Key points:

- electronic cigarettes (e-cigarettes) are battery-powered devices that heat a liquid often containing nicotine and flavourings into an inhalable form – awareness and use of e-cigarettes among adult smokers and ex-smokers has risen rapidly in Scotland and the UK over recent years with negligible current use among adults who have never smoked.

- because they are new products there is no direct evidence on the long-term safety of e-cigarettes themselves; analysis of the emissions from e-cigarettes finds many fewer potentially hazardous chemicals than in tobacco smoke, with those that exist typically in much lower quantities – most experts expect e-cigarettes to prove considerably less harmful to the user than tobacco smoking.

- although e-cigarettes use does result in ‘second-hand vapour’ to some extent, these levels are likely to be very low and there is as yet no scientific consensus that such exposures pose a general risk to the health of bystanders.

- e-cigarettes have been shown to deliver nicotine to the body effectively, though this varies by device type and configuration – current e-cigarettes seem to deliver nicotine more slowly than smoking tobacco.

- there is little high-quality research on e-cigarette for stopping or as a substitute to smoking tobacco; one better quality randomised controlled trial from New Zealand found an e-cigarette with relatively poor nicotine delivery was about as effective as a medicinal nicotine patch, while a well-designed observational study from England found smokers who attempted to stop using an e-cigarette were more likely to be abstinent from smoking than those who quit using medicinal nicotine bought over-the-counter, or no aid.

- the limited data on e-cigarette use among young people does not suggest a strong ‘gateway to smoking’ effect in the UK at present, but research on the issue is sparse and there is apparent disagreement and confusion over what a ‘gateway’ effect would look like were it to exist – researchers have recently highlighted the need for common standards and understanding in this area.

- other issues to be addressed relating to e-cigarettes include adequate safety controls to prevent accidental injury, monitoring of trends in ‘dual use’ (e-cigarette use combined with continued smoking), regulation of marketing activity, and the involvement of the tobacco industry in the e-cigarette market.

- Under new European regulations, by May 2016, e-cigarettes will be subject to either voluntary medicines regulation if they want to make claims to treat or prevent disease, or for products that do not seek to make therapeutic claims, a range of new controls on product quality, safety, and marketing.
What are e-cigarettes?

‘Electronic cigarette’ (e-cigarette) is the most commonly used term for a family of non-tobacco, non-medicinal, nicotine delivery devices that have become increasingly popular in recent years in Scotland and the rest of the UK. E-cigarettes come in a wide variety of different configurations, and are made and sold by many different manufacturers. Most e-cigarettes share common features of basic operation and have a battery (varying in size, type, capacity, and voltage) that is used to pass a current through a resistance coil (the atomiser) that is in contact with a fluid. The heat from the coil generates an aerosol from the fluid, without combustion, which is then able to be inhaled by the user (the aerosol is often referred to as ‘vapour’ hence the term ‘vaping’ is often used to describe e-cigarette use). The fluid used in most e-cigarettes normally consists of a carrier liquid of propylene glycol or glycerine (or a combination of the two), often nicotine (in a variety of concentrations), and frequently additives to enhance the palatability of the aerosol, such as flavourings.

Physically, some types of e-cigarettes are made to resemble tobacco cigarettes with the ‘filter’ part of the e-cigarette being a cartridge containing the heating element and fluid (the ‘cartomiser’), while the battery is typically made to look like the tobacco-containing part of a traditional cigarette. These are sometimes referred to in the UK as ‘first generation’ e-cigarettes or ‘cigalikes’ and are either sold as disposable, or with replaceable pre-filled sealed cartridges. ‘Second and third generation’ e-cigarettes typically do not resemble tobacco cigarettes and often have larger batteries and refillable liquid reservoirs (often called ‘clearomisers’ or ‘tank’ systems) or other more advanced features (such as variable voltage systems to alter the ‘vaping’ experience). In contrast to cigarette-like e-cigarettes where the whole cartridge normally needs to be replaced when it is empty, these e-cigarettes allow the user to refill the device with any of the different types of liquid (often referred to as ‘e-liquid’ or ‘e-juice’) themselves without replacing the reservoir each time, a practice users report as more economical.

