This briefing considers the key questions in the debate concerning the public health and regulatory response to e-cigarettes.
CONTENTS

ABBREVIATIONS .............................................................................................................................................. 4

INTRODUCTION .................................................................................................................................................. 5

1. WHAT IS AN ELECTRONIC CIGARETTE? ........................................................................................................... 5
   A. WHO INVENTED THE E-CIGARETTE? .............................................................................................................. 5
   B. HOW DOES IT WORK? ................................................................................................................................... 6
   C. HOW EFFECTIVE ARE THEY IN DELIVERING NICOTINE? .............................................................................. 7

2. HOW BIG IS THE MARKET FOR E-CIGARETTES? ............................................................................................ 8
   A. HOW MUCH IS THE MARKET WORTH IN THE UK? ......................................................................................... 8
   B. WHAT ARE THE REASONS FOR MARKET GROWTH? ..................................................................................... 8
   C. WHO ARE THE MAIN PLAYERS IN THE E-CIGARETTE MARKET? ............................................................ 8
   D. HOW DOES THE E-CIGARETTE MARKET COMPARE WITH THE SMOKING CESSTION MARKET? ... 9

3. WHAT HAS BEEN THE UP-TAKE OF E-CIGARETTES? .................................................................................. 9
   A. WHAT IS THE PREVALENCE AMONGST ADULTS? ......................................................................................... 10
      Great Britain ..................................................................................................................................................... 10
      Scotland ......................................................................................................................................................... 10
   B. WHAT IS THE PREVALENCE AMONGST CHILDREN AND YOUNG PEOPLE? ............................................. 11
      Great Britain ..................................................................................................................................................... 11
      Scotland ......................................................................................................................................................... 11

4. WHAT IS THE PUBLIC PERCEPTION OF E-CIGARETTES? ............................................................................. 11

5. WHAT ARE THE HEALTH EFFECTS OF USING E-CIGARETTES? ................................................................. 12
   A. OVERALL HEALTH EFFECTS ....................................................................................................................... 12
   B. HOW HARMFUL IS NICOTINE? .................................................................................................................... 12
   C. WHAT ABOUT THE RISKS OF POISONING ASSOCIATED WITH E-LIQUID NICOTINE CARTRIDGES? ... 13
      The ingestion of nicotine e-liquid ................................................................................................................... 13
      Mislabelling of nicotine products .................................................................................................................... 14
      Other toxicants in e-liquid .............................................................................................................................. 14
   D. IS THERE ANY RISK FROM THE NICOTINE VAPOUR AND THE HEATING PROCESS? ........................... 14
      Heating propylene glycol (PG) and vegetable glycerine (VG) ...................................................................... 14
      Other potential toxins .................................................................................................................................. 15
   E. WHAT IS THE EVIDENCE ON SECOND-HAND EXPOSURE? ..................................................................... 15

6. I’VE HEARD OF E-CIGARETTES EXPLODING – WHY DOES THIS HAPPEN? .............................................. 16

7. DO E-CIGARETTES HELP PEOPLE TO STOP SMOKING? ............................................................................. 16
   Studies of e-cigarette use in smokers wanting to quit ....................................................................................... 17
   Studies of e-cigarette use in smokers not wanting to quit ................................................................................. 18
   What does the evidence tells us? ...................................................................................................................... 19

8. DO E-CIGARETTES NORMALISE SMOKING AND LEAD YOUNG PEOPLE TO TAKING IT UP? .......... 19

9. HOW SHOULD E-CIGARETTES BE REGULATED? ........................................................................................... 20

10. WHAT REGULATION IS IN THE PIPELINE AT EU LEVEL? ................................................................. 22
    When does the TPD enter into force? .................................................................................................................. 23
    How will the TPD be implemented in the UK? .................................................................................................. 23

11. HOW ARE E-CIGARETTES REGULATED IN THE UK/ SCOTLAND? ......................................................... 25
    Current regulation ............................................................................................................................................. 25

12. IS THERE AN AGE LIMIT FOR USING E-CIGARETTES? ........................................................................... 27
    UK ................................................................................................................................................................... 27
    England and Wales ......................................................................................................................................... 27
    Scotland .......................................................................................................................................................... 28

13. WHAT ARE THE RULES ON ADVERTISING? ............................................................................................. 28
14. CAN E-CIGARETTES BE USED IN PUBLIC PLACES? ................................................................. 31
    Voluntary bans ....................................................................................................................... 31

15. HOW ARE E-CIGARETTES TAXED? .................................................................................. 32

16. HOW ARE E-CIGARETTES REGULATED ELSEWHERE IN THE WORLD? ................. 33
    USA ........................................................................................................................................ 33
    WHO survey .......................................................................................................................... 33

SOURCES ................................................................................................................................. 35
# ABBREVIATIONS

A number of abbreviations are used frequently throughout this briefing:

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASH</td>
<td>Action on Smoking and Health</td>
</tr>
<tr>
<td>BMA</td>
<td>British Medical Association</td>
</tr>
<tr>
<td>AIHA</td>
<td>American Industrial Hygiene Association</td>
</tr>
<tr>
<td>ECITA</td>
<td>Electronic Cigarette Industry Trade Association</td>
</tr>
<tr>
<td>MHRA</td>
<td>Medicines and Healthcare Regulatory Products Agency</td>
</tr>
<tr>
<td>NRT</td>
<td>Nicotine Replacement Therapy</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organisation</td>
</tr>
</tbody>
</table>
INTRODUCTION

Electronic cigarettes (e-cigarettes) have become popular devices, normally used to obtain nicotine. Originating as an alternative to tobacco cigarettes, a significant public health debate is underway concerning what role (if any) they should have in smoking cessation strategies and how they should be regulated. Hajek et al (2014) have summed up the debate as follows:

“Commentators in favour of EC [electronic cigarettes] restrictions believe that the product has a potential to increase cigarette use by re-normalizing smoking, i.e. reducing motivation of smokers to quit completely, providing a gateway to smoking for non-smokers or facilitating an increase in smoking prevalence indirectly. They argue that EC should be banned or submitted to much stricter controls than smoked tobacco. They emphasize evidence that nicotine can be addictive and warn that health risks from long term EC use may yet emerge.

