are increasingly relying on e-cigarettes to help them give up, ¹² and that a majority of people have found them more effective than traditional NRT. ¹³

The World Health Organisation has stated that "the electronic cigarette is not a proven nicotine replacement therapy" ¹⁴ and much of the research into e-cigarettes has been unable to assess whether they help people to quit.

Quitting all nicotine remains the safest and most reliable way of giving up smoking. Further research into the efficacy of e-cigarettes as an aid to quit is required before the Irish Cancer Society can recommend these devices. There is evidence that smokers relying on e-cigarettes to quit are using them alongside tobacco and becoming 'dual-users'. ¹⁵ The use of even a small number of cigarettes is detrimental to a person's health and increases their chances of developing lung cancer.

E-cigarettes could be a tool for harm reduction in the future, but for this to happen, studies of the long-term effects must be concluded and the regulation of <u>all</u> e-cigarettes as medicinal products is a must. The revised EU Tobacco Products Directive means Ireland must regulate any e-cigarette with a nicotine level above 20mg/ml as a medicinal product. The Department of Health should go further. Such regulation should inform tobacco smokers in making decisions on the best way for them to quit.

Legislation

There are currently no regulations governing the sale or safety of e-cigarettes. The devices are not considered tobacco or medicinal products and are regulated in the same way as other consumer products such as watches and toys. For this reason, no two brands of e-cigarette are the same and the Irish Cancer Society has serious concerns with regard to their safety and efficacy.

In 2014, agreement was reached to include e-cigarettes in the European Union's Revised Tobacco Products Directive (TPD). ¹⁶ The new rules which must come into effect in Ireland by 2016 include:

- banning the sale of e-cigarettes to under-18s
- improved safety and quality requirements for products
- new packaging and labelling requirements
- E-cigarette manufacturers will be required to notify Member States before placing new products on the market and report annually on the sales volumes of the products, types of users and their preferences and trends.

specific rules on advertising

However the Irish Cancer Society believes that the onus is on the Irish authorities to build on the provisions of the Tobacco Products Directive and introduce further regulation on:

- classifying all e-cigarettes as medicinal products
- banning of certain flavours of e-cigarette liquid
- marketing and advertising
- the 're-normalisation' of smoking

Legislation around Europe¹⁷

Country	Status
Austria	Classified as a medicinal device; liquid containing nicotine regulated as a pharmaceutical
Belgium	Medical licence required for the sale of refills or cartridges of liquid containing nicotine.
Denmark	Nicotine-containing devices regulated as a pharmaceutical product
France	Presented as cessation treatment – listed as a pharmaceutical
	If not, >10mg of nicotine – listed as a pharmaceutical;
	<10mg of nicotine – general safety rules
Sweden	Liquid containing nicotine regulated as a pharmaceutical
UK	By 2016, all e-cigarettes to be regulated as medicines
■ IRELAND	Consumer regulation only

Marketing

The vast majority of e-cigarette users are smokers who see them as an alternative to tobacco. Nevertheless, there is a growing market for e-cigarettes and 96% of the adult population are aware of the device. ¹⁸ The Irish Cancer Society welcomes government moves to ban the sale of e-cigarettes to people under the age of 18. ¹⁹

The Society and the Irish Heart Foundation commissioned research on branding and packaging as part of our campaign for the introduction of standardised packaging of tobacco. It is clear from this research that branding and marketing is integral to teens' lives and the focus groups indicated that design and marketing influenced everything from perception of quality to the likely users of the brand.²⁰ It is for these reasons that we believe there is an urgent need to regulate the marketing of e-cigarettes.

E-cigarettes are not classified as a tobacco product in Ireland and therefore are not subjected to the same restrictions on advertising and marketing. The Advertising Standards Authority of Ireland (ASAI) has no specific provisions in their code regarding e-cigarettes, however the Department of Health are providing input to a revised Code that will include e-cigarettes. The Society welcomes this and envisages that it will reflect the revised EU Tobacco Products Directive (TPD) which includes a ban on advertising in the press, on radio and television and at events involving several EU countries. However, TPD provides only a base for countries to regulate domestic marketing and advertising. TPD won't regulate the many exotic flavours available for e-cigarettes, for example. Neither will it regulate the many innovations happening in branding and marketing.

Numerous flavours from beer to banana and bubblegum and variations such as e-shisha are promoted in colourful and innovative packaging. Blu Ecigs, for example, introduced 'smart packs' that alert users when they come into fifty feet of other users – both packs start vibrating and flashing a blue light. The packs can be set to transmit Facebook and Twitter profiles in the event that users do not wish to approach others in real life settings, but would rather make virtual friends.

- 'E-cigarette uptake and marketing', A Report for Public Health England ²³

The Irish Cancer Society wants to ensure marketing of e-cigarettes continues to 'denormalise' smoking rather than renormalise it.

The Tobacco Industry

The growth in the e-cigarette market has seen independent developers and suppliers being acquired by tobacco companies in pursuit of profit. All major tobacco multinationals are now active in the e-cigarette industry and this is a cause of concern to the Irish Cancer Society.