E-cigarettes are relatively new products and the market changes rapidly, because of this terminology is also rapidly changing and different terms are often used colloquially or in marketing to refer to the same products, or substantively similar products. E.g. the different terms ‘e-cigarettes’, ‘e-shisha’, ‘vape pens’, ‘personal vapourisers’ ‘shisha pens’ can often refer to the same technology. Most e-cigarettes currently on the market are manufactured in China, imported to their target markets, and sold to the consumer via third party resellers.

Who uses e-cigarettes in Scotland/Great Britain and what type of e-cigarette do they use?

Adult awareness and use of e-cigarettes has increased rapidly in Scotland, as it has in the rest of the UK. In 2010 only 3% of adult (age 18+) smokers in Scotland reported using an e-cigarette, while by early 2014 this had risen to 17%4. The graphs below show patterns of e-cigarette use, by smoking status, among a large sample of adults in Great Britain5.
E-cigarettes use among current adult cigarette smokers in Great Britain (2010 -2014)

Unweighted base: GB adult smokers (2010, n=2297; 2012, n=2093; 2013, n=1895; 2014, n=1776)

E-cigarettes use among ex- and never smoking adults in Great Britain (2012 – 2014)


E-cig current use and experimentation among current and ex-smokers has increased rapidly over time, while current use among adult never tobacco cigarette smokers is, at present, negligible. This survey gives very similar estimates of e-cigarette use to the only other large general population survey of e-cigarette use among adults available at the present time.\(^6\)

The principal reasons e-cigarette users report for their use are as a stop-smoking aid, as an aid to prevent relapse to smoking, and to reduce smoking.\(^7\) There are an estimated 2.1 million adult e-cigarette users in Great Britain in March 2014, approximately one-third being ex-smokers with the remaining two-thirds being current smokers.\(^7\)

When looking at product choice among current e-cigarette users (both the type of e-cigarette they first used, and the type they are using now) in the graph below, most e-cigarette users started with a cigarette-like device (either disposable or rechargeable), but were more likely to report use of a rechargeable, refillable ‘second generation’ type device for the e-cigarette they are using now.
How hazardous are e-cigarettes to their users or bystanders?

E-cigarettes are new products, and as such there are no long term studies on the health effects of the products themselves. Because of this, judgements around the likely hazards of e-cigarettes are made from looking at chemical analysis and short-term studies on the products themselves and studies of long-term exposure to the chemicals present in e-cigarettes in other contexts.

Many e-cigarettes contain nicotine, the primary psychoactive dependence-inducing component of tobacco. Nicotine itself, in the doses smokers (or users of therapeutic nicotine replacement therapies – NRTs) are normally exposed to, is not considered especially harmful to health. High quality controlled trials of short term treatment with therapeutic nicotine finds side-effects are common but normally mild and transient. Most trials only involve a short duration of NRT administration, with relatively short follow-up, however longer-term studies with extended duration of NRT use have not shown NRT to increase the risk of adverse cardiac outcomes (when followed up for 5 years), nor cancer (when followed up for 12.5 years).

Reviews of the many long-term studies of lower-toxicant smokeless tobacco products as used in some Scandinavian countries (that deliver nicotine, but also other chemicals such as tobacco-specific N-nitrosamines) find that use is not associated with cancer at most sites, or at sites where associations have been found, they are typically of lower magnitude than smoking. The use of these products may be associated with poorer cancer outcomes, once cancer has already been diagnosed. Use of these products is not strongly associated with the incidence of cardiovascular disease, though, as with cancer outcomes, it may be associated with greater likelihood of a fatal case.

