Policy Position Summary

Cancer Research UK is determined to reduce deaths from smoking-related cancers and supports measures to help people quit. Electronic cigarettes (e-cigarettes) are almost certainly much safer than tobacco cigarettes and may help smokers to cut down or quit smoking. A balanced approach is needed towards e-cigarettes – one that maximises their potential to help people quit smoking, whilst minimising the risks of unintended consequences that could promote smoking.

Regulation and safety of e-cigarettes

It is important that regulation does not stifle the development of e-cigarettes nor make accessing these products more difficult for smokers. The revised EU Tobacco Products Directive will introduce the regulation of e-cigarettes contents, capacity and promotion, but will only require products that make cessation aid claims to be licensed as medicines. We recognise there are risks inherent in this dual track approach for e-cigarette regulation but welcome progress towards ensuring these products are safer, more effective, and readily accessible to smokers. We support light-touch MHRA licensing of e-cigarettes making cessation claims as it will provide a system for assessing the products and evidence supporting their claim, and for tracking adverse reactions.

Preventing e-cigarette use among children

It is important that adequate protections exist to stop the promotion of e-cigarettes to young people. The new CAP/BCAP marketing rules are a positive step, but further measures are needed to prevent e-cigarettes appealing to young people. We also welcome the Government’s ban of the sale of nicotine containing products such as e-cigarettes to under-18s.

The use of e-cigarettes indoors

At present, we do not believe there is enough evidence to justify an indoor ban on e-cigarettes. E-cigarette vapour does contain toxicants; however this is usually at levels which are far lower than those found in tobacco cigarettes.

Tobacco industry involvement

Article 5.3 of the WHO Framework Convention on Tobacco Control (FCTC) seeks to protect public health policy from interference by vested interests. It is critically important that the tobacco industry’s investment in the e-cigarette market does not provide them with an opportunity gain such influence.

Our research into e-cigarettes

We believe more evidence is needed on the impact of e-cigarettes to help inform smokers and policymakers looking to reduce the harm from tobacco. This is why we are increasing our investment in e-cigarette research, promoting the development of a prioritised research agenda, and facilitating information sharing within the research community.
Background

Electronic cigarettes (e-cigarettes) are devices that allow users to inhale vaporised nicotine dissolved in propylene glycol or glycerine through a device often shaped like a cigarette. The majority of e-cigarette users are also smokers.\(^1\) It is estimated that in the UK 18% of smokers were currently using e-cigarettes in 2014 – approximately 2.1 million people.\(^2\) This has increased from 3% in 2010.\(^3\)

The first generation of e-cigarettes (sometimes called ‘cig-alikes’) are products designed to look like normal tobacco cigarettes and carry a glowing LED tip at the end. Alongside these we have also begun to see greater use of second generation ‘tank style’ e-cigarettes, which can be refilled by the owner. Some second and third generation ‘customisable models’ also allow for the power to be adjusted, which can affect nicotine delivery.

It has been suggested that consumption of e-cigarettes will overtake traditional cigarettes in the next decade.\(^4\) The main reason smokers report having used e-cigarettes is to “help me reduce the amount of tobacco I smoke, but not stop completely” (48%); followed by “help in a quit attempt” (30%); and “to save money compared with tobacco smoking” (37%).\(^1\) This reflects the results of the Smoking Toolkit Study which has shown a sharp rise in the number of smokers using e-cigarettes in quit attempts (see Figure 1).\(^5\)

While nicotine is addictive, and not entirely harmless, e-cigarettes do not contain the extensive cocktail of cancer-causing chemicals found in tobacco.\(^6\) While the long term health consequences of e-cigarette use are uncertain, short term studies have suggested they may have only mild adverse effects\(^7\) and these may be reduced compared to smoking.\(^8\) They are almost certainly far safer than tobacco cigarettes\(^9\) given that tobacco is associated with more than one in four cancer deaths in the UK.\(^10\)

However as a relatively new product, there remains uncertainty as to how effective they are in helping people quit smoking, the long term health consequences of their use and their impact on youth behaviour and attitudes to smoking more widely. Cancer Research UK published a research agenda written by experts at the University of Stirling highlighting the key questions that require further research.\(^11\)

Figure 1: Aids used in most recent quit attempt (n=9783)\(^12\)

![Graph of aids used in most recent quit attempt](image)

Regulation and safety of e-cigarettes

There are a range of e-cigarette products available on the market. But currently the quality and safety varies within and between brands.\(^13\) Cancer Research UK believes that regulation is needed to improve the safety of all e-cigarettes.
There is a consensus that e-cigarettes are almost certainly much safer than smoking tobacco cigarettes, however, the full health implications of e-cigarette use are currently unknown. The level of toxicants found in e-cigarette vapour is generally substantially lower than that found in tobacco cigarette smoke. However, the health implications of long-term exposure to nicotine and propylene glycol/glycerine, the main chemicals in e-cigarette vapour, are also not fully understood. There is some evidence that suggests that nicotine may promote tumour growth in animals and in human cells. There have been mixed results in early stage data as to whether e-cigarette vapour could be toxic to human cells. Although these issues warrant further investigation, the evidence indicates that using e-cigarettes is almost certainly much safer than smoking tobacco.