EC advocates believe that, on the contrary, the product has a potential to reduce and, if it continues to develop, eventually end cigarette use by allowing smokers to switch to a safer product. They argue that achieving this potential requires little government expenditure and involvement and that it is in the public health interest to allow EC to compete with cigarettes in the market-place. They emphasize evidence that use of nicotine without tobacco toxicants poses minimal risks, except in the case of well-defined subpopulations such as pregnant smokers.”

This description may be seen by some as presenting the extremes of the argument. In reality, the debate may be much more nuanced with many of those with an interest in the discussion placing themselves somewhere in the middle. Nevertheless, the quote neatly presents the different grounds of contention. However, as Hajek et al (2014) also point out, what both sides do agree on is that any regulation placed on the devices should be based on evidence.

It should be noted that the literature and our understanding of e-cigarettes is constantly evolving as new studies on different aspects of their use and effects are being published. Thus, the analysis in this briefing can only ever be considered to be a snapshot of what the evidence base is suggesting at one point in time.

In addition, the briefing does not seek to address every question that has been posed about e-cigarettes or their effects. Neither should the briefing be considered to be a systematic review of the evidence. Its key aims are to identify the key questions being posed in the debate and to provide examples of the evidence being presented as part of that debate.

1. WHAT IS AN ELECTRONIC CIGARETTE?

An electronic cigarette (also known as an e-cigarette, ‘electronic nicotine delivery system’ (ENDS), or vapouriser) is best known as a battery-powered device, resembling a cigarette, which is designed for the purpose of providing inhaled doses of nicotine by way of a vapourised solution (Polosa et al, 2013), though not all e-cigarettes contain nicotine. In this briefing the term ‘e-cigarette’ will be used. The act of using an e-cigarette is often referred to as “vaping”.

A. WHO INVENTED THE E-CIGARETTE?

The invention of the modern e-cigarette is widely credited to a pharmacist, Hon Lik, from China, who patented his device in 2003 (Hajek et al, 2014). Other sources also note the contribution of Herbert A Gilbert, an inventor from the United States who, in 1965, developed and patented “a smokeless non-tobacco cigarette […] to provide a safe and harmless means for and method of smoking by replacing burning tobacco and paper with heated, moist, flavoured air” (Google Patents, Online). However, this latter product was never marketed.
B. HOW DOES IT WORK?

The typical components that make up a nicotine e-cigarette are shown in Figure 1. Many e-cigarettes are powered by a re-chargeable lithium ion battery. The battery powers an atomiser (in some makes this is activated by inhalation, in others it is manually switched on), and a heating coil heats liquid nicotine that is contained in a cartridge. The liquid nicotine then becomes a vapour and is inhaled. Flavourings are also added, and many makes have LED lights as a cosmetic feature which mimics the traditional cigarette glow.

Figure 1: The components of an e-cigarette

The key advantage for the smoker is that they still take in nicotine but without many of the toxic chemicals that accompany nicotine in cigarette smoke, though the debate concerning the health implications of e-cigarettes is discussed in greater detail below.

Figure 1 describes the basic elements of an e-cigarette. However, e-cigarettes have evolved rapidly, largely due to competition in the market (Hajek et al, 2014). This has led to a proliferation of manufacturers who each try to differentiate their products from the others. As a result, the range of products available has grown and e-cigarettes now come in various sizes, colours and vapour flavours. As shown in Figure 2, as new generation of e-cigarettes have been developed they appear less and less like tobacco cigarettes:

Figure 2: The three generations of e-cigarette

WHO (2014, p 2) has found that in 2014 there were 466 e-cigarette brands and over 7,000 flavours. As well as e-cigarettes other devices have been designed to look like cigars, pipes and hookahs. The newer generations of e-cigarettes can take many different forms, from rectangular (as in Figure 2) to a large cylindrical form to pens and USB sticks. Bauld et al,
2014) discuss how such innovations have arisen as brands seek to differentiate themselves from one another. They also note a number of other developments, including:

“Supersmoker Club has introduced an e-cigarette with Bluetooth that is compatible with androids, iOS devices or tablets to allow users to make calls or listen to music while vaping. Smokio has developed an e-cigarette that gives smokers statistics about their consumption via a mobile app.” (p 14).

ECITA (Online) has published a document\(^1\) that illustrates the diversity of e-cigarettes and other nicotine delivery devices.

However, another recent development has been the ability of users to modify certain products at home to alter the delivery of nicotine. This has caused concern amongst some organisations, including WHO (2014, p 2). This is based on the possibility of users being able to alter the delivery of nicotine and also other substances, including illegal drugs. The use of illegal drugs would in itself be an offence. However, ECITA (Online) state that the strength of nicotine and other factors in e-liquids are also controlled through regulations.

This diversity of e-cigarette, the large number of flavours and the ability to modify devices raise issues in both ascertaining the public health impact of the devices and establishing a regulatory regime. For example, significant research has been carried out on earlier generation e-cigarette types, but this may not necessarily be applicable to newer generations of the devices nor the way people use them.

C. HOW EFFECTIVE ARE THEY IN DELIVERING NICOTINE?

Nicotine is the addictive component of tobacco, which is why it is used in tobacco substitutes.

Through smoking a tobacco cigarette the nicotine is delivered throughout the lung and is absorbed in two ways: i) through systemic venous circulation\(^2\) from the orpharynx and large airways, and ii) through pulmonary circulation\(^3\) from the small airways and alveoli. It is the latter route that provides the rapid delivery of nicotine to the brain. However, it is currently thought that nicotine via an e-cigarette is absorbed in a different and slower way, primarily though the upper airway. (Britton and Bogdanovica, 2014, p 6).

It has been estimated that 15 x 70ml puffs are needed to deliver 1mg of nicotine through an e-cigarette. This compares to 12 x 46ml puffs needed to deliver 1.5 – 2.6mg nicotine through a conventional cigarette (National Centre for Smoking Cessation and Training (NCSCT)) (2014, p 6). However, a recent evaluation has found that newer generation e-cigarettes are quicker to deliver nicotine compared to older types of device, but they are still not as quick as tobacco cigarettes (ASH Scotland, 2014c, p 6). When comparing e-cigarettes with conventional NRT products, some studies have suggested that e-cigarettes can result in blood nicotine levels similar to oral NRT products, but with delivery being achieved at a faster rate (NCSCT, 2014, p 9).