Overall, nicotine delivered in forms other than via smoked tobacco does not have strong associations with disease, though there remains poor evidence in some groups (particularly during pregnancy, where there are potential developmental risks and a lack of good studies conducted in humans). Nicotine on its own is much less hazardous than smoking. Although public understanding of this in the UK appears to have improved over time, it remains poor as people tend to overestimate the risks posed by nicotine.
The carrier liquid used in many e-cigarettes is propylene glycol (PG). Toxicology reviews consider PG as presenting a low risk to human health, and its inclusion in other substances intended for human consumption (e.g. in food) has been approved by regulators for many years. Both PG and another commonly used carrier fluid vegetable glycerine (VG) are ingredients in an existing medical preparation of nicotine; the nicotine mouthspray. However, the type of exposure to PG/VG resulting from e-cigarettes use (long-duration high intensity inhalation of an aerosol generated by heat) does not have a precedent, and a review of the probable health effects of such exposure to PG/VG concludes that monitoring and surveillance of health outcomes is warranted.

Flavourings used in e-cigarettes to make use more palatable are often food additives, that, while normally considered safe for oral consumption, may present health concerns when inhaled. A lab study of liquid cytotoxicity (being toxic to cells) of 35 e-liquids found that cytotoxicity was unrelated to nicotine content, but was correlated with the number and concentration of flavourings, suggesting this should be an area of continued investigation and monitoring.

As a result of the heating process, the constituents of the aerosol generated from e-cigarettes may be different from the constituents of the liquid. Because of this, the most informative analyses of the probable risk profile of e-cigarettes to the user are those that analyse the aerosol itself, as they examine levels of contaminants and other potentially harmful agents regardless of whether they come from a contamination of the liquid (or the use of a problematic flavourings), or arise as a by-product of heating. Several studies exist on this topic including many unpublished lab reports, the results of which have been summarised in a recent systematic review.

These studies vary widely in methods, quality, and devices studies (and owing to the diversity and rapidly evolving nature of the e-cigarette market, cannot be taken to represent all devices). Substances tested for by these studies include polycyclic aromatic hydrocarbons (a family including several established carcinogens), volatile organic compounds (e.g. acrolein, acetaldehyde, formaldehyde) and metals (e.g. cadmium, lead). Overall, these studies tend to detect many fewer potentially hazardous chemicals than found in tobacco smoke with those that are found being at much lower quantities; however there is significant variation between devices. Comparing the contaminants to commonly used standards for involuntary workplace exposures, the review concludes that, based on studies to date, e-cigarette users are unlikely to be exposed to levels of contaminants that would warrant concern.

A recent study suggests that, when using higher voltage configurations e-cigarettes could be capable of producing similar levels of one carcinogen, formaldehyde, in comparable levels to those found in cigarette smoke. A commentary on the research suggests that this is probably a result of the thermal breakdown of the carrier liquid that would be expected to occur at high temperatures, and notes that, when the devices are used at lower voltages, formaldehyde emissions are several magnitudes lower than tobacco smoke. These kind of analyses could have important implications for device design and safety.

Several studies have attempted to examine likely exposure to bystanders from e-cigarette use (i.e. ‘second-hand vapour’). These studies confirm that e-cigarette use results in emission and exposure to some toxins, as would be expected given the processes involved. Analyses of the emissions find pollutants are either at low concentrations compared to equivalent emissions from cigarette smoke, or below the limit of detection for...
the measurement instruments used\textsuperscript{39,37}. In one study\textsuperscript{27} nicotine in air was found at about one-tenth of the concentration present in second-hand tobacco smoke. Measurements of the concentration of respirable ‘particulate matter’ (often used as a marker of tobacco cigarette smoke \textsuperscript{4,6,40}) taken from these studies may not be directly comparable with the equivalent measurements of smoke generated by tobacco combustion. It is not clear if researchers working on the issue of ‘second-hand vapour’ have adequately calibrated measurement instruments to reflect differences in the physical properties of e-cigarette emissions (likely to be larger droplets in liquid state) when compared to the combustion generation carbon-based solid particles from traditional cigarettes\textsuperscript{41}. While the small particles of second-hand smoke can linger for many hours in the air after a tobacco cigarette has been extinguished, it is likely the larger particles generated by e-cigarette use settle faster, which has implications for likely levels of bystander inhaled exposure\textsuperscript{42}. Overall, there is not scientific consensus that second-hand exposure to e-cigarette emissions poses a general risk to the health of bystanders, though as with other forms of more common indoor air pollution it may cause irritation or other adverse reactions among some sensitive population sub-groups.

