



Policy statement

Electronic cigarettes

Introduction

The use of e-cigarettes is a contentious tobacco control issue. Health professionals are divided about the possible harms that e-cigarettes present and their potential as a healthier alternative to smoking, due to a lack of evidence regarding the long-term effects of these products. However, trends show that smokers and ex-smokers are increasingly using e-cigarettes as a smoking cessation aid.

Policy statement

Evidence on the safety and long-term effects of e-cigarettes is still emerging. More research is needed into the efficacy and health impacts of these products, and the extent to which they act as a gateway for people to start smoking.

We recognise that e-cigarettes are increasingly being used as a cessation aid. It is therefore important they should be regulated (and responsibly marketed) for this purpose.

E-cigarettes as a quitting aid

- We would like to see the medicinal regulation of all e-cigarettes to ensure the safety, quality and efficacy of these products and to ensure they are regulated according to how they are increasingly being used – as cessation aids.
- We believe there is pressing need for further research, including long-term studies and attitudinal surveys, on the effects of nicotine use.

Marketing of e-cigarettes

- We believe e-cigarettes should be advertised only as an alternative to tobacco.
- E-cigarettes should not be advertised in ways or through channels that could make them appealing to non-smokers, and children and young people.
- We advocate monitoring of e-cigarette marketing to ensure that it does not interfere with existing quit messages, or encourage non-smokers or children to start using these products.

Use of e-cigarettes in public places

- We are concerned that the widespread use of e-cigarettes in public places could undermine the progress that has been made through the smoking ban and similar legislation - making smoking in public appear socially "acceptable" once again
- Continued research is needed on the impact of e-cigarette use in public places
- We support a ban on the sale of e-cigarettes to under 18s and urge that this be made UK-wide at the earliest opportunity.

Background

What are electronic cigarettes?

An electronic cigarette (e-cigarette) is a battery powered device that simulates standard tobacco cigarettes by vaporising nicotine and other chemicals into an inhalable vapour, which delivers nicotine straight to the blood stream via the mouth and lungs. E-cigarettes are a relatively recent innovation in the delivery of nicotine and are designed to look and feel similar to standard cigarettes.

Types of electronic cigarettes

A typical e-cigarette consists of three main components: a battery, an atomiser and a cartridge containing nicotine. However, there is a significant variation in the styles, shapes and sizes of e-cigarettes. E-cigarettes typically take the following forms:

- **First generation:** These are similar in appearance to cigarettes, do not contain liquid nicotine and are available as single items (disposable) or rechargeable in 'cigarette-like' packs.
- **Second generation:** These do not resemble cigarettes and are more sophisticated devices with longer lasting batteries. The user fills the cartridge with nicotine fluid and there is a greater choice of fluid flavour/strength. These are predominantly used by experience users.
- **Third generation modified e-cigarettes** (also known as 'mods'): personalised e-cigarettes/vapourisers, where voltage and strength can be altered by the user to influence the strength and taste of the product.¹



Research indicates that second and third generation models are better for providing more effective nicotine delivery.²

There are also other e-cigarette products called 'e-shisha', which commonly include fruit flavourings, and 'e-cigars' which are designed to look and feel like real cigars.



