

## Electronic Cigarettes



Nearly 3m people in the UK use electronic cigarettes. This briefing updates [POSTnote 455](#). It summarises the latest data on scale of use, safety and quality of e-cigarettes, and their value as a stop-smoking tool. It also explores the implications of the new EU Tobacco Products Directive and regulatory approaches in the UK.

### Background

E-cigarette use has increased rapidly in recent years<sup>1,2,3</sup> with nearly 3m users in the UK. There is ongoing debate over whether e-cigarettes are harmful or beneficial to public health.<sup>4,5</sup> Advocates emphasise evidence pointing to lower health risks than from smoking tobacco and for their value as a tool to help people stop smoking.<sup>1,2,6</sup> Critics express concerns that e-cigarettes might prolong nicotine use and undermine tobacco control.<sup>4,5</sup> Concerns that they might encourage smoking among non-smokers and children have not been realised thus far.<sup>1</sup> E-cigarettes are regulated as tobacco-related products via the EU Tobacco Products Directive.<sup>7,8</sup> The regulations restrict nicotine concentration and volume, composition and promotion.<sup>1,9,10,11</sup>

### Tobacco smoking in the UK

Combined data from the devolved administrations suggest that there are around 96,000 smoking-related deaths per year in the UK.<sup>12,13,14,15</sup> It is estimated that smoking is responsible for over a third of all deaths from respiratory diseases, and over a quarter of all deaths from cancers in England.<sup>12</sup> Currently, 18% of adults and 3% of 11-15 year-olds smoke.<sup>16,17</sup> Smoking prevalence has declined across all

### Overview

- Nearly 3m people in the UK use e-cigarettes. The market is growing rapidly.
- The e-cigarette market has been led by small companies, but all the major tobacco companies have products.
- A growing body of evidence shows that e-cigarettes are much less harmful than tobacco.
- There is evidence showing that e-cigarettes can help smokers quit tobacco.
- Current evidence suggests that e-cigarettes do not encourage tobacco smoking among non-smokers or children.
- Most e-cigarettes are regulated as tobacco-related products, via new EU legislation. There are a wide range of potential impacts of the EU Directive, which are uncertain.
- Producers must license e-cigarettes as medicines if they make health claims, such as effectiveness as a stop-smoking tool.

age groups since surveys began in 1974,<sup>16,17</sup> and is thought to reflect fewer people taking up smoking rather than increased quit rates.<sup>1</sup>

Tobacco is a major source of revenue for the Treasury: it received £9.5bn from tobacco during the 2015-16 financial year (excluding VAT).<sup>18</sup> Action on Smoking and Health (ASH) estimates that smoking costs the NHS in England around £2bn per year.<sup>19</sup> Health costs arise from problems caused by the inhalation of smoke, not from the nicotine content.<sup>1,20</sup> UK tobacco control policy emphasises harm reduction that aims to replace tobacco smoking with less harmful sources of nicotine.<sup>1,2</sup> E-cigarettes are an increasingly popular alternative source.<sup>1</sup>

### Electronic cigarettes

E-cigarettes produce a vapour typically containing nicotine, which users inhale. They have three main components:<sup>1</sup>

- a battery-powered heating element
- a cartridge (replaceable) or tank (refillable) containing a solution made of propylene glycol, glycerine, nicotine, water and flavourings
- an atomiser that vapourises the solution when heated.

**Box 1. E-cigarette product innovation**

The first-generation of e-cigarettes ('cig-a-likes') resembled tobacco cigarettes. They became widely available in the UK in the mid-2000s and are usually disposable.<sup>1</sup> Second-generation products typically resemble fountain pens, and are rechargeable, with a replaceable cartridge or refillable tank.<sup>1</sup> The most recent are third-generation products are typically diverse in appearance. They are rechargeable with a refillable tank. Users can modify power and resistance to adjust nicotine delivery and vapour density, can download software to monitor usage patterns, and can personalise devices aesthetically.<sup>1,21</sup>