**Do e-cigarettes help people quit smoking?**

In order for e-cigarettes to be effective as an aid to help people stop smoking, or as a substitute for tobacco smoking, they should be able to deliver nicotine effectively. While an early study\textsuperscript{42} found the two brands tested did not deliver nicotine to their participants, subsequent studies\textsuperscript{43,44,45} have found e-cigarettes are capable of delivering nicotine (the early study involved first-time e-cigarette users and older technology, which is likely to explain its results). Comparison of different configuration of e-cigarettes in a recent evaluation\textsuperscript{46} found that newer generation higher performance e-cigarettes were faster at delivering nicotine than older ‘cigarette like’ models, however both configurations of e-cigarettes were significantly slower at delivering nicotine than a conventional tobacco cigarette.

The evident commercial success of e-cigarettes has been driven by anecdotal reporting of many cases of successful smoking cessation and substitution among long-term tobacco smokers. This has also been found among surveys among (self-selecting) populations of dedicated e-cigarette users\textsuperscript{47,48} and a longitudinal study\textsuperscript{49} has found low rates of relapse to smoking among this group (though this study has several weaknesses including very high loss to follow-up).

An issue common with these type of studies is their recruitment of participants from online e-cigarette enthusiast forums, where positive experiences with e-cigarettes will be over-represented. Several experimental studies enrolling participants from the general population (to overcome these issue of self-selection) have been conducted\textsuperscript{50,51,52,53,54}. These generally show favourable results for e-cigarettes in terms of cessation and cigarette reduction outcomes, however several of these studies are small, lack a control group, and are the product of only two research teams (one in Italy and another in New Zealand).

The most methodologically robust of these studies (from New Zealand\textsuperscript{54}) is a moderately sized randomised controlled trial that found approximate equivalency between the one brand of e-cigarette tested (an early model with relatively poor nicotine delivery\textsuperscript{55}) and a conventional NRT patch. While the primary analysis in this study was unable to conclude that e-cigarettes were superior to the NRT patch for cessation (in part due to the low overall cessation rates observed across all participants in the study), a secondary analysis of self-reported cessation suggested a marginally higher overall effect on cessation for e-cigarettes.
compared to the NRT patch, with the time till relapse to smoking being twice as long in the e-cigarette group\textsuperscript{65}.

Outside of experimental studies that may impose artificial constraints on behaviour, the cessation effects of e-cigarettes have been examined in observational studies of e-cigarette use in the general population (i.e. examining outcomes in cessation between e-cigarette users and non-users in general health or tobacco control surveys)\textsuperscript{56,57,58,59}. These studies do not show strong associations between e-cigarette use and cessation from smoking. However, most of these studies were not designed with the intent of examining cessation outcomes, none adequately control for the many ways in which smokers who quit using a form of assistance differ from those who do not (e.g. differing nicotine dependence, a well-established issue in similar studies of medicinal NRT\textsuperscript{60,61}), or involve poor measurement of e-cigarette use (e.g. being unable to discriminate between the use of e-cigarettes in a concerted effort to stop/substitute for smoking and experimentation with no intent of sustained use). Recent research from a large general population survey England has made attempts to improve on the issues present in previous observational studies, and finds that smokers who attempted to stop using e-cigarettes were more likely to report abstinence from smoking compared to those who attempted to stop with NRT bought over-the-counter, or those who used no aid\textsuperscript{62}.

**Are e-cigarettes a gateway to smoking for young people?**

A concern expressed around e-cigarettes is that they will act as an entry product to nicotine for children and young people – who would otherwise never have smoked – who would then go on to smoke tobacco due to their experiences with e-cigarettes. This is a difficult proposition to assess, and similar claims have been asserted, but also challenged, in relation to lower-risk smokeless tobacco\textsuperscript{63,64,65,66}. The difficulty arises because, although associations between starting one nicotine product use and subsequently going on to use another may be uncovered by research, the associations are not necessarily causal (i.e. it is the use of e-cigarettes that causes later smoking) and may be explained by shared risk factors that predispose individuals to engage in both behaviours\textsuperscript{66}.