Lorillard – the third largest tobacco company in the United States – paid €113 million for the e-cigarette company Blu in 2012 and paid €38 million to the Scottish-based Skycig in 2013. ²⁴ Philip Morris (PMI), the brand behind Marlboro bought the e-cigarette start-up Green Smoke Inc. for €83 million in February 2014. ²⁵ British American Tobacco (BAT) – which owns PJ Carroll in Ireland – merged its wholly-owned subsidiary Nicoventures with their own Research and Development Department to create 'Vype' e-cigarette. ²⁶

"This is a huge growth opportunity. We want to lead."

- Dr David O'Reilly, British American Tobacco²⁷

Academics suggest the Big Tobacco's involvement in e-cigarettes will merely serve to 're-normalize' an industry that is determined to be seen as a responsible business with a legitimate product.²⁸

The Irish Cancer Society maintains that the WHO Framework Convention on Tobacco Control (FCTC) must be upheld.²⁹ The Convention recognises the 'fundamental and irreconcilable conflict between the tobacco industry's interests and public health policy interests'. Article 5.3 of the Convention also states that Government must protect health policy from the vested interests of the tobacco industry.

Ireland is a signatory to FCTC and it is imperative that State bodies continue to maintain a distance from the vested interests of the tobacco industry.

E-cigarettes and the Workplace Smoking Ban

Ireland recently marked ten years since the introduction of the Workplace Smoking Ban, which was designed to reduce the risk to employees of second-hand smoke and to encourage more smokers to quit. The ban has been an unqualified success with the number of smokers falling by a quarter in ten years. ³⁰

While there is little doubt second-hand vapour from an e-cigarette is less harmful than second-hand tobacco smoke, vapour does contain toxicants. ³¹ Further research is required into the impact of exposure to e-cigarette vapour.

Allowing e-cigarettes to be used in places where tobacco is banned could delay or prevent quit attempts by those who would otherwise have quit. Wales has proposed the inclusion of e-cigarettes in the existing workplace smoking ban 'to ensure their use does not undermine smoking prevention and cessation by reinforcing and normalising smoking'.³²

In Ireland, it is not illegal to use e-cigarettes in the workplace, but the vacuum in the absence of regulation means that individual companies have already banned e-cigarettes including the HSE, Dublin Bus, Irish Rail and some shopping centres.³³

The Irish Cancer Society believes the workplace smoking ban should not be undermined.

In deciding whether e-cigarettes undermine the workplace smoking ban, businesses and organisations should consider:

- Do you have concerns about the relative safety and harm from e-cigarettes?
- Are you considering a ban to continue projecting a 'clean, healthy' image of your business?
- Does a ban need to cover 'lookalike' e-cigarettes or all vapour-emitting devices?
- Is a ban practical for your business? 34

The future of e-cigarettes

Product innovation is seeing a boost in the sales of e-cigarettes, with companies vying for a share of the industry worth around €115 million globally per year. ³⁵ In Ireland, there are an estimated 134,000 current users of e-cigarettes with an increasing number of people trialling them to cut down or quit smoking.

Companies are coming up with new ways of attracting smokers with e-cigarettes housing Bluetooth technology, devices linked to mobile phone apps and products that emit no vapour when exhaled in order to 'revolutionise vaping in public places'. ³⁶

The EU Tobacco Products Directive – which will introduce regulations on e-cigarettes for the first time including a ban on selling to under-18s and restrict marketing – must be introduced in Ireland by the end of 2016. The Department of Health here has stated its intention to introduce some regulations by the end of 2014.

The Irish Cancer Society welcomes the introduction of laws covering a thus far unregulated industry. However, in the absence of proven safety and efficacy, the Society wants the Department of Health to regulate ecigarettes as medicinal product.

This is the only method by which e-cigarettes can be regarded as an aid to the quitting of smoking.

For information and support on how to quit smoking, call the HSE Quit Team on Freefone 1800 201 203 or visit Quit.ie

http://www.irishtimes.com/news/politics/oireachtas/alarming-rise-in-nicotine-poisoning-in-children-could-lead-to-fatalities-d%C3%A1il-hears-1.1793736

 $\frac{http://oireachtasdebates.oireachtas.ie/debates\%20authoring/debateswebpack.nsf/takes/dail2014051300032}{?opendocument\#EE00550}$

¹ Callahan-Lyon P., *Tobacco Control* 2014; 23:ii36-ii40

² Amárach Research on behalf of the Irish Cancer Society, July 2014

³ 44% of ex-smokers opposed the use of e-cigarettes in places where smoking is banned, as opposed to 14% of smokers and 44% of non-smokers - *Amárach Research on behalf of the Irish Cancer Society, July 2014*

⁴ Nick Lavingue, (2013) The Mirror, 21 December 2013, http://www.mirror.co.uk/news/uk-news/e-cigarette-dangers-fire-chiefs-warning-2949094