The majority of vapers use second- or third-generation products. They offer more efficient nicotine delivery than first-generation products. Some are comparable to tobacco cigarettes in terms of blood nicotine concentration that they deliver. However, nicotine delivery remains much slower than tobacco cigarettes.<sup>1</sup>

There are over 450 brands of e-cigarette and 7,500 flavours of solution.<sup>22</sup> Product innovation is extremely rapid (Box 1). The increasing lack of resemblance to tobacco cigarettes has led to calls for the adoption of alternative terminology such as 'vaping products' or 'vaping devices'.<sup>9</sup>

**Patterns and trends in use in the UK**

The use of e-cigarettes ('vaping') increased rapidly after their introduction to the market, but appears to have slowed in the last two years.<sup>23,24</sup> ASH's annual survey estimates that there are 2.8m people ('vapers') using e-cigarettes, 98% of whom are current or ex-smokers.<sup>24</sup> Use trebled from 700,000 in 2012 to 2.1m in 2014, then slowed to fewer than 1m new users between 2014 and 2016.<sup>24</sup> Vaping is evenly distributed across age groups, slightly more popular among women and higher socio-economic groups,<sup>23</sup> but reasons for these patterns are unclear. Key statistics are:

- 61% of smokers (up from 22% in 2012), and 19% of ex-smokers (11% in 2012) have tried an e-cigarette<sup>24</sup>
- 19% of smokers (up from 4% in 2012), and 8% of ex-smokers (1% in 2012) currently vape<sup>24</sup>
- 46% of smokers who currently vape and 65% of ex-smokers who currently vape have been using e-cigarettes for over a year.<sup>24</sup>
- 5% of 11 year olds and 26% of 16 year olds have tried an e-cigarette. Regular use by children is rare and almost entirely confined to those who have already used tobacco.<sup>25,26</sup>

**Current market**

E-cigarettes are sold online and on the high street, in convenience stores, supermarkets, pharmacies and specialist 'vape' shops.<sup>27</sup> Robust UK-wide data on actual purchasing trends are not available, but there appears to be both strong online competition and growth in high street retail, including specialist shops.<sup>27,28</sup> E-cigarettes were the fastest-growing UK supermarket product of 2014, with sales increasing by 50% during that year.<sup>1</sup> Other estimates suggest that overall UK sales rose from £25m to £459m between 2011 and 2014, which appears to reflect user preference for newer-generation devices. The UK market is the world's second-largest behind the US.<sup>1</sup>

The market has been led by small companies, but all the major tobacco companies are increasingly involved, mainly through acquisitions of other companies.<sup>29</sup> Tobacco industry products have been based on designs that resemble tobacco cigarettes, but are diversifying.<sup>1</sup> Their range of alternative products to cigarettes also includes 'heat-not-burn' products, which contain tobacco but are claimed to present reduced risk to users because of the lack of combustion.<sup>1,30</sup> Many stakeholders (including public health figures, vaping advocates and charities) highlight a conflict of interest in tobacco companies' involvement. Some acknowledge that they need to adapt to a changing marketplace, with others concerned about their influence on the public health agenda.

**Impact on consumers**

In the last 12 months, the Royal College of Physicians<sup>1</sup> and Public Health England<sup>2</sup> have published extensive evidence reviews of the safety and quality of e-cigarettes. These reviews investigated public perceptions of harm, health effects on vapers and bystanders, technical safety and quality and their value as a stop-smoking tool.

**Public perceptions of harm**

25% of the UK public think that e-cigarettes present a risk of harm similar to that of tobacco smoking, compared with 7% in 2013.<sup>24</sup> The understanding of the relative harms of e-cigarettes is improving amongst smokers who vape. 69% of smokers who vape think that e-cigarettes are less harmful than tobacco, up from 55% in 2015.<sup>23</sup> However, smokers who do not vape have a worsening understanding of the relative harms. 29% of smokers who do not vape think that e-cigarettes are less harmful than tobacco, down from 40% in 2015.<sup>23</sup> One survey found that the majority of 11-16 year olds think e-cigarettes are harmful.<sup>26</sup> Their perceptions of harm also seemed to be influenced by flavours. Compared to their harm perceptions of e-cigarettes in general, young people believe tobacco flavour to be more harmful, and fruit flavours to be less harmful.<sup>26</sup>