Very limited data exists on e-cigarette use among young people in the UK, and no data currently exists for Scotland alone. One survey by ASH\textsuperscript{67} of around 1,400 11 to 18 year olds in Great Britain in 2013 who were aware of e-cigarettes found that sustained use of e-cigarettes was rare, and, at the time of the survey, confined almost entirely to children who already have a history of use of tobacco cigarettes. However, because the sample was recruited via parents who were members of a commercial online survey panel, potential biases due to panel recruitment or accurate completion of the survey (e.g. if parents or householders were present while the survey was being completed by the young person) may exist. A convenience sample of 671 young people aged 13 to 18 in Wales that took part in an online survey for ASH Wales in late 2013/early 2014 found similar results\textsuperscript{68}.

A 2013 survey conducted with around 6,000 students aged 14 to 17 in Cheshire and Merseyside found around 13% of young people surveyed reported ‘having accessed’ e-cigarettes (this definition includes both ‘having bought’ and ‘having tried’ e-cigarette so gives no idea of intensity of usage) with most ‘access’ again concentrated in young people who have a history of smoking tobacco cigarettes. E-cigarette access was also strongly positively associated with another behavioural risk factor (alcohol consumption)\textsuperscript{69}. No data on e-cigarette use among young people in Scotland exists, though it will be reported in the large, nationally representative, SALSUS survey of 13 and 15 year olds which was conducted during 2013 and is due to report in November 2014\textsuperscript{70}. 

\textsuperscript{62}E-cigarettes briefing May 2014
Surveys from the United States conducted for the US Centres for Disease Control and Prevention (CDC)\textsuperscript{71} have shown an approximate doubling of both ‘ever’ and ‘current’ (within the last 30 days) use among middle and high school students between 2011 and 2012. CDC also report that, in 2012, around 7\% of high school students who had ever used e-cigarettes reported never smoking conventional cigarettes. The same survey shows that tobacco cigarette smoking continued to decline during the 2011 and 2012 period\textsuperscript{72}, and, as shown by a separate large survey of the US student population, has continued to decline throughout 2013\textsuperscript{73}, suggesting that, if a gateway effect does exist, it is not sizeable enough to change overall reductions in tobacco cigarette prevalence.

Recent cross-sectional surveys involving large datasets of e-cigarette use in Korean\textsuperscript{74} and US\textsuperscript{75} adolescents, found use was associated with cigarette smoking, attempts/intent to quit, but not with abstinence from conventional cigarettes. Because of the design and limitations of these studies, the finding are consistent with both the theory that e-cigarettes encourage tobacco cigarette use, and the opposing theory that e-cigarettes are being used as alternatives to smoking by the adolescent smokers that are most heavily addicted to nicotine or otherwise predisposed to engage in risky behaviours. Hence these findings are not enlightening as to whether gateway effects are happening in these populations.

Taken as a whole, the limited data available for the UK is not suggestive of a strong gateway effect at present as there appears to be limited sustained use among never smoking young people, though this should not be taken to conclude that such an effect could not exist (or even that it exists to some extent at present, but the current evidence is inadequate to detect it). Because the existence of ‘gateway’ effects is challenging to either confirm or deny and there is apparent disagreement on the issue, academics working in the area have recently made a call for clarity on the criteria needed for evidence to demonstrate either the existence or absence of a gateway effect, to set a standard upon which researchers could agree\textsuperscript{76}. Such an approach could facilitate a more balanced and evidence-led assessment of risks posed by a potential gateway effect to smoking, which could then be weighed against the potential benefits of e-cigarettes as a route away from smoking.