⁵ Marie O'Halloran, (2014) The Irish Times, 14 May 2014,

⁶ Dáil Debates, 13 May 2014, *Tobacco Control Measures*,

- ¹⁸ Amárach Research on behalf of the Irish Cancer Society, July 2014
- ¹⁹ Hugh O'Connell, (2014) The Journal, 25 June 2014, http://www.thejournal.ie/e-cigraettes-regulations-ban-1535919-Jun2014/
- ²⁰ 'The Impact of tobacco branding and standardised packaging on young people', Ignite Research on behalf of the Irish Cancer Society and Irish Heart Foundation, September 2013
- ²¹ Letter from Mr Frank Goodman, Chief Executive, ASAI, to Ms Kathleen O'Meara, Irish Cancer Society, 2 April 2014
- ²² For more information on the EU Revised Tobacco Products Directive, see: http://ec.europa.eu/health/tobacco/products/revision/
- ²³ Bauld, L. et al, (2014), *E-Cigarette uptake and marketing: a report commissioned by Public Health England*, **Public Health England**
- ²⁴ Drugfree.org (2013), *Tobacco Companies Move into E-Cigarette Business*. [website. http://www.drugfree.org/uncategorized/tobacco-companies-move-into-e-cigarette-business; and Progressive
- Media Company News (2014). Lorillard reports fourth quarter & full year 2013 results, 13 February 2014 ²⁵ Esterl M (2014). *Altria expands in e-cigarettes with Green Smoke*. The Wall Street Journal.
- http://online.wsj.com/news/articles/SB10001424052702304626804579360552508696542
- TobaccoTactics (2014). Companieshouse, Nicoventures Holding Ltd, Webcheck, latest entry 21 January 2014. http://www.tobaccotactics.org/index.php/E-cigarettes#cite_note-0
- John Arlidge, (2013) The Sunday Times, 15 December 2013, Relax. Light up your life with an e-cig.
- ²⁸ Peeters S, et al. Tob Control 2014;0:1–7. doi:10.1136/tobaccocontrol-2013-051502
- ²⁹ For more information on the WHO Framework Convention on Tobacco Control, see: http://www.who.int/fctc/about/en/
- ³⁰ HSE statistics taken from Smoking Prevalence Statistics 2004-2012, available from: http://www.hse.ie/eng/about/Who/TobaccoControl/Research/acc fig 2 1.jpg
- ³¹ Goniewicz et al. (2013), Levels of selected carcinogens and toxicants in vapour from electronic cigarettes, Tobacco Control, doi:10.1136/tobaccocontrol-2012-050859
- ³² Welsh Government (2014), Listening to you: Your health matters, White Paper published 2 April 2014
- ³³ Michael Sheils-McNamee (2014), The Journal, 9 July 2014, http://www.thejournal.ie/electronic-cigarettes- blanchardstown-1559880-Jul2014/
- Taken from 'Will you permit or prohibit e-cigarette use on your premises?', a briefing note by ASH UK, Royal Society of Public Health, Trading Standards Institute, UK Centre for Tobacco and Alcohol Studies and the Chartered Institute of Public Health, January 2014, see: http://ash.org/wp-content/uploads/2014/02/ASH-Ecig-briefing.pdf

 35 Chittock M (2014). Focus on e-cigarettes: A touch of the vapours. The Grocer, February 15th: 51-52, 54
- ³⁶ PR Newswire Europe (2014). *British e-cigarette brand launches vapourless e-liquid to address vaping bans* March 12

⁷ Benowitz NL. Cigarette smoking and cardiovascular disease: *Pathophysiology and implications for treatment.* Prog Cardiovasc Dis 2003;46:91-111

⁸ Dasgupta et al. (2009), Nicotine induces cell proliferation, invasion and epithelial-mesenchymal transition in a variety of human cancer cell lines, Int J Cancer, 124(1):36-45

⁹ World Health Organisation, 'Electronic nicotine delivery systems: Report by WHO', 21 July 2014

¹⁰ Ipsos MRBI poll on behalf of the Irish Cancer Society, January 2014

¹¹ Fenton, K. (2014), E-Cigarettes and harm reduction: where are we now and what next?, Public Health

¹² West, R, *Trends in electronic cigarette use in England*, Smoking Toolkit Survey, Presentation.

¹³ Brown J, Beard E, Kotz D, Michie S & West R. Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study. Published online 20 May 2014

¹⁴ World Health Organization. Report on the scientific basis of tobacco product regulation: third report of a WHO study group. Geneva, World Health Organization, 2009

¹⁵ 36% of current e-cigarette users in Ireland smoke regular tobacco as well as e-cigarettes - *Amárach Research* on behalf of the Irish Cancer Society, July 2014

¹⁶ For more information on the EU Tobacco Products Directive see: <u>http://europa.eu/rapid/press-</u> <u>release_MEMO-14-134_en.htm</u>

17 Tiessen et al. (2010), Assessing the Impacts of Revising the Tobacco Products Directive, RAND Europe