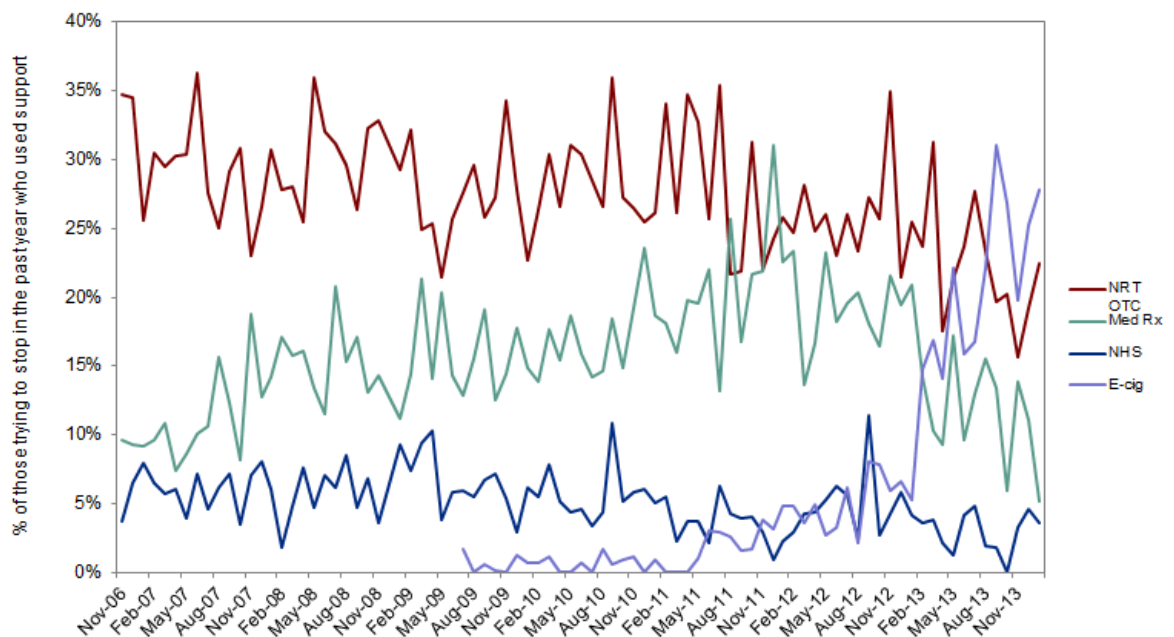
¹ Dawkins L. E-cigarettes: a brief guide. The E-cigarette Summit, Science Regulation and Public Health, The Royal Society, London, November 12th 2013. Presentation available at: <http://e-cigarette-summit.com/presentations/>

² Ibid.

Who and how many people use e-cigarettes?

It is estimated that there are more than 2 million current users of e-cigarettes in the UK.³ The number of people reporting having tried e-cigarettes has tripled since 2011 when 700,000 people reported using the devices. More than half (51.7%) of smokers and ex-smokers have now tried e-cigarettes.

Current evidence indicates that e-cigarettes are used by both smokers and non-smokers, but there is currently little evidence of use in the UK by those who have never smoked or by children.⁴ According to the Smoking Toolkit study, a monthly household survey that collects information regarding individuals smoking habits, an estimated 1 in 6 current or former smokers use e-cigarettes, with 1 in 10 using them daily.⁵ Furthermore, almost 1 in 3 quit attempts involve use of e-cigarettes.⁶



NRT OTC: Nicotine replacement therapy bought over the counter; Med Rx: Prescription medication; NHS: NHS Stop Smoking Service; E-cig: Electronic cigarette



Support used in quit attempts – Smoking Toolkit Study⁷

However, in the US there is some evidence to suggest that e-cigarette use among children is increasing. The Centers for Disease Control and Prevention published data from the National Youth Tobacco Survey showing that the percentage of high school students who reported ever using an e-cigarette rose from 4.7 per cent in 2011 to 10.0 per cent in 2012.⁸

³ Action on Smoking and Health. ASH Briefing: electronic cigarettes; 2014. Available at http://www.ash.org.uk/files/documents/ASH_891.pdf

⁴ Ibid.

⁵ West R, Beard E, Brown J. Trends in electronic cigarette use in England. The E-cigarette Summit, Science Regulation and Public Health, The Royal Society, London, November 12th 2013. Presentation available at: <http://e-cigarette-summit.com/wp-content/uploads/2013/11/2-Prof-WestTrends-in-ecigarette-use-in-England-2.pptx>

⁶ Ibid.