Currently e-cigarettes are regulated as consumer products. We believe that to improve the quality and safety of e-cigarettes further specific regulations are needed. The revised Tobacco Product Directive was agreed by the EU in March 2014 and will come into force in May 2016. E-cigarettes will be regulated under this Directive unless the product claims to help people quit smoking or is shown to be a medicinal product by its function.

E-cigarettes not licensed as medicines will have to meet a number of requirements. They will not be allowed to contain more than 20mg/ml of nicotine and must ensure consistent delivery of nicotine. The e-liquid will be required to be pure and not have ingredients harmful to human health other than nicotine. A maximum size of 10ml for refillable cartridges and requirements for mechanisms to prevent leakage and breakage will also be established.

The products will also have to carry a health warning of either: “This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers.” Or, “This product contains nicotine which is a highly addictive substance.” The products will also have to list their ingredients, the nicotine content and delivery per dose. The TPD also established rules for the advertising of e-cigarettes (see below).

EU member states have the power to regulate flavours of e-cigarettes if they have justified grounds for doing so. Member states also have the power to ban an e-cigarette product if they can show it is a proportionate response and they have justified grounds to believe that the product is harmful to humans. If they take this option they must inform the EU Commission immediately. If three member states undertake this action, then the Commission has the power to ban the specified product across the EU.

**Preventing e-cigarette use among children**

Uptake of e-cigarettes by children is of concern because nicotine use in adolescence may cause lasting adverse consequences for brain development. There is also concern that the use of e-cigarettes may renormalize the use of tobacco among children, but there is insufficient evidence to support this view.

Currently, there is little evidence that children are using e-cigarettes. In particular, among children who have never smoked only 1% of children surveyed have used an e-cigarette once or twice in the UK. However, this is subject to regional variation with some areas showing evidence of higher use. For example, 5% of year 6 children in Wales who had never smoked reported having used an e-cigarette. Similarly, in the North West, 2.4% of 14-17 year olds across Cheshire and Merseyside who have never smoked have reported using an e-cigarette. Given these variations and the risk of harm, it is important that adequate protections are put in place to stop the promotion of e-cigarettes to young people and prevent those under-18 from purchasing them.

We are pleased by the UK Governments’ decisions to ban those under-18 from buying e-cigarettes, and the ‘proxy’ purchasing of e-cigarettes for under 18s, which is likely to come into force in 2015.

**The promotion of e-cigarettes**

Cancer Research UK published a report written by experts at Stirling University on the marketing of e-cigarettes in November 2013. It highlighted e-cigarette marketing practices that are attractive to non-smokers and young people as well as current smokers. The study also showed that some of this marketing
may promote smoking. These promotions may influence children and young people who would not otherwise have smoked to use e-cigarettes. These promotions could also ‘renormalise’ the idea of smoking by confusing or contradicting the messages about the harms of smoking and undermine public health efforts to deter young people from taking up smoking.

The promotion of e-cigarettes currently is regulated by the Committee on Advertising Practice (CAP) and Broadcasting Committee on Advertising Practice (BCAP) rules that are administered by the Advertising Standards Agency (ASA). As e-cigarettes do not contain tobacco they are not covered by the same regulations that currently bans advertising of tobacco products. However e-cigarettes cannot be co-branded with cigarettes as tobacco brand-sharing is banned in the UK.

E-cigarettes making claims about quitting would require licensing under the Medicines and Healthcare products Regulatory Agency (MHRA), which would restrict promotions to keep closely to the medical claim. The content of medical products promotion is also regulated under the CAP and BCAP codes.

When it comes into effect in May 2016, Article 20 of the TPD will restrict the advertising or promotion of e-cigarettes (that are not making a cessation claim) in a similar way to the EU Directive on Tobacco Advertising 2003 which banned cross-border tobacco advertising in broadcast media. The revised TPD will ban e-cigarette advertising in the press, on radio, television, online and at events involving several EU countries. It will not regulate domestic-only advertising (e.g. promotion on billboards and point of sale), or any sponsorship. It will also not regulate the marketing of flavours. The Directive allows member states to pursue further regulation for domestic advertising of e-cigarettes.