The American Industrial Hygiene Association (AIHA) (2014, p 6) points to a study that suggests that some e-cigarette products may deliver different levels of nicotine to their users each time they are used, even if the cartridges contain the same nicotine content. This may be due to the devices themselves, for example, there is evidence that the cooling of the heating element as

---

\(^1\) It should be noted that this is presented for illustrative purposes only. Its use in this briefing should not be taken as an endorsement of any arguments made within it.

\(^2\) Venous circulation is the part of your circulatory system that involves veins, like the vena cavae and pulmonary veins. Veins are blood vessels that carry blood to your heart.

\(^3\) Pulmonary circulation is the movement of blood from the heart to the lungs and back to the heart again. Pulmonary circulation includes both arterial and venous circulation.
an e-cigarette is being used may lessen nicotine delivery (WHO, 2014, p 2). Alternatively, there are studies suggesting that user behaviour may also affect the levels of nicotine delivery and absorption (Hajek et al, 2014). Factors may include the length of puff, depth of inhalation and frequency of use.

2. HOW BIG IS THE MARKET FOR E-CIGARETTES?

WHO (2014, p 2) notes research showing that in 2014 there were 466 e-cigarette brands worldwide, and that in 2013 US$3bn was spent globally on e-cigarettes. It also points to studies that suggest sales may increase by a factor of 17 by 2030. However, it notes that there is some uncertainty as to the potential for growth, and that certain companies have recently reported a slow-down in sales. WHO also considers that one of the difficulties in analysing the market is the lack of data for many countries.

This section of the briefing will reflect mainly on the UK market. Given that e-cigarettes only took a foothold in the UK market around seven years ago, evidence on the size of the market is still emerging. Nevertheless, there is some data available on how much the market is worth and information on the main players in the market.

A. HOW MUCH IS THE MARKET WORTH IN THE UK?

Across the UK, it has been estimated that the e-cigarette market was worth £193m in sales in 2013, an increase of 340% compared to the £44m of 2012 (Mintel, Online). However, it is thought that the market could be worth £340m by 2015 (Chittock, 2014). No specific Scottish data could be found.

B. WHAT ARE THE REASONS FOR MARKET GROWTH?

Hajek et al (2014) suggest that, initially at least, the growth in the sales of e-cigarettes was consumer led and through word of mouth. However, when considering the UK specifically, Chittock (2014) suggests that the key motivator for growth has been the relative lack of regulation (up to now), and the consolidated nature of the UK market (see 2C, below).

How the products have been marketed may also help to explain market growth. Bauld et al (2014, p 10-12) discuss how the marketing of e-cigarettes has focussed on promoting them as cheaper and healthier alternatives. In addition, e-cigarettes have been positioned as being socially attractive. Tools such as celebrity endorsements, online promotions, mobile phone apps and other forms of social media have publicised them as lifestyle products. One study found that media marketing on four of the top brands (Skycig, Vype, Gammuci and E-Lites) amounted to £8m in 2013. Examples of recently launched individual campaigns include Nicoventures £3.6m TV campaign, which aimed to position its product as an alternative to smoking, and the £20m campaign of Skycig aimed at promoting the product as a positive lifestyle choice for smokers. As Bauld et al (2014, p 14) note (already referred to under Question 1B) with increased marketing has also come innovation as brands seek to differentiate themselves from one another.

C. WHO ARE THE MAIN PLAYERS IN THE E-CIGARETTE MARKET?

A large number of e-cigarette companies have emerged following the introduction of e-cigarettes to the UK market. One study states there have been several e-cigarette start-ups and the establishment of 250 independent suppliers since e-cigarettes first came onto the UK market (Bauld et al, 2014, p 4). Another found that in just over 1 year (1 May 2012 to 26 June 2013) a total of 121 product trademark applications were made (De Andrande, 2013, p i).
However, WHO (2014, p 8) notes that, whilst initially the e-cigarette market was dominated by companies with no links to the tobacco industry, all the main tobacco companies now sell e-cigarettes. Bauld et al (2014, p 4) discuss how a number of independent e-cigarette companies have been taken over by large multinational tobacco companies. For example:

- **British American Tobacco** was the first major tobacco group to buy a British e-cigarette company when it acquired CN Creative in December 2012. BAT had previously set up the wholly-owned subsidiary Nicoventures to develop and commercialise regulated nicotine products. CN Creative merged with BAT Research and Development and Nicoventures in August 2013 when it launched the e-cigarette, Vype.
- In October 2013, the third largest US tobacco firm Lorillard entered the UK market when it acquired the independent Edinburgh based e-cigarette brand, Skycig, for £30 million. The product generated £2.4 million in net sales in the quarter following the acquisition.

WHO (2014, p 8) believes that the future role of e-cigarettes will be strongly determined by the commercial interests of the industry manufacturing and selling e-cigarettes. Its principal concern is that if the market is concentrated under the ownership of tobacco companies, then the market will be a means of supporting these companies towards “maintaining the status quo in favour of cigarettes for as long as possible”. It contends that the tobacco companies are competing aggressively with independent e-cigarette companies to gain market share on the e-cigarette market. As to possible reasons for such developments, financial analysts have suggested that growing sales of e-cigarettes could threaten sales of cigarettes (Hajek et al, 2014). Whilst noting this possibility, which WHO refers to as “providing a longer term source of profit should the cigarette model prove unsustainable”, WHO is also of the opinion that “selling these products is intended to bring reputational benefits to these companies, as they can pretend to be part of the solution to the smoking epidemic” (2014, p 8).

However, the Electronic Cigarette Industry Trade Association (ECITA) (2014a) contends that, whilst it is the case that the large tobacco companies have entered the market, they number fewer than ten brands in the e-cigarette market, compared to the hundreds of independent e-cigarette companies. It added that it is also seeing consolidation amongst the non-tobacco e-cigarette companies. One example ECITA gave was of the US company, Electronic Cigarettes International Group acquiring three brands Vapestick, VIP and 10 Motives. It also noted that in these acquisitions the brand names are allowed to continue, whilst when tobacco companies take over e-cigarette companies they tend to subsume the independent brand.