⁷ Smoking Toolkit Study. Monthly tracking of key performance indicators – STS120720; 2014. Available at: <http://www.smokinginengland.info/downloadfile/?type=sts-documents&src=20>

⁸ Centers for Disease Control and Prevention. E-cigarette use more than doubles among U.S. middle & high school students from 2011-12; 2013. Available at: <http://www.cdc.gov/media/releases/2013/p0905-ecigarette-use.html>

Current regulatory arrangements in relation to e-cigarettes

E-cigarettes are marketed as ‘alternative smoking devices’ rather than smoking cessation devices to aid quitting, and by not making any health claim they have avoided being regulated as medical devices like Nicotine Replacement Therapy (NRT) to date. Despite their claimed function, as an alternative to smoking, anecdotal evidence indicates that smokers are using e-cigarettes to help cut down or quit.

At present e-cigarettes are covered under general product safety regulations and monitored by trading standards.^{9,10} However, without medicinal regulation these products have not been subject to rigorous testing to ensure their safety, quality and efficacy.

Recent regulatory developments

Following a public consultation and extensive scientific and market research, the Medicines and Healthcare Products Regulatory Agency (MHRA) had announced plans to regulate all e-cigarettes as medicinal products from 2016, to ensure the safety, quality and efficacy of these products. However, following agreement on the Tobacco Products Directive there will now be a dual regulatory process, for general consumer e-cigarettes and for those seeking a medicinal license.

The revised Tobacco Products Directive will require the following of all consumer e-cigarettes:

- **Safety and quality requirements**

There will be a maximum nicotine concentration level for e-cigarettes and maximum volumes for cartridges, tanks and containers of nicotine liquids. These will have to be child and tamper-proof and protected against leakage to limit the risk of exposing consumers – in particular children – to the risks of handling or ingestion. Only ingredients of high purity may be used in the nicotine-containing liquid, and e-cigarettes will be required to deliver the nicotine doses at consistent levels under normal conditions of use. This means that a similar level of nicotine should be delivered each time an e-cigarette is puffed for the same amount of time and with the same strength.
- **Packaging and labelling**

Health warnings on e-cigarette packs will be mandatory, as will instructions for their use, information on addictiveness and toxicity, a list of all substances contained in the product and information on the product's nicotine content. No promotional elements will be allowed on packs.
- **Monitoring**

Member State authorities and the Commission will be able to act in cases of justified safety concerns relating to these products. Authorities will monitor the market for any evidence that e-cigarettes lead to nicotine addiction or to traditional tobacco consumption, especially in young people and non-smokers, and the Commission will report on safety concerns and market developments.

⁹ Medicines and Health Regulatory Authority. The Regulation of Nicotine Containing Products (NCPs) MHRA; 2013. Available at: <http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con286834.pdf>

¹⁰ Trading Standards. Guidance on electronic cigarettes and E-liquids; 2013.

- **Marketing**

Existing rules for cross-border advertising and promotion of tobacco products will also apply to e-cigarettes.

E-cigarette manufacturers will also have to notify Member States when new products come on the market and report annual on sales and user types. The new rules will not apply to medicinal e-cigarettes (as set out in Directive 2001/83/EC on medicinal products for human use) or medical devices (Directive 93/42/EEC on medical devices), but will cover all consumer electronic cigarettes placed on the EU market. The new Directive should enter into force in May 2014. Member States will then have two years to bring national legislation into line with the revised Directive – the new rules should apply in the first half of 2016.

At present the MHRA is encouraging e-cigarette manufacturers to opt in and is as a result processing applications for several products, which could gain a licence as early as 2014.