In November 2014 new CAP/BCAP rules for e-cigarette advertising were introduced. These rules sought to permit e-cigarettes to be shown in advertisements on television without promoting smoking. The new rules prohibit advertisements that promote any design or imagery that might reasonably be associated with a tobacco brand and anything that puts tobacco use in a positive light. The rules also prohibit endorsements from health professionals, health or medicinal claims for non-licensed products and anything that undermines existing health messages. They also require products to state whether they contain nicotine.

The rules also seek to prevent advertisements appealing to young people. Advertisements are prohibited from encouraging non-smokers or non-nicotine users to use e-cigarettes, or appealing to under 18s, or showing people who are or may seem to be under 25. There are also some limited broadcast and marketing restrictions to reduce young people’s exposure to such marketing.

These new rules will be reviewed in October 2015 to see whether they remain fit for purpose. Overall, these rules are a progressive step to reducing the promotion of e-cigarettes to non-smokers and young people. However, they do not address all the concerns about e-cigarette marketing.

Concerns remain about the fact that e-cigarette marketing can include celebrity endorsements which can appeal to children and young people. Furthermore, we believe that free distribution of e-cigarettes should be prohibited as it may enable non-smokers including young people to gain access to e-cigarettes or initiate use. We also believe e-cigarette sponsorship and promotion at sporting events should be prohibited. Sponsorship is a form of marketing which can lead to mass exposure to a product and may be more likely to appeal to young people through the association with sporting events. For example in recent years e-cigarette companies have sponsored motor racing teams and football clubs.

At the moment, we do not believe there is sufficient evidence or justification to restrict outdoor billboards, leafletting or point of sale advertising. But given the rapid evolution of this market and the pace of research in this field, it is important that policies on e-cigarette marketing are reviewed regularly to reflect the latest evidence.

**Quitting and harm reduction through e-cigarettes**

Smoking is the largest preventable cause of cancer in the world and accounts for nearly one in five cancer cases in the UK. Cancer Research UK encourages those who smoke to quit entirely. A range of cessation services and approaches are available to help smokers quit. Using prescription medication and behavioural
support from NHS Stop Smoking Services has a well-evidenced benefit – roughly trebling the chance of quitting success.\textsuperscript{29}

The randomised controlled trials conducted so far suggest a potential benefit for e-cigarettes for smoking cessation, but evidence remains limited and of low quality at this stage.\textsuperscript{30} For example, one of these small trials has suggested that e-cigarettes may help people to quit,\textsuperscript{31} but this trial, was not big enough to show which was more effective out of e-cigarettes, placebo e-cigarettes containing no nicotine, or NRT patches. An additional study suggests that among smokers who have attempted to quit without professional support, those who use e-cigarettes are more likely to report continued abstinence than those using licensed NRT.\textsuperscript{32}

The effectiveness of nicotine delivery is unclear given that it varies across products and user’s behaviour. Studies have revealed the inconsistency of nicotine delivery\textsuperscript{33}, and research evidence shows that nicotine levels in e-cigarette liquids do not necessarily reflect nicotine levels in the vapour.\textsuperscript{34} However, e-cigarette users may be able to control the amount of nicotine that they absorb from e-cigarettes.\textsuperscript{35}

While quitting is always the best option, harm reduction approaches whereby smokers reduce smoking, provide long-term benefit as the likelihood of subsequent quitting increases. In 2013 the National Institute for Health and Care Excellence (NICE) developed guidance on a harm reduction approach to smoking, supporting the use of licensed nicotine-containing products to help smokers cut down, for temporary abstinence and as a substitute for smoking.\textsuperscript{36}

It has been suggested that e-cigarettes could play a role in harm reduction. However dual use of e-cigarettes alongside tobacco cigarettes could, alternatively, potentially fuel nicotine addiction. E-cigarettes may allow smokers to get a nicotine hit where they are currently unable to smoke (for example, where smoking is banned by smokefree legislation) and discourage quitting. There is currently not enough evidence to say which of these scenarios is more likely.

We believe more evidence is needed to help inform smokers to make choices about e-cigarettes as a potential quit aid. We also support light-touch MHRA licensing of e-cigarettes as it will provide a system for assessing the products and evidence supporting their claim, and for tracking adverse reactions.

**E-cigarette use in areas covered by smokefree legislation**

Currently there is insufficient evidence to support an indoor ban on e-cigarette use. The smokefree legislation has not only helped reduce the public’s exposure to the harm caused by second hand smoke\textsuperscript{37}, it is also encouraging people to quit\textsuperscript{38}, and reducing children’s exposure to the deadly habit.\textsuperscript{39} The main reason for the introduction of the smokefree legislation was to protect people from the harms of second hand smoke. The relatively limited evidence to date suggests toxicants are present but mostly at lower levels in second-hand e-cigarette vapour than cigarette smoke\textsuperscript{40, 41, 42}, and there is no evidence as to whether chemicals at this level would cause any harm to bystanders.