D. HOW DOES THE E-CIGARETTE MARKET COMPARE WITH THE SMOKING CESSATION MARKET?

In its research, Mintel (2014) noted that the smoking cessation aid market – including products such as gum, tablets and patches - has experienced annual growth of around 6-10% between 2009 and 2012. However, it indicates that sales of products have slowed, and that, in 2013, the market for smoking cessation aids grew by only 1.7% to reach a value of £131 million. It believes that the rise in popularity of e-cigarettes has hampered the growth in the smoking cessation market.

3. WHAT HAS BEEN THE UP-TAKE OF E-CIGARETTEs?

Given that e-cigarettes are a relatively new phenomenon, there is limited data on up-take in Scotland or the rest of the UK. The Scottish Government has stated that whilst it has not commissioned its own research, it has added a question on e-cigarette use to the Scottish Schools Adolescent Lifestyle and Substance Use Survey 2013-14. Findings from this survey will be available in late 2014. In addition, new questions on the use of electronic cigarettes were
added to the Scottish Health Survey in 2014 and the data from this will be available in September 2015 (Scottish Parliament, 2014a).

ASH has also commissioned a survey on e-cigarettes in Great Britain (excluding Northern Ireland). In addition, ASH Scotland recently commissioned YouGov to undertake a poll on e-cigarette use. The findings from these are discussed in the sections below.

A. WHAT IS THE PREVALENCE AMONGST ADULTS?

Great Britain

ASH (2014b) commissioned a series of surveys between 2010 and March 2014, which included questions on e-cigarettes. By applying the results to the most recent population data it estimated the prevalence of electronic cigarette usage in Great Britain. Overall it estimates that 2.1 million adults use e-cigarettes across Great Britain. Of these, around 700,000 are ex-smokers, whilst around 1.3 million are smokers who used an e-cigarette alongside tobacco.

When considering data across surveys over several years, it found that 8.2% of current smokers had tried electronic cigarettes in 2010, but that by 2014 the figure had risen to 51.7%. In 2010 the number of current smokers who also use electronic cigarettes on a regular basis was 2.7%. This had grown to 17.7% by the time of the 2014 survey.

Another review has noted that, in general, e-cigarette users are more likely to be current smokers than ex-smokers. According to this review, they tend to be younger, better educated and from higher socio-economic groups than non-users (NCSCT, 2014).

The 2014 ASH survey also examined why people tried e-cigarettes and found that the principal reasons given by ex-smokers were to help a quit attempt (71%) and “to help me keep off tobacco” (48%). The principal reason given by current smokers was to “help me reduce the amount of tobacco I smoke, but not stop completely” (48%) followed by “to save money compared with smoking tobacco” (37%).

Recent statistics published as part of the Smoking Toolkit Study in England (West et al, 2014) have shown that over a two year period prevalence of e-cigarettes use increased rapidly between the second quarter of 2011 until the third quarter in 2013 but had not grown in the subsequent 12 months. In addition, the study found that:

- 20% of smokers and 30% of recent ex-smokers use e-cigarettes
- use of e-cigarettes by never-smokers and long-term ex-smokers remains extremely rare
- 30% of quit attempts involve use of e-cigarettes making them the most popular method of stopping smoking

However, interestingly, it also found that the prevalence of both smoking and use of any nicotine product had declined.

Scotland

ASH Scotland (2014a) has also commissioned surveys on the use of e-cigarettes. These found that in 2010 3% of adult smokers in Scotland used e-cigarettes, but that by the 2014 survey this figure had risen to 17%.
B. WHAT IS THE PREVALENCE AMONGST CHILDREN AND YOUNG PEOPLE?

Great Britain

ASH (2014b, p 4-5) found in a 2013 survey that regular use of e-cigarettes amongst children and young people was rare and was confined almost entirely to those who currently smoked or who had previously smoked. Among those who smoked more than 6 cigarettes a week and had heard of e-cigarettes, 48% had tried e-cigarettes once or twice, 7% had used them more than once a month and 5% had used them once a week.

Scotland

In its survey from July 2014, ASH Scotland (2014b) found that:

- 24% of respondents aged 13 and 14 reported ever having used an e-cigarette. This rises to just under half of 15 to 18 year olds
- 2% of non-regular smokers and 15% of regular smokers were regular e-cigarette users

This survey also asked questions on the reason for trying e-cigarettes for the first time, and the findings included:

- 59% who were not regular smokers wanted to try e-cigarettes to see what they were like (this was the largest single response). The equivalent response from regular smokers was 50%.
- Similar prevalence of regular smokers and non-regular smokers wanting to try e-cigarettes after seeing a friend using them (34% and 33% respectively).
- 23% of regular smokers wanted to try them after seeing a family member using them compared to 16% of non-regular smokers.
- 29% of regular smokers wanted to try them to help them stop smoking normal cigarettes compared to 10% amongst non-regular smokers.
- 11% of regular smokers and 45% of non-regular smokers wanted to try them after seeing advertising for the products.

4. WHAT IS THE PUBLIC PERCEPTION OF E-CIGARETTES?

The surveys on e-cigarettes tend to concentrate on uptake. However, the recent ASH and ASH Scotland surveys include questions aimed at gauging general views on e-cigarettes amongst those surveyed.

The ASH survey from earlier this year found that just over a third (35%) of British adults surveyed believed that electronic cigarettes are good for public health while around a quarter (22%) disagreed (2014b, p 1). The survey undertaken by YouGov (2014) for ASH Scotland (published April 2014) found that, across all those surveyed, 32% either strongly agreed or agreed that, on balance, e-cigarettes were good for public health. However, amongst those that had never smoked the result was 24%, compared to 55% amongst those that smoked. This suggests that those who have smoked or who are current smokers are more likely to see a public health benefit to e-cigarettes.