In February 2014, Westminster voted to ban the sale of e-cigarettes to those under 18 years of age in England as part of the Children and Families Bill.¹¹ This will come into effect from autumn 2014 and will also apply in Wales.¹²

Research regarding e-cigarettes

To date, e-cigarettes have been subjected only to minimal scientific study and there are no studies regarding the effects of their long-term use. There is a lack of empirical research regarding the effectiveness of e-cigarettes as a smoking cessation aid and some medical professionals have expressed concern regarding inadequate data about their contents and emissions.¹³ Contrasting research studies have recently been published on this issue. For example, a recent small randomised controlled trial of 657 people by the University of Auckland has found that e-cigarettes may be as effective as nicotine patches, though the researchers that conducted the study concluded that more research was urgently needed to clearly establish their overall benefits and harms at both individual and population levels.¹⁴ In contrast, a very small Phase I trial of 32 people by the University of Athens in September 2012 suggested that they may be damaging to the lungs.¹⁵ A separate University of Auckland study of 40 participants found that e-cigarettes have a low toxicity profile, are well tolerated, and are associated with only mild adverse effects equivalent to a nicotine inhaler.¹⁶ However, the authors again stressed the need of further research examining longer-term safety, potential for long-term use and efficacy as a cessation aid.

The MHRA's expert review on the regulation of NCPs identified research studies that had detected additives and potentially harmful contaminants in e-cigarettes. The review group found that 'available safety data was mainly limited to surveys in which patients report only minor side effects, such as mouth and throat irritation, headache,

¹¹ <http://news.sky.com/story/1209590/smoking-in-cars-with-children-will-be-banned>

¹² <http://www.walesonline.co.uk/news/wales-news/legislation-ban-e-cigarettes-under-18s-6671769>

¹³ German Cancer Research Center (ed.), 2013, Red Series Tobacco Prevention and Tobacco Control Volume 19: Electronic Cigarettes – An Overview, German Cancer Research Center: Heidelberg, http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/RoteReihe/Band_19_e-cigarettes_an_overview.pdf

¹⁴ NHS Choices. Vaping 'matches patches for stopping smoking'; 2013. Available at:

<http://www.nhs.uk/news/2013/09september/Pages/e-cigarettes-as-good-as-patches-for-quitting-smoking.aspx>

¹⁵ NHS Choices., E-cigarettes 'may damage lungs'; 2013. Available at:

<http://www.nhs.uk/news/2012/09september/pages/e-cigarettes-may-damage-lungs.aspx>

¹⁶ Bullen C, McRobbie H, Thornley S, Glover M, Lin R, Laugesen M. Effect of an electronic cigarette on desire to smoke and withdrawal, user preferences and nicotine delivery: randomized cross-over trial. Tobacco Control 2010; 19: 98–103. Available at: <http://europepmc.org/abstract/MED/20378585>

dizziness, and nausea. Furthermore, more serious adverse events had been reported in the literature and media, such as possible aspiration pneumonia, and second-degree burns to the face following the product exploding in a consumer's mouth.¹⁷ Based on the evidence they gathered, the expert review group concluded that the long-term safety of the components contained within e-cigarettes to the consumer was unknown.

Research from Germany has since suggested that e-cigarettes are not emission free and their pollutants could be of health concern for users and secondhand smokers.¹⁸ This small study, using nine volunteers, was designed to replicate e-cigarette use in typical indoor environments, with results indicating that their use increases fine particle air pollution and levels of potentially carcinogenic compounds in people who use them.

E-cigarettes and harm reduction

Evidence indicates that e-cigarettes may be less harmful than smoked tobacco and as such have a potential role to play as part of a harm reduction strategy. Whilst quitting smoking is always the best option for smokers, a harm reduction approach helps smokers who are not currently able to quit to cut down and use alternative substitutes for smoking, where necessary indefinitely.

In June 2013, the National Institute for Health and Care Excellence (NICE) published guidance on harm reduction.¹⁹ Reflecting new developments in relation to harm reduction, the NICE guidance acknowledges that some smokers use e-cigarettes as smoking cessation aid. However, it does not recommend the use of e-cigarettes as they are currently unlicensed and NICE reports that there is little evidence available regarding their safety quality and efficacy.²⁰ Instead, NICE recommends that nicotine-containing products licensed by the MHRA should be used.

