

## Cancer Research UK Briefing: Electronic Cigarettes

### Summary of key points

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.

We support the use of high quality e-cigarettes because we believe that they have significant potential to help smokers who aren't otherwise ready or able to quit smoking by providing them with much safer alternatives to smoked tobacco.

It is important that regulation does not stifle the development of this market nor make accessing these products by smokers more difficult. However, safeguards not currently available under existing consumer regulation are required to give potential consumers much needed assurance that they are as safe and effective as nicotine replacement therapy and to ensure that they are not marketed to non-smokers, including children. We welcome the Government's move to ban the sale of nicotine containing products such as e-cigarettes to under-18s.

The revised EU Tobacco Products Directive will introduce 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 this progress towards ensuring these products are safer and more effective whilst still readily accessible to smokers.

It is also important that the tobacco industry's investment in the e-cigarette market does not provide them with an opportunity to participate as a stakeholder in public health and influence health policy.

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.

### Background

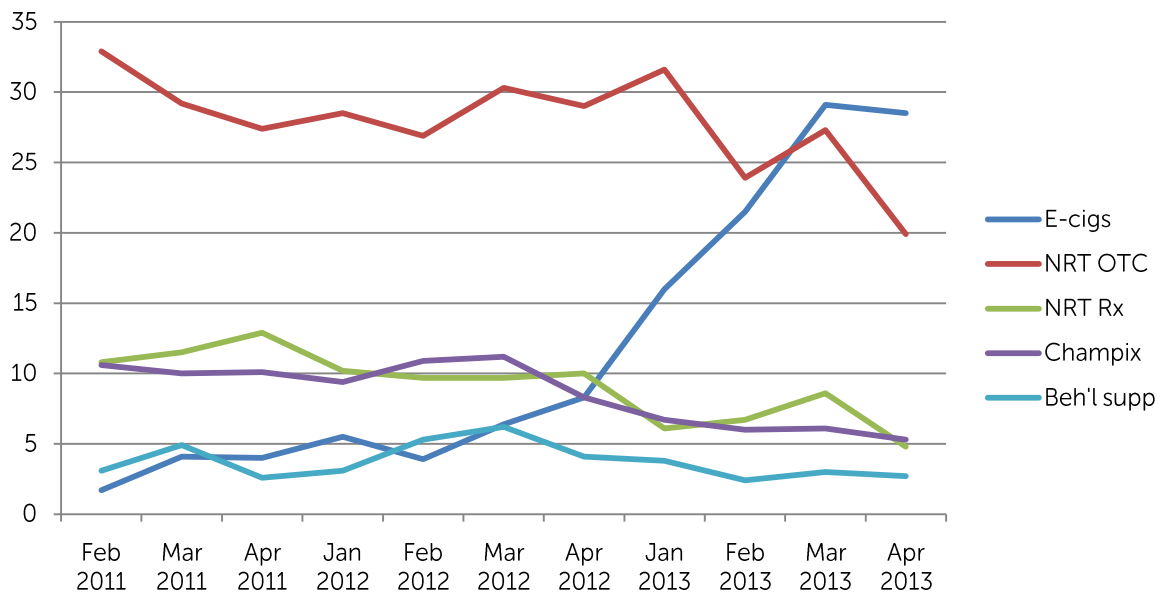
Electronic cigarettes (e-cigarettes) are devices that allow users to inhale vaporised nicotine dissolved in propylene glycol or glycerine through a device often shaped like a cigarette. They are predominantly used by current or ex-smokers and it is estimated that in the UK 18% of smokers were using e-cigarettes in 2014 – approximately 2.1 million people.<sup>1</sup> This has increased from 3% in 2010 and is likely to increase further as the market grows.<sup>1</sup> However, other estimates suggest that e-cigarette use is higher with about 16% of smokers in England using them.<sup>2</sup>

Some have suggested that consumption of e-cigarettes will overtake traditional cigarettes in the next decade.<sup>3</sup> 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%).<sup>1</sup> 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.<sup>2</sup>

While nicotine is addictive, and not entirely harmless, e-cigarettes do not contain the extensive cocktail of cancer-causing chemicals found in tobacco.<sup>4</sup> While the long term health consequences of e-cigarette use are uncertain, they are almost certainly far safer than tobacco cigarettes<sup>5</sup> given that tobacco is associated with more than one in four cancer deaths.<sup>6</sup>

However as a new product, there remains uncertainty as to whether they are effective 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.<sup>7</sup>

Figure 1: Aids used in most recent quit attempt



### 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.<sup>8</sup> There have been concerns about the safety of e-cigarettes with a few reports of e-cigarettes exploding<sup>9 10</sup> and cases of refill cartridges leaking. Cancer Research UK believes that regulation is needed to ensure that e-cigarettes match the safety and quality of licensed forms of nicotine replacement therapy (NRT).

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.<sup>4</sup> However, the health implications of long-term exposure to nicotine and propylene glycol, 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<sup>11 12 13</sup> and in human cells.<sup>14</sup> There are also some further very preliminary unpublished results that suggest that e-cigarettes promote tumour growth in human cells.<sup>15</sup> Despite these concerns, 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. In December 2013, the EU Commission, EU Parliament, and the Council of Ministers came to an agreement on the Tobacco Products Directive (TPD).<sup>16</sup> The TPD was approved in March and will come into force in summer 2016. E-cigarettes will be regulated under the Directive unless a product claimed to help people quit smoking or was 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.