The ASH survey of 2013 found that the understanding of e-cigarettes among children was generally good. Children who had heard of electronic cigarettes believed that they were less harmful than cigarettes to the user (74%) and those around them (79%). Most (51%) 16-18 year olds who had heard of electronic cigarettes believe that they contain nicotine.
5. WHAT ARE THE HEALTH EFFECTS OF USING E-CIGARETTES?

Those who smoke tobacco cigarettes expose themselves to a range of harmful toxins that are released through the burning of the tobacco. Non-tobacco, non-smoked nicotine products such as e-cigarettes do not involve the burning of tobacco. For this and other reasons, the general view is therefore, that any risks associated with e-cigarettes are less than those linked to tobacco (see below). However, given that e-cigarettes are presented as an alternative to smoking, and with many of them containing nicotine, questions remain whether or not they result in any harmful effects on health – not just on users, but also on those around them.

As with many of the issues surrounding e-cigarettes, research into health effects is at an early stage. WHO (2014, p 4) notes that, given the relatively recent introduction of e-cigarettes into the market place, it is unlikely that there will be conclusive evidence on any association with diseases such as cancer for years or even decades. West (2014) contends that:

“Given how long it took to discover the link between smoking and lung cancer when the risks were so great, we have to accept that it will probably be more than 30 years before we would have a chance of being able to use epidemiology to quantify risks from e-cigarette use. In fact we may never be able to do so because we are chasing a moving target in terms of the products and their development.”

This section of the briefing concentrates on outlining what the current evidence base indicates thus far.

A. OVERALL HEALTH EFFECTS

Hajek et al (2014) note a number of studies that have looked at the general health impact of e-cigarettes on users, also referred to as “adverse events”. In the main these have been categorised as being mild or moderate, including symptoms of mouth and throat irritation, and dry coughs. AIHA (2014, p 15) also makes note of self-reporting from users indicating that other symptoms include nausea, changes in heart rhythm and dizziness.

B. HOW HARMFUL IS NICOTINE?

Nicotine is the addictive element in tobacco cigarettes. As already discussed one of the main reasons for the creation of e-cigarettes was to provide nicotine without the other harmful effects associated with smoking tobacco. However, this leads to questions concerning the safety of nicotine itself.

WHO (2014, p 3) states that nicotine may contribute to cardiovascular disease and, although not a carcinogen itself, may function as a “tumour promoter”. It also states that nicotine may be involved in neuro-degeneration and aspects of the biology of malignant diseases.

The question then arises as to whether the dose of nicotine provided via an e-cigarette is enough to cause health problems. ECITA (2014a) makes note of one study⁴, which analysed the nicotine content in cartridges from five e-cigarette brands and the nicotine delivery in the vapour, and indicated that “there is little concern that e-cigarettes can harm their users by delivering toxic nicotine levels”. This was not just because the researchers observed low toxicity levels, but also because they found that an “over-enthusiastic user” would be warned of higher levels of nicotine by nausea.

---

⁴ Undertaken by researchers from the Tobacco Dependence Research Unit, Wolfson Institute of Preventative Medicine, Queen Mary University of London, and commissioned by the Medicines and Healthcare Products Regulatory Authority (2013a, p 20)
ASH Scotland (2014c, p 4) notes research showing that nicotine, either in the doses smokers or those using NRT are used to, is not considered particularly harmful to health. It points to studies showing that short-term use treatment with therapeutic nicotine did find side effects, though these were normally mild and temporary. It also noted that available studies of long term use of NRT do not indicate any increase in the risk of cardiac outcomes nor cancer.

However, ASH Scotland (2014c) and WHO (2014, p 4) note that there is evidence to suggest that caution should be exercised by pregnant women, and that there may be potential developmental risks also.

Overall, ASH Scotland (2014c, p 4) found that nicotine delivered in forms other than tobacco smoke does not have strong associations with disease, though also that there is a need for more research into this area.

C. WHAT ABOUT THE RISKS OF POISONING ASSOCIATED WITH E-LIQUID NICOTINE CARTRIDGES?

The ingestion of nicotine e-liquid

One potential risk is focuses on accidental ingestion or absorption of nicotine liquid (also referred to as “e-liquid”) from e-cigarettes. Traditionally, it has been thought that a 60mg dose of nicotine is fatal for human adults. However, there is doubt as to the veracity of this figure, since it appears to have been based on questionable experiments carried out in the 19th century (NCSCT, 2014, p 11). ASH Scotland (2014c, p 8) refers to research that suggests the fatal dose may be between 500-1,000mg. Hajek et al (2014) notes records that show people surviving suicide attempts after consuming liquid containing up to 1,500mg of nicotine.

WHO (2014, p 4) found that most countries do not monitor incidents of nicotine ingestion. However, it points to reported incidents from the United States and UK indicating that these have grown in line with the growth in e-cigarettes. ASH Scotland (2014c) believes that a high strength 10ml refill bottle of e-cigarette nicotine solution could pose a significant risk, noting that there was one suspected case of fatal poisoning from e-cigarette liquid in a child from Israel. More recently, in the UK a two year-old girl accidentally licked some liquid, though recovered (BBC News, 2014).

Discussing the safety of e-liquids, the Electronic Cigarette Industry Trade Association (ECITA, 2014b), taking it that 500mg of nicotine was sufficient to kill a person, stated that this was the equivalent of drinking more than two typical 10 ml e-liquid bottles containing a strong 2.5% concentration. It considered that since nicotine is an emetic, it would be very difficult to consume even one bottle without vomiting.

It should be noted that there are regulations governing a range of chemicals including nicotine. Within the EU, by 2015, most industrial chemicals must be categorised according to the European Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (known as the ‘CLP regulations’). Countries, such as the UK, which previously had their own classification systems, have been gradually harmonising these with the new regulations. (Health and Executive, Online). However, ECITA (2014c) believes that officials from across the EU are wrongly categorising liquid nicotine into higher risk CLP regulation categories:

“A report by the toxicology consultancy bibra concluded that the concentrations of nicotine in the vast majority of e-liquid (which is below 25mg/ml or 2.5%) do not require any type of hazard warning for acute oral and dermal toxicity. The report stated that even

---

5 A substance that causes vomiting.
stronger concentrations of nicotine only merit being classed in the lowest official hazard level of CLP Category.”