**Health effects on vapers and bystanders**

Health concerns have been focused on vapers inhalation of vapour, and bystanders' passive exposure to vapour. The inhaled and exhaled vapour varies depending on device characteristics and user behaviour. There have been concerns about possible adverse health effects for the user from inhaling vapour that can contain propylene glycol, glycerine, nicotine, flavourings, metallic elements and carcinogenic substances such as nitrosamines.<sup>1,31,32</sup> Since 2014, there has been more research into vapour content (rather than solution content). The amount of chemicals inhaled, rather than their presence alone, is the important determinant of toxicity, and current data suggest that the levels of toxins and contaminants within inhaled vapour do not pose significant health risks.<sup>1,31,32</sup> Laboratory studies using cells have suggested that inhalation of vapours containing flavourings can increase airway inflammation, but there is no evidence of a clear risk to people.<sup>1</sup> The consensus is that long-term health risks to vapers require

monitoring, but are “unlikely to exceed 5% of the harm from smoking tobacco”.<sup>1,2</sup> Health risks to bystanders are smaller still, as current evidence shows that levels of nicotine and contaminants released via exhaled vapour are negligible.<sup>1,2,32</sup>

### Technical safety and quality

There have been reports of fires and battery explosions (primarily caused by faulty or incompatible chargers), and poisoning from ingestion of solution.<sup>2</sup> Public Health England’s review of national data concluded that these risks are ‘comparable to similar electrical goods and potentially poisonous household substances’.<sup>2</sup> Examples of mislabelled solution content have mostly declared higher concentrations of nicotine than were actually present in liquids or cartridges. Tamper-proof packaging and accurate labelling are requirements of the EU Tobacco Products Directive.<sup>7</sup>

### Value as a stop-smoking tool

Survey data suggest that two-thirds of tobacco smokers would like to stop smoking, and about one-third will attempt to do so in any one year.<sup>33</sup> Since 2013, e-cigarettes have overtaken nicotine replacement therapy (‘NRT’, such as gum or patches) as the most popular choice of stop-smoking tool. Around 40% of smokers making a quit attempt in 2015 used e-cigarettes, compared with 26% who used NRT.<sup>34</sup> From 2013-14, NRT market value decreased by around £8m,<sup>35</sup> although there is no evidence showing that this was directly caused by a rise in e-cigarette use. Vapers report that they use e-cigarettes to help them to quit or reduce smoking.<sup>24</sup>

#### *Evidence for effectiveness as a stop-smoking tool*

The Royal College of Physicians examined clinical trial and survey data on a range of stop-smoking tools to determine the relative likelihood of a successful quit attempt. These tools included NRT, e-cigarettes and two prescription drugs that reduce nicotine cravings (neither contains nicotine). The report concluded that when assessed by successful quit attempts, e-cigarettes are:<sup>1</sup>

- 50% more effective than unsupported attempts, including over-the-counter NRT used without professional support
- of similar effectiveness as prescribed NRT or drugs
- less effective than NRT or drugs used with regular face-to-face support from NHS Stop Smoking Services.

Evidence for the effectiveness of e-cigarettes as a stop-smoking tool is limited by the low number of randomised controlled trials (the strongest form of clinical trial), but includes several other less robust trials.<sup>1</sup> Trials have involved first-generation products, and potential effectiveness is likely to be higher when quit attempts involve later-generation products that deliver nicotine more efficiently.<sup>1,36</sup> Early data suggests use of e-cigarettes within NHS Stop Smoking Services would be at least as successful as other stop-smoking tools on offer.<sup>1</sup> A randomised controlled trial exploring the effectiveness of e-cigarettes compared with NRT within NHS Stop Smoking Services is in progress; it is due to complete in 2018.<sup>37</sup> Attitudes towards e-cigarettes within Stop Smoking Services

vary,<sup>38</sup> but many public health organisations and professionals recommend that such services should support smokers who are using e-cigarettes, including not dissuading pregnant women who use e-cigarettes from continuing to do so.<sup>21,39,40</sup> The National Institute for Health and Care Excellence will update smoking cessation guidelines in 2018.