Like cigarettes, e-cigarette vapour has also been shown to include ‘particulate matter’.\textsuperscript{43} This is a ‘catch-all’ term for small particles of a variety of substances and small particulate matter (PM2.5) has been classified as a IARC Group 1 carcinogen.\textsuperscript{44} More studies are needed to understand the impact of exposure of e-cigarette vapour particularly in the long term.

The smokefree legislation has also had the additional effect of ‘denormalising’ smoking which helps to facilitate quit attempts.\textsuperscript{45} Concerns have been raised that the introduction of new behaviours that imitate smoking may undermine the denormalisation of smoking and may affect the number of people who quit. As such they may delay or prevent quit attempts by those who might otherwise have quit. Alternative hypotheses also exist: that use of e-cigarettes may increase the denormalisation of smoking tobacco itself by reducing the proportion of people who smoke and reducing the number of smoking role models. In these scenarios applying smokefree legislation to e-cigarette users who are trying to quit may undermine their quit attempt by placing them with smokers. More research is needed to understand how smokefree laws affect smoking initiation and cessation.
In the UK, it is not illegal to use e-cigarettes in enclosed public spaces. However, this remains an issue of contentious policy debate. The Welsh Government is considering implementing a ban on e-cigarette use in public places. Currently, there are no plans to support a similar measure in the rest of the UK, though in Scotland most health boards have banned them on hospital grounds.  

Some businesses have also chosen to ban the use of e-cigarettes rather than ask staff to differentiate when enforcing smokefree legislation. Businesses should make reasoned decisions on whether to allow the use of e-cigarettes in their premises based on the best available information, whilst continuing to maintain the integrity of smokefree legislation.

**Tobacco industry involvement**

It is a growing concern that the tobacco industry is investing in e-cigarettes. Cancer Research UK calls for the strongest possible measures to restrict tobacco companies marketing their deadly products, and the protection of public health policy from their influence.

The World Health Organisation’s Framework Convention on Tobacco Control (FCTC) Article 5.3 says that Governments must protect health policy from the vested interests of the tobacco industry. This global agreement recognises the fundamental and irreconcilable conflict between the tobacco industry’s interests and public health policy interests. This reflects the industry’s history in blocking, amending and delaying public health legislation.

There has been substantial investment in e-cigarettes in the UK and globally over the last two years. British American Tobacco (BAT) has produced both ‘Voke’ which has obtained an MHRA license and ‘Vype’ which is being promoted as a consumer product. In addition, Phillip Morris International (PMI) have purchased ‘Nicolites’, Japan Tobacco International (JTI) has purchased ‘E-lites’ and Lorillard owner of ‘blu’ have expanded their brand through the purchase of ‘SkyCig’, although ownership of the blu brand is expected to transfer to Imperial Tobacco in the coming months.

Given the outcome of the TPD, the tobacco industry will be in a position to both promote some lines of e-cigarette products as consumer products - “alternatives” to smoking including as options for continuing dual use, and other lines as cessation aids, part of the solution to smoking. It has been argued given their past involvement in the harm reduction debate, their control of the e-cigarette market would serve to maintain the dominance of the traditional cigarette.

Given the tobacco industry’s growing interest in the e-cigarettes market, there is also concern about whether the industry will use this opportunity to engage in public health policy making. The integrity of Article 5.3 of the FCTC must be maintained. Therefore it is important that the tobacco industry’s involvement in the e-cigarette market does not provide them with an opportunity to participate as a stakeholder in public health and influence health policy.

**Cancer Research UK’s investment in e-cigarette research**

To help answer the many outstanding questions on e-cigarettes, CRUK is increasing its investment in e-cigarette research. This will be focused on answering questions on the long term impact of e-cigarette use, understanding how they might help people to quit and the wider consequences of e-cigarette use particularly among young people.

As well as funding research, we are running a series of research workshops in 2015 bringing together researchers to support the development of better proposals in this field. Furthermore, with Public Health England, CRUK has established the UK E-cigarette Research Forum to bring together researchers and experts to explore the questions and issues that emerge from new e-cigarette research.
Cancer Research UK recognises that e-cigarettes may help smokers quit or cut down the amount they smoke. With further research we hope to be better able to assess their effectiveness as quit aids and their long term impact on health. To ensure that the impact of e-cigarettes is entirely positive we are also mindful of potential unintended consequences. We welcome the ban on the sale of e-cigarettes to under-18s and call for the enforcement of comprehensive marketing regulation to prevent e-cigarettes appealing to non-smokers and young people. In addition, we must ensure that the tobacco industry does not use e-cigarettes as a means to become a stakeholder in public health. We believe that this approach will help maximise the potential for e-cigarettes to help reduce the number of people smoking.

References

3 ibid
5 ibid
12 ibid
18 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