Concerning the accidental ingestion by children, it has called for those using e-cigarettes to be aware of using the products safely and to only use them in the ways directed (BBC News, 2014). It also mandates its members to provide clearly labelled e-liquid in child-proof containers (ECITA, 2014c).

Mislabelling of nicotine products

There have been some concerns raised that the labelling of cartridges may not be accurate. A study of five popular brands in the UK found that, whilst being labelled as containing 18-24mg of nicotine, they in fact could contain anything between 12.8-33.0mg. In addition some reports indicate that cartridges labelled as having no nicotine have actually contained the chemical, though in some cases only in trace levels. However, more recent studies appear to show that there is now relatively good consistency in labelling. (NCSCT, 2014, p 8 and Hajek et al, 2014).

Other toxicants in e-liquid

The carrier liquid used in the nicotine cartridges of many brands is propylene glycol (PG). It is considered to pose a low risk to human health, and is an approved additive (E1520) used as a carrier of flavour and/or colour in various foods and drinks (Food Standards Agency, Online). In addition to PG, another carrier fluid which is often used is vegetable glycerine (VG). Both VG and PG are ingredients in nicotine mouth spray (ASH Scotland, 2014c, p 5).

Hajek et al (2014) note that, as with nicotine in NRT, nicotine in e-liquids is extracted from tobacco and as a result includes a number of toxins. However, studies show that these are at very low levels, and in some cases analysis has shown some of them not to be present. Others were found, but at similar levels to NRT products. One study has also found metal particles to be present in e-liquid from one model of e-cigarette, but the report did not assess the clinical significance of the levels detected.

Finally, a study looking into how toxic 35 e-liquids were to human cells found that the toxicity was unrelated to nicotine content, though it did find a correlation with the number and concentration of flavourings. However, as with many other aspects of the evidence concerning e-cigarettes, this is an area that requires more investigation and monitoring. (ASH Scotland, 2014c, p 5).

D. IS THERE ANY RISK FROM THE NICOTINE VAPOUR AND THE HEATING PROCESS?

Because of the way an e-cigarette works (see Figure 1) there are concerns about the toxins that would result from the heating process that produces the vapour, and the content of the vapour itself.

Heating propylene glycol (PG) and vegetable glycerine (VG)

As noted above, the most commonly used carrier fluids for nicotine in e-cigarette cartridges are PG and VG. It has been suggested that when they are heated in an e-cigarette there could be implications to long term, high intensity inhalation.

A common short-term effect of exposure to PG includes eye and respiratory irritation. However, a study has shown that chronic exposure to PG indoors can induce or exacerbate conditions such as asthma and eczema in children. Another found that people exposed to theatre fog containing PG experienced acute and chronic respiratory problems (Hajek et al, 2014).
However, in terms of e-cigarette use, only a number of mild adverse effects (for example mouth and throat irritation, and dry cough) have been documented, and a small number of more serious adverse events have been reported. Of these, two were respiratory diseases and the other cardiac, but in all cases there was a reversal in symptoms when the user stopped using the e-cigarette. (NCSCT, 2014, p 8).

VG is considered to be non-toxic. However, when heated to high temperatures it can produce acrolein, which is toxic. Acroleine is also present in tobacco cigarette smoke, but studies have shown the substance is present at much lower levels in e-cigarettes. (Hajek et al., 2014).

Nevertheless, ASH Scotland (2014c, p 5) considers that the type of exposure to PG/VG resulting from e-cigarette use does not have a precedent and notes one review that concludes that this should be an area of further monitoring and evaluation.

**Other potential toxins**

There is evidence that e-cigarettes contain toxic substances, including small amounts of formaldehyde and acetaldehyde, which are carcinogenic. One study has considered the link between the voltage of the e-cigarette and the levels of formaldehyde. It found that high voltage devices could produce levels of formaldehyde similar to tobacco smoke. It is suggested that the lower voltage devices produce much lower levels of the substance. This, it has been argued, does have implications for the safety and design of the products. (ASH Scotland, 2014c, p 5).

Studies have also found traces of carcinogenic nitrosamines and toxic metals, including cadmium, nickel and lead, in e-cigarette vapour (Britton and Bogdanovica, 2014, p 7). These levels are at much lower quantities than in tobacco smoke, and these studies have tended to find that the vapour from e-cigarettes contains far fewer hazardous chemicals overall; though this can differ markedly between devices. (ASH Scotland, 2014c, p 5). AIHA (2014, p 12) notes that more research is needed to quantify the likely exposure to such metals during vaping. However, it contends that all of the elements found in the vapour have the potential to adversely affect the respiratory system, whilst some can affect reproduction and development (e.g. lead) and others are or may be carcinogenic (e.g. nickel and lead).

Other studies have considered the acute effects of e-cigarette use. Short-term use in both smokers and ex-smokers has not been shown to have any adverse effects as regards haematology, blood chemistry and cardiovascular function. However, e-cigarette use has been associated with increased heart rate after overnight abstinence, though this is an expected side effect. Meanwhile, two studies considering the effect of e-cigarette use on respiratory function have found little or no effect. (NCSCT, 2014, p 12).

Again, it is widely recognised that more research into the long term effects of e-cigarette vapour is required.

**E.WHAT IS THE EVIDENCE ON SECOND-HAND EXPOSURE?**

Most second hand smoke from a tobacco cigarette is sidestream smoke from the burning tip. However, e-cigarettes do not produce side stream vapour, only the aerosol exhaled by the user themselves. The chemicals that are generated do not include most of those found in tobacco smoke, though those that are include nicotine, flavours, aroma transporters, glycerol and PG. However, current evidence suggests that any pollutant levels are much lower than for tobacco cigarettes (Hajek et al, 2014).