Related themes and concerns raised in relation to e-cigarettes

At present, public health professionals remain divided regarding the possible effects of e-cigarettes. Advocates believe that e-cigarettes have the potential to prevent the premature death of millions of smokers, contrastingly, critics believe that e-cigarettes undermine efforts to prevent smoking and present health and safety concerns.²¹ Key concerns raised in relation to e-cigarettes include:

- **Renormalisation of smoking**

As e-cigarettes resemble cigarettes there are concerns that they undermine the denormalisation of tobacco use.²² Concerns have been raised that the use of e-

¹⁷ Medicines and Health Regulatory Authority. The Regulation of Nicotine Containing Products (NCPs) MHRA; 2013. Available at: <http://www.mhra.gov.uk/home/groups/comms-ic/documents/websitesources/con286834.pdf>

¹⁸ Schober W, Szendrei K, Matzen W, Osiander-Fuchs H, Heitmann D, Schettgen T, Jörres RA, Fromme H. Use of electronic cigarettes (e-cigarettes) impairs indoor air quality and increases FeNO levels of e-cigarette consumers. *Int J Hyg Environ Health* Dec 2013, doi:10.1016/j.ijheh.2013.11.003. Available at: <http://europepmc.org/abstract/MED/24373737>

¹⁹ National Institute for Health and Care Excellence. Tobacco: harm-reduction approaches to smoking, NICE public health guidance 45; 2013 Available at: <http://www.nice.org.uk/nicemedia/live/14178/63996/63996.pdf>

²⁰ Ibid.

²¹ British Medical Association. Why are we concerned about e-cigarettes; 2013. Available at: <http://bma.org.uk/working-for-change/improving-and-protecting-health/tobacco/e-cigarettes>

²² De Andrade M, Hastings G. Tobacco Harm Reduction and Nicotine Containing Products: Research Priorities and Policy Directions. *Social Marketing. Cancer Research UK*; 2013. Available at: http://www.cancerresearchuk.org/prod_consump/groups/cr_common/@nre/@pol/documents/generalcontent/tobacco-harm-reduction.pdf

cigarettes models smoking to young people and queries have been raised as to whether e-cigarettes serve as a gateway to smoking conventional cigarettes – some reports suggest this may already be happening to some extent.²³ Critics of the tobacco industry have raised concerns about dual usage, smokers using e-cigarettes alongside smoked tobacco, however, at present there appears to be no evidence that this is occurring.

- **Enforcement of smokefree legislation**

At present, e-cigarettes are not subject to smokefree legislation and users are able to use them in public places at individual business owners' discretion.²⁴ However, there is disagreement within the public health community regarding whether it is appropriate to bring e-cigarettes under existing smokefree law. A number of areas of the US have moved to ban their use in enclosed public places – including both Chicago and New York City.²⁵

Action on Smoking and Health (ASH) has suggested that there is little evidence of the harm of e-cigarettes to date, and that nicotine products are less harmful than smoked tobacco.²⁶ In contrast, the British Medical Association and Public Health Wales believe e-cigarettes should be brought under smokefree legislation to prevent the renormalisation of smoking and protect others from being exposed to e-cigarette vapours.^{27,28}

2nd April 2014 the Welsh Health Minister Mark Drakeford launched The 'Listening to you – Your health matters' White Paper which sets out a series of proposals for legislation to help further improve and protect people's health and wellbeing in Wales. On electronic cigarettes he said:

"I have concerns about the impact of e-cigarettes on the enforcement of Wales' smoking ban. That's why we are proposing restricting their use in enclosed public places.

"I am also concerned that their use in enclosed public places could normalise smoking behaviour.

"E-cigarettes contain nicotine, which is highly addictive, and I want to minimise the risk of a new generation becoming addicted to this drug."

There is a ban on smoking e-cigarettes in public places in Ukraine, Italy, Turkey. Israel has announced measures to ban smoking of e-cigarettes in public places

- **E-cigarette marketing and sponsorship**

Academic research and public health charities have drawn attention to the need to actively monitor e-cigarette advertising to ensure that they do not interfere with quit smoking messages and do not encourage uptake of smoking amongst young people.

²³ Ibid.