It is possible that the forthcoming 2013 SALSUS dataset in Scotland\textsuperscript{70} – a large dataset containing rich information on other risk factors for smoking and substance use – could be used to help in setting this standard, by examining whether never smoking e-cigarette using young people possess many of the risk factors for tobacco smoking (i.e. to investigate whether, even if they did not currently smoke tobacco at the time they were trying e-cigarettes, they were nevertheless highly at risk for doing so).

Other issues

**Accidental injury, quality control/product defects**

The fatal adult human dose for nicotine was, until relatively recently, thought to be around 50 to 60mg\textsuperscript{77}. A current investigation into acute nicotine toxicity\textsuperscript{78} suggests these values are too low by a substantial margin, and that the true value is likely to be instead in the region of 500 to 1,000mg. Even if these higher thresholds are accepted, the quantity of nicotine in a 10ml refill bottle of nicotine e-liquid at the higher strength end of currently available products still has the potential to be a hazard if ingested or otherwise absorbed, especially for children. In the US calls to poison centres involving e-cigarette liquid have increased in line with the increase in prevalence of e-cigarettes use\textsuperscript{79}. There is one suspected fatal case of poisoning from e-cigarette liquid in a child from Israel\textsuperscript{80}. This highlights the importance of proper packaging, labelling, and storage instructions for e-liquids.
As described previously, toxicant emissions from e-cigarettes appear to vary substantially by device configuration\(^1\). The quality of manufacture and materials used (e.g. in the quality of the wicking material used to supply liquid to the heating element, the composition of the metal heating element, purity of ingredients used in the liquid) are likely to impact on user exposure to undesirable toxicants, and there appears to be significant room for improvement in some devices\(^3\). As with other rechargeable battery-powered devices, safety during charging to avoid accidental fires and injury may be improved by the incorporation of adequate overcharge protection on the devices themselves, and the provision of clear instructions on charging by the manufacturer.

**Dual use**

‘Dual use’ – continued use of smoked tobacco alongside e-cigarettes – has been highlighted as a particular concern surrounding e-cigarettes. Because even low levels of continued smoking still confers substantial health risks, the magnitude of benefits that can be expected from reduced smoking alone (without cessation) are uncertain\(^2\). The introduction of e-cigarettes to the market could be problematic if it extended the duration of tobacco cigarette smoking in those who would otherwise have stopped.

As this issue is related to the effectiveness of e-cigarettes as a cessation or substitute for tobacco smoking (because, if, on average, e-cigarettes cause more continued smoking than they prevent, this will start to become apparent in studies of e-cigarettes that examine cessation outcomes), the research already described in the section dealing with cessation applies to some extent to questions of dual use. Looking at other analogous products, in a systematic review of randomised controlled trials of medicinal NRT products among smokers who had no intention to quit smoking, dual use of NRT and smoking resulted in more, not less, abstinence from smoking at follow-up (approximately doubling quit rates\(^3\)). Continued monitoring of surveillance data and well-designed observational studies are necessary to determine if e-cigarettes are different in this regard from NRT.

At the population level, although the majority of e-cigarette use in Great Britain is dual use (approximately two-thirds of e-cigarette users being current smokers with the remained being ex-smokers\(^1\)), population level data from a large, regular survey in England\(^4\) shows that there has been a recent sharp decline in cigarette smoking prevalence, and an increase in quit attempts and success rates in quitting that correlate with the rise in popularity of e-cigarettes among smokers. While this cannot necessarily demonstrate that e-cigarettes are responsible for causing these outcomes, this data is inconsistent with a large effect of e-cigarette dual use in prolonging smoking.