### **E-cigarette marketing and preventing use by children**

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.<sup>1</sup> However given that this is a growing market 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 Government's decision to ban those under-18 from buying e-cigarettes, which is likely to come into force in 2015. However, we believe that urgent action is needed to protect children from promotion and advertising 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 promoted smoking. These promotions may influence children and young people who would not otherwise have smoked to use e-cigarettes. These could 'renormalise' the idea of smoking by confusing or contradicting the messages about the harms of smoking. This could undermine public health efforts to deter young people from taking up smoking.

The marketing of e-cigarettes currently falls between tobacco products regulation, that cover cigarettes, and medicinal regulation, that covers NRT. As e-cigarettes do not contain tobacco they are not covered by the same regulations that currently bans advertising of tobacco products. However a "tobacco advertisement" is defined as an advertisement whose purpose or whose effect is to promote a tobacco product. Therefore if a specific advertisement was proven to promote tobacco products it is possible that it would be banned under the law, although this has yet to be tested.<sup>17</sup> E-cigarettes also 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 by the Committee on Advertising Practice (CAP) / Broadcasting Committee on Advertising Practice (BCAP) rules that are administered by the Advertising Standards Agency (ASA).

When it comes into effect in summer 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 and sports sponsorship. The revised TPD will ban e-cigarette advertising in the press, on radio, television and at events involving several EU countries. It will not regulate domestic-only advertising (e.g. promotion on billboards and point of sale), online promotions 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. This means that the UK could ban e-cigarette advertising in the media not covered by the TPD or even introduce a blanket ban as it did previously with all tobacco products under the Tobacco Advertising and Promotions Act. The content of advertisements is regulated by the voluntary CAP/BCAP rules that are administered by the ASA. CAP/BCAP have launched a consultation on new rules to control the content of e-cigarette adverts, which are hoped would come into force by the end of this year. The proposed rules seek to ensure that e-cigarette marketing does not appeal to non-smokers including people under 18.

We believe that it is too long to wait until 2016 for the regulation of e-cigarette advertising under the TPD. We welcome the CAP/BCAP consultation as effective guidance and regulations cannot come soon enough.

## 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.<sup>18</sup> This global agreement recognises the fundamental and irreconcilable conflict between the tobacco industry's interests and public health policy interests.<sup>19</sup> This reflects the industry's history in blocking, amending and delaying public health legislation.<sup>20</sup>

British American Tobacco (BAT) has produced both 'Voke' which is seeking an MHRA license and 'Vype' which is being promoted as a consumer product and which has its own branded 'Vype' bar in Shoreditch that is "bringing smokers and non-smokers back together".<sup>21</sup> Given the outcome of the TPD they will therefore 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.<sup>22</sup>

Given the tobacco industry's growing interest in the e-cigarettes market, there is 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.

## 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 cases.<sup>23</sup> 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 - trebling the chance of quitting success.<sup>24</sup> E-cigarettes may have a role in helping people to quit smoking but the evidence for their effectiveness is limited, as is the evidence as to whether they may also serve to sustain an addiction to nicotine.

One small trial has suggested that e-cigarettes may help people to quit.<sup>25</sup> But this trial, comparing e-cigarettes to NRT patches only, was not big enough to show which was more effective out of e-cigarettes, placebo e-cigarettes containing no nicotine, or NRT patches. Other studies including a randomised trial have compared different strengths of e-cigarettes with each other.<sup>26 27</sup> But none of these other studies have been able to assess whether they help people quit. Larger studies, comparing e-cigarettes to other scientifically proven smoking cessation methods, are needed before e-cigarettes can be recommended as a safe or effective way to stop smoking.

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<sup>28</sup>, and research evidence shows that nicotine levels in e-cigarette liquids do not necessarily reflect nicotine levels in the vapour.<sup>29</sup> However, e-cigarette users may be able to control the amount of nicotine that they absorb from e-cigarettes.<sup>30</sup>

While quitting is always the best option, harm reduction approaches whereby smokers cut down or reduce smoking provide long-term benefit as the likelihood of subsequently 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.<sup>31</sup>

It has been suggested that e-cigarettes could play a role in harm reduction. However dual use of e-cigarettes alongside tobacco cigarettes could 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 effective quit aids. We also 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.

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

The smokefree legislation has not only helped reduce the public's exposure to the harm caused by second hand smoke<sup>32</sup>, it is also encouraging people to quit<sup>33</sup>, and reducing children's exposure to the deadly habit.<sup>34</sup> The main reason for the introduction of the smokefree legislation was to protect people from the harms of second hand smoke. Second hand smoke is more harmful than second hand vapour from e-cigarettes. E-cigarette vapour does contain toxicants however this is usually at levels which are far lower than those found in tobacco cigarettes.<sup>35</sup> E-cigarette vapour has also been shown to include 'particulate matter'.<sup>36</sup> This is a 'catch-all' term for small particles of a variety of substances and has been linked to a range of health harms as part of other complex mixtures like air pollution and cigarette smoke.<sup>37</sup> 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.<sup>38</sup> The introduction of new behaviours that imitate smoking may undermine the denormalisation of smoking and may affect the number of people who quit. In addition dual users may use e-cigarettes as a means to 'get round' the smoking ban. As such they may delay or prevent quit attempts by those who might otherwise have quit. Although it also is possible that 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 e-cigarette users and their ability to quit.

In the UK, it is not illegal to use e-cigarettes in enclosed public spaces. However, some businesses have 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, whilst continuing to maintain the integrity of smokefree legislation.

**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 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.**

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