It has also been suggested that e-cigarettes produce larger particles which settle faster than the smaller second-hand tobacco smoke particles, which it has been shown linger for many hours after a tobacco cigarette has been smoked. (NCSCT, 2014, p 12).
WHO (2014, 8-9) contends that just because e-cigarettes contain, on average, lower levels, of toxicants than the emissions from tobacco does not mean that this is acceptable to bystanders. It argues that exhaled aerosol may increase the risk of disease to bystanders, especially in those products that do produce higher toxicant levels. AIHA (2014, p 6) is also concerned that any perception amongst users that e-cigarettes are safer than tobacco cigarettes may cause them to consume e-cigarettes at a greater rate than tobacco cigarettes, and therefore generate greater amounts of second-hand contaminants.

Overall, based on current research evidence, it appears that the health risks of passive exposure to e-cigarette vapour is low (Britton and Bogdanovica, 2014, p 7). Though, it should be noted that no long term study has yet been conducted (Hajek et al, 2014).

6. I’VE HEARD OF E-CIGARETTES EXPLODING – WHY DOES THIS HAPPEN?

A number of fire and rescue services from across the UK have issued warnings about the safety of e-cigarette batteries, including East Sussex Fire and Rescue Service (Online), South Wales (ITV.com, 2014) and London Fire Brigade (2014). Most recently, in August 2014 Merseyside Fire & Rescue Service issued a safety warning and advice on e-cigarettes. This followed the death of a man in his home which was linked to a charging e-cigarette that exploded, caught fire and ignited the oxygen tube of an oxygen concentrator.

As shown in Figure 1, above, the heating coil in an e-cigarette is powered by a rechargeable lithium ion battery. These have been known to catch fire or even explode if they are overcharged, defective or damaged. This can lead to a cycle of heating called ‘thermal runaway’ and may cause a fire. Of particular concern is the use of chargers not suitable for e-cigarettes, chargers not meeting UK specifications, or not realising that the charger does not have an in-built switch-off mechanism when the battery is fully charged.

This is obviously not an issue unique to e-cigarettes, but illustrates that they are prone to risks as with any similar consumer product.

ECITA (2014a) has advised that it recently worked with the British Compressed Gases Association (2014) to develop a patient information leaflet for those using e-cigarettes but who also use oxygen. This should be given to all relevant patients. In addition, it has introduced battery and charger safety testing for members and non-members and included this in its code of practice. Finally, it is currently undertaking investigations (ECITA, 2014f) into the causes and possible solutions to avoid injury in the event that a battery goes into thermal runaway.

7. DO E-CIGARETTES HELP PEOPLE TO STOP SMOKING?

It has been argued that the commercial success of e-cigarettes has been driven by anecdotal reporting of successful smoking cessation and substitution by long term smokers (ASH Scotland, 2014b). However, as discussed above, the general problem with examining e-cigarettes is the vast array of products along with the lack of reliable and good quality evidence in the literature on long term usage.

Nevertheless this is a crucial question in public health terms. This part of the briefing does not seek to provide a systematic review of the evidence that has been published so far. However, it does seek to draw the reader’s attention to examples of the type of studies that have been undertaken, what they show and also their limitations. Descriptions of the different research methods used across the studies are shown in footnotes.
For the purposes of this briefing, the studies considering this issue have been differentiated between those where e-cigarette use has been examined amongst smokers wanting to quit on the one hand, and those where smokers do not want to quit on the other.

Studies of e-cigarette use in smokers wanting to quit

There have been a number of surveys that have shown a link between e-cigarette use and quitting or cutting down smoking. However, these have been criticised for being self-selecting and recruiting participants from dedicated users who may not be representative of all users (See ASH Scotland, 2014b, p 6 and NCSCT, 2014, p 10).

More robust surveys have collected data from cohorts of smokers who wish to quit and whose behaviour has been followed up over time. Several of these, often referred to in reviews, are shown in Box 1. Again, in terms of the relationship between e-cigarette use and smoking cessation, the results are mixed. They too have limitations. For example in their longitudinal study on e-cigarette use, Etter and Bullen (2014) themselves acknowledge that their study was limited by, amongst other factors, its reliance on self-reports of the use of e-cigarettes and tobacco. ASH Scotland (2014c, p 7) has reviewed the remainder of the studies listed in Box 1, and found that most of the studies were not designed with the intent of examining cessation outcomes.

Brown et al (2014) undertook a cross-sectional analysis based on a large representative sample of adults in England. The aim was to assess the effectiveness of e-cigarettes when used to aid smoking cessation, compared with NRT bought over-the-counter and unaided quitting in the general population. Overall, they found that, among smokers who had attempted to stop without professional support, those using e-cigarettes were more likely to report continued abstinence than those who used a licensed NRT product bought over-the-counter or no aid to cessation.

Box 1: Examples of recent cohort studies

**Etter and Bullen (2014):** found that of those in their study that were both smokers and using e-cigarettes at baseline, 46% had stopped smoking when followed up after a year. Amongst those that were still smoking there was a decrease in cigarette consumption. Among recent quitters who had quit smoking for less than 1 month and were vaping daily at baseline, 8% relapsed to occasional smoking after 1 month and 5% after one year, but none relapsed to daily smoking.

**Popova and Ling (2013):** undertook a longitudinal study that, in part, considered the relationship between e-cigarette use amongst smokers and quit attempts. It followed up participants one year after baseline. They found that e-cigarette use by smokers was not followed by greater rates of quitting or by reduction in cigarette consumption one year later.

**Adkison et al (2013):** in a four country study, did not find any difference in quitting rates between smokers who also used e-cigarettes against those that didn’t. However, they did find that e-cigarette users were more likely to reduce their cigarette consumption.

**Vickerman et al (2013):** using data from callers to a number of smoking quit lines, found that e-cigarette users were significantly less likely to be tobacco abstinent 7 months after they received intervention from the quitline compared with participants who had never tried e-cigarettes.

---

6 A cohort study is a type of observational study. A cohort is any group of people who are linked in some way and followed over time. Researchers observe what happens to one group that's been exposed to a particular variable. This group is then compared to a similar group that hasn't been exposed to the variable.

7 In a longitudinal study subjects are followed over time with continuous or repeated monitoring of risk factors or health outcomes, or both. Such investigations vary enormously in their size and complexity.