**Marketing and advertising**

Concurrent with the growth of e-cigarette popularity has been a rapid growth in the general visibility of e-cigarette marketing through a variety of advertising channels\(^5,6\). This has caused concern in that, even if the target of adverts are exclusively adult smokers, the relatively free rein that advertisers currently have regarding e-cigarettes means there are likely to be knock-on effects in generating interest in the product and e-cigarette brands among never smokers and young people. There is a well-established evidence base on the effects of tobacco advertising and promotion on adolescent smoking uptake\(^7\), and given similarities in tone and technique of some e-cigarette advertising to tobacco cigarette advertising from previous decades, it is plausible widespread marketing of e-cigarettes will have the consequence (intended or unintended) of generating some degree of interest and trial in never smokers and young people. There are currently processes underway to attempt to bring more regulatory control to the marketing of e-cigarettes, see the section that follows on ‘what regulations apply to e-cigarettes in the UK?’
The tobacco industry
The majority of the current e-cigarette market in the UK consists of a multitude of small and medium sized businesses and several larger companies that are independent of the tobacco industry. However, in recent years major international tobacco companies have either acquired existing e-cigarette companies, or brought new e-cigarette products to market themselves. This has provoked comment that tobacco industry motives in this field are unlikely to revolve around the sole goal of reducing health harms and saving lives\(^8\). Analysis of tobacco industry documentation\(^8\) has suggested that tobacco companies’ involvement in harm reduction is an opportunistic tactical adaption to the shifting policy environment on tobacco that it foresees will secure reputational benefits with policy makers and public health groups. These developments can be expected to raise new challenges around limiting tobacco industry involvement in, and interference with, public health policy.

What regulations apply to e-cigarettes in the UK?
In 2010, the UK Medicines Regulator, the Medicines and Healthcare products Regulatory Agency (MHRA) consulted on bringing all unlicensed nicotine products (including e-cigarettes) into their medicines regulatory framework\(^9\). Following responses to the consultation, the MHRA conducted a period of scientific and market research and announced in June 2013 that it wanted to proceed with medicinal regulation, and that it expected all e-cigarettes in the UK would be regulated as medicines in line with the (at the time ongoing) negotiations on the European Tobacco Products Directive\(^10\) by 2016. In October 2013 during a key vote on the Directive at the European Parliament, mandatory medicinal regulation was rejected and an alternative system was proposed. European lawmakers agreed upon a ‘two-track’ system whereby e-cigarettes that make a therapeutic claim to treat or prevent disease (including smoking cessation claims) will be subject to regulation as medicines. All other e-cigarettes may remain on the market provided they meet certain requirements, including:

- a maximum nicotine concentration and volume for e-cigarette devices and refill containers, with requirements for child and tamper-proofing
- mandatory consumer warnings on e-cigarettes packaging with information on ingredients
- a requirement for manufacturers to notify countries before placing new products on the market, to provide details on the ingredients and emission of the products, and to provide data of sales volumes and profile of product consumers
- a ban on many forms of advertising (most forms of advertising that have a cross-border effect including television and radio advertising) – advertising that only has a local effect such as point of sale advertising or billboards will not be covered

These measures are expected to come into force in May 2016. The European Tobacco Products Directive will not set age of sale limits on e-cigarettes at the European level; this is a matter that individual countries must take forward and the Scottish Government has indicated its intent to legislate on this matter once it has identified the most appropriate means.

The MHRA continues to encourage manufacturers to voluntarily submit products for medicines regulation in the intervening period. E-cigarettes sold on the market at present must also be in compliance with existing regulations, such as general products safety legislation and the Chemicals (Hazard Information & Packaging for Supply) Regulations 2002.
As e-cigarettes do not burn tobacco or another ‘lit substance or mixture’ they do not come under the legislation governing Scotland’s smoke-free public places. Individual public and private sector bodies in Scotland are responsible for creating and implementing their own policies on e-cigarette use.

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4 All figures, unless otherwise stated, are from YouGov Plc. Total sample size was 1064 adults. Fieldwork was undertaken between 5th to 14th March 2014. The survey was carried out online. The figures have been weighted and are representative of all Scotland adults (aged 18+).

5 All figures, unless otherwise stated, are from YouGov Plc. Total sample size (2014) was 12,269 adults. Fieldwork was undertaken between 5th to 14th March 2014. The survey was carried out online. The figures have been weighted and are representative of all GB adults (aged 18+). Unweighted bases from previous years: 2010 (12,597); 2012 (12,432); 2013 (12,171).


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