²⁴ Action on Smoking and Health. ASH Briefing: Electronic cigarettes; 2013. Available at: http://ash.org.uk/files/documents/ASH_715.pdf

²⁵ <http://www.businessweek.com/articles/2014-02-06/e-cigarettes-fda-regulation-looms-for-1-dot-5-billion-industry>

²⁶ Ibid.

²⁷ British Medical Association. BMA Briefing: E-cigarettes in public places and workplaces; 2013. Available at: <http://bma.org.uk/working-for-change/improving-and-protecting-health/tobacco/e-cigarettes>

²⁸ <http://www.wales.nhs.uk/sitesplus/888/news/30545>

E-cigarettes have been aggressively promoted both in the UK and around the world, and concerns have been raised that promotional images and messages used in e-cigarette advertising are very similar to cigarettes advertising used in the past.²⁹

There has been an increase in e-cigarette sponsorship of sports events, including motor racing, football and football stadia.^{30,31} This includes Merthyr Town renaming their ground the "Cigg-e Stadium".³² E-lites, a leading an e-cigarette company, has also signed a partnership deal with leading national entertainment venue, the O2 Arena in London, which will permit smoking of e-cigarettes during events.³³ Several brands have also begun to produce TV advertising.

In recognition of the need to provide greater clarity and controls in relation to e-cigarette advertising, the Committee of Advertising Practice (CAP) has announced plans to introduce new advertising rules for electronic cigarettes that will give clarity to advertisers and ensure e-cigarettes are promoted responsibly. CAP's consultation launched in February 2014 and the BHF responded in April 2014 supporting the steps to make advertising of e-cigarettes socially responsible.³⁴

- **Tobacco industry involvement in manufacturing e-cigarettes**

Large tobacco companies have entered into the e-cigarette business and/or are developing their own e-cigarette devices. Their involvement has raised concerns regarding dual usage, with fears that tobacco companies may use e-cigarettes to entice people to take up smoked tobacco. There are also concerns that they may use the issue of e-cigarettes to rehabilitate their public image – allowing 'Big Tobacco' to inappropriately engage in discussions regarding public health.

Major UK pharmacies are beginning to sell e-cigarettes owned by the tobacco industry. Boots started selling Fontem's Puritane (owned by Imperial Tobacco) in its pharmacies in February 2014, while Lloydspharmacy is selling NicoVentures's Vype (owned by British American Tobacco).³⁵ This is not supported by the Royal Pharmaceutical Society, which has said that until there is a licensed product they cannot support their sale in pharmacies.³⁶

Vype also featured in broadcast advertising on 17 February 2014 – the first advert from a tobacco company in 20 years.³⁷ These advertisements carry the strap line "pure satisfaction for vapers" on television but "pure satisfaction for smokers" online.

For more information, please contact policy@bhf.org.uk

²⁹ De Andrade M, Hastings G. Tobacco Harm Reduction and Nicotine Containing Products: Research Priorities and Policy Directions. Social Marketing. Cancer Research UK; 2013. Available at: http://www.cancerresearchuk.org/prod_consump/groups/cr_common/@nre/@pol/documents/generalcontent/tobacco_harm-reduction.pdf

³⁰ <http://www.bbc.co.uk/news/uk-england-derbyshire-23876166>

³¹ <http://www.britishsuperbike.com/partners.aspx>

³² <http://www.bbc.co.uk/news/uk-wales-south-east-wales-23779140>

³³ <http://www.theo2.co.uk/about/e-lites.html>

³⁴ <http://www.cap.org.uk/News-reports/Consultations/~media/Files/CAP/Consultations/CAP%20and%20BCAP%20consultation%20on%20the%20marketing%20of%20e-cigarettes.ashx>

³⁵ http://www.pionline.com/news/boots_and_lloyds_join_the_vaping_fold_by_selling_ecigarettes

³⁶ Ibid.

³⁷ <http://www.telegraph.co.uk/culture/tvandradio/10645228/Smoking-is-back-on-TV-for-first-time-in-20-years.html>