Online survey data have shown that when asked, ex-smokers using e-cigarettes reported less dependency on e-cigarettes than on tobacco cigarettes.<sup>41</sup> However, those using third-generation products reported higher levels of e-cigarette dependency than those using first-generation products, which suggests that the efficiency of nicotine delivery is a factor in the addictiveness of e-cigarettes.<sup>41</sup>

#### *‘Dual use’ of tobacco and e-cigarettes*

There has been an overall decline in tobacco smoking. It is unclear whether dual use of tobacco and e-cigarettes is an aid or a barrier to quitting tobacco.<sup>1</sup> Around 40% of current smokers who vape say they do so to help reduce rather than quit tobacco use.<sup>24</sup> In 2014/15, around 450,000 smokers in England used NHS Stop Smoking Services, continuing a yearly decline from a high of around 800,000 in 2011/12.<sup>42</sup> One reason for the decline may be the increased use of e-cigarettes.<sup>42</sup> However, remaining smokers may be the most firmly addicted and difficult to reach.<sup>43</sup>

### Wider social impacts

Some public health stakeholders have expressed concerns about the potential for e-cigarettes to re-normalise smoking or act as a gateway into smoking for non-smokers and children.<sup>1</sup> There is no evidence to support either outcome.

- While the use of e-cigarettes has been increasing, the prevalence of tobacco smoking has been decreasing.<sup>23,24</sup>
- E-cigarettes are not used regularly by non-smokers.<sup>24</sup>
- Although children are increasingly aware of e-cigarettes and flavours, the majority are unaware of specific brands, and experimentation does not lead to regular use.<sup>25,26</sup>

Some stakeholders are concerned that vaping in public places undermines smoke-free policies.<sup>1</sup> The use of e-cigarettes in public places is not covered by UK smoke-free legislation,<sup>44</sup> with decisions made by individual organisations.<sup>1,45,46</sup> The World Health Organisation<sup>47</sup> and the British Medical Association<sup>48,49,50</sup> have favoured vaping bans in public places, arguing there is a lack of evidence for public health benefits and citing concerns about the renormalisation of tobacco smoking. The Public Health (Wales) Bill, which included a proposal to ban vaping in enclosed public places, was narrowly defeated in March 2016.<sup>51</sup> Some large organisations (transport companies, sports stadia and café chains) prohibit vaping on their premises, but others adopt a more permissive approach (which may include dedicated ‘vaping’ areas).<sup>52</sup> In May 2016 Nottingham University Hospitals NHS Trust became the first hospital trust in England to lift a vaping ban within its grounds.<sup>53</sup> Prisons in England and Wales sell single-use e-

cigarettes to support the intention to make prisons smoke-free.<sup>1,54</sup>

## Regulation of e-cigarettes

E-cigarettes that contain nicotine are regulated either as tobacco-related products or as licensed medicines. Tobacco-related products are regulated via Article 20 of the EU Tobacco Products Directive (TPD).<sup>7</sup> Producers wishing to make specific health claims (such as effectiveness at helping people stop smoking) must license their products through the Medicines and Healthcare Products Regulatory Agency (MHRA).

### Tobacco-related products: the EU TPD

The EU TPD was transposed into UK law on 20 May 2016.<sup>8</sup> Article 20 refers to e-cigarettes. It stipulates safety and quality standards, including a leak-proof refill mechanism and tamper-proof packaging, and the need for consistent nicotine delivery. It limits tank and refill container volume, and nicotine solution concentration. It also restricts marketing, requires the provision of product information and stipulates that products cannot be sold to under 18s.<sup>7</sup> The MHRA is the designated 'competent authority' monitoring compliance, with local Trading Standards authorities enforcing compliance.<sup>55</sup> Responsibility to comply lies with producers (those who manufacture or import e-cigarette products or solutions). Retailers must remove non-compliant stock from sale by 20 May 2017.<sup>55</sup> Most stakeholders agree that some regulation of e-cigarette products is needed, but the merits of Article 20 of the TPD have been the subject of debate.<sup>9,11,56</sup>

#### *Safety and quality standards*

Those in favour of TPD safety and quality standards (including some public health figures and charities) argue that they will reassure users and protect children.<sup>1,57,58</sup> Other stakeholders (including user advocates and trade representatives) question the necessity of these standards, arguing that general consumer products standards within a self-regulating industry are more proportionate.<sup>59,60</sup> In 2015, the British Standards Institute (BSI) published voluntary standards for manufacturing, importing, testing and labelling of products, developed in consultation with user groups, manufacturers and the Trading Standards Institute.<sup>61</sup> The BSI document frequently refers to the TPD.<sup>61</sup> It is unclear how far BSI standards have been adopted.<sup>1</sup>

#### *Solution concentration and volume limitations*

Survey data suggest that around 10% of vapers use products which exceed TPD limits on nicotine concentration (20mg/ml) and tank capacity (2ml).<sup>24</sup> Some charities suggest that limits may promote product innovation, for example the development of more efficient devices that lower the concentration of nicotine required.<sup>57</sup> User advocates and trade representatives argue that innovation may be stifled as small producers limit their product ranges to meet regulations and the administrative burden.<sup>59</sup> This could inadvertently benefit large corporations.<sup>59</sup> It has also been suggested that the solution and volume limitations

may hinder quit attempts by heavier smokers.<sup>1,62</sup> Finally, there are concerns about creating inadvertent support for a black market by encouraging vapers to circumvent product limitations, for example by mixing their own solutions from nicotine concentrate purchased outside the EU.<sup>63</sup>

#### *Marketing restrictions and information requirements*

In 2014, the UK Committee for Advertising Practice published interim codes for advertising e-cigarettes.<sup>64,65</sup> These codes contain standards to protect children, to block the indirect promotion of tobacco products, and on the acceptability of health claims. The TPD extends the limitations in these codes by restricting advertising (including TV, radio, online and print). Some argue that these restrictions are likely to lead to a substantial increase in campaigns via permitted fixed marketing media (such as billboards and bus-stops). In April 2016, the Scottish Parliament ruled to exceed the minimum requirements of the TPD by banning all forms of advertising.<sup>66</sup>

Some stakeholders (including charities and public health professionals) have welcomed the TPD marketing regulations because they restrict campaigns designed to appeal to young people.<sup>58</sup> However, others are wary that marketing restrictions and required health warnings about the addictiveness of nicotine may send mixed messages about relative harms to smokers, and discourage them from trying e-cigarettes.<sup>1,58</sup> Some argue that regulations that allow manufacturers to provide product information, but do not allow product promotion, may be difficult to enforce because of challenges in interpretation.<sup>58</sup>

### Licensing e-cigarettes as medicines

The other route to market is via an MHRA medicines licence. This requires producers to provide evidence about the safety and efficacy of e-cigarettes as a stop-smoking tool compared with existing nicotine products (such as NRT products, which are licensed for general sale in a wide range of retailers as well as on prescription).<sup>67</sup> Currently one e-cigarette (available in two strengths of nicotine), manufactured by a British American Tobacco subsidiary,<sup>68</sup> has a medicines licence, granted in November 2015. This is raising the question that a tobacco company's product might be recommended as a stop-smoking tool and made available through the NHS. It is licensed for general sale but is not yet available to purchase or prescribe. At the time of writing, there is no information in the public domain about other licence applications that may have been submitted.

E-cigarettes with a medicines licence are exempt from TPD Article 20. They may be available for prescription, benefit from a VAT rate of 5% (compared to 20% for e-cigarettes regulated via the TPD), and appeal to consumers seeking reassurances about safety and quality.<sup>1,2,59,69</sup> However, the cost and time to obtain a licence may be a barrier for small businesses and be incompatible with the pace of innovation.<sup>1,59</sup> Anecdotal evidence suggests that many vapers are attracted to e-cigarettes because they are not licensed medicines, as they do not want to be medicalised.<sup>70</sup>

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