8 A cross-sectional study is another type of observational study. The defining feature of a cross-sectional study is that it can compare different population groups at a single point in time i.e. a snapshot.
There has so far been one randomised control trial\(^9\) considering the use of e-cigarettes amongst smokers wishing to quit. Bullen et al’s (2013) study centred on 657 people from Auckland, New Zealand, who intended to quit smoking. They were split randomly into three groups (e-cigarettes, patches and placebo e-cigarettes). From 1 week before quitting to 12 weeks after quit day the participants received low-level behavioural support via voluntary telephone counselling. The aim was to see how many from each group had quit six months after quit day, with the objective of determining whether e-cigarettes were more effective than NRT patches at helping smokers quit. Overall, after 6 months 7.3% of those using e-cigarettes were verified as having abstained from smoking, with the corresponding figure for patches being 5.8% and that for the placebo group 4.1%. Statistically, the study did not find that e-cigarettes were more effective than NRT patches in helping smokers to quit. However, it did perhaps show that e-cigarettes (with or without nicotine) were at least as effective as NRT patches at helping smokers to quit. The authors accepted their study had a number of limitations, including that the sample size meant that the significance of what was found was not statistically high.

### Studies of e-cigarette use in smokers not wanting to quit

NCSCT (2014, p 10) notes a smaller number of prospective cohort studies\(^10\) that have considered the effect of e-cigarettes in the smoking patterns of smokers who were not ready to quit. Included was a study by Polosa et al (2011), which monitored possible changes in smoking habits amongst 40 regular smokers who were unwilling to quit, but who were experimenting with a type of e-cigarette. In brief, after six months, 22.5% had quit smoking tobacco cigarettes. In a further 32.5% there was a 50% reduction in cigarette smoking. In a follow-up study of the same cohort, Polosa et al (2014) found that, after 24 months, 12.5% had quit smoking, and 27.5% of participants had reduced their cigarette smoking by 50% or more. Overall, combined reduction and smoking abstinence was shown in 40% of participants. This, the authors believe shows that the use of e-cigarettes could substantially decrease consumption in smokers not intending to quit.

ASH Scotland (2014c, p 6) discusses these studies amongst a number of others conducted by a research team in New Zealand. Whilst noting that the studies enrol people from the general population, thus overcoming issues of self-selection, ASH Scotland has found them to be small, lacking in a control group\(^11\) and only been carried out by the same two research teams.

Caponnetto et al (2013) undertook a randomised control trial that evaluated, amongst other factors, smoking reduction and abstinence in smokers not intending to quit. A total of 300 recruited participants from Catania, Italy were randomised into three groups, and given differing sizes of nicotine cartridges over differing periods of time. During the study period, each participant was visited at set intervals at which cigarette use per day and carbon monoxide levels were measured. There were no consistent differences between the groups. Smoking reduction was documented in 22.3% at week 12 and 10.3% at week 52. Complete abstinence from tobacco smoking was documented in 10.7% at week 12 and 8.7% at week 52. The study concluded that, in smokers not intending to quit, the use of e-cigarettes (with or without nicotine) decreased cigarette consumption and led to lasting smoking cessation. The authors accepted

\(^9\) A study in which a number of similar people are randomly assigned to 2 (or more) groups to test a treatment. One group (the experimental group) receives the treatment being tested, the other (the comparison or control group) receives an alternative treatment, a dummy treatment (placebo) or no treatment at all. The groups are followed up to see how effective the experimental treatment was. Outcomes are measured at specific times and any difference in response between the groups is assessed statistically. This method is also used to reduce bias. It is seen as one of the most robust research methods, second only to a systematic review.

\(^10\) A prospective cohort study is one that follows over time a group of similar individuals (cohorts) who differ with respect to certain factors under study, to determine how these factors affect rates of a certain outcome.

\(^11\) In experimental designs, a control group is the "untreated" group with which an experimental group (or treatment group) is contrasted. It consists of units of study that did not receive the treatment whose effect is under investigation.
that there were a number of limitations with their study, including that: there were significant levels of drop out and the fact that the type of e-cigarette used in the study had become obsolete and there were now more effective newer models available. NCSCT (2014, p 10) also considered that the small sample size made it difficult to make any firm conclusions based on the results.

What does the evidence tells us?

A number of recent reviews, including those of ASH Scotland (2014c) and WHO (2014) have commented on the limited evidence that exists, which would confirm one way or another whether e-cigarettes are an effective method for quitting tobacco smoking.

Britton and Bogdanovica (2014) and Hajek et al (2014) believe that some of these preliminary studies do suggest that e-cigarettes could support efforts to quit or reduce tobacco smoking. However, whether this is entirely down to e-cigarettes or other factors such as the behaviour of users requires further study.

The issue of dual use and harm reduction that arises from the evidence base thus far is also a matter of some debate. WHO (2014) accepts that e-cigarettes are likely to help some smokers switch away from tobacco cigarettes to e-cigarettes, but believes that for a sizeable number of smokers they may only lead to a reduction in cigarette use. Its concern is that this will lead to dual use of e-cigarettes and tobacco cigarettes, resulting in much smaller benefits to the smoker. However, ECITA (2014a) contends that at any given time, there are likely to be more dual users than those who have fully switched because of the increasing numbers of new e-cigarette users. It adds that until the new user has fully switched over to vaping they will continue smoking while trying different products to find out what works for them. This, they argue, can skew the data.

ASH Scotland (2014c, p 9) and Hajek et al (2014) also point to studies from England that reflect on the statistics showing that much e-cigarette use is amongst current tobacco smokers. At the same time, there has been a decline in tobacco smoking, and an increase in quit attempts and successful quits. ASH Scotland (2014c) points out that this does not necessarily mean that the one has caused the other. However, it adds that the findings appear inconsistent with the concern that e-cigarettes would prolong smoking.

Meanwhile, Britton and Bogdanovica (2014, p 19) note that whilst there is evidence that e-cigarettes may support smoking cessation, in that they draw in smokers who would otherwise not use a nicotine substitute, they might also reduce it because they take smokers away from NHS smoking cessation services. They argue that the: “optimum solution for population health is to maximise both the use of electronic cigarettes among smokers, and the proportion of users who engage with [stop smoking services]”.

As with the other key areas of debate concerning e-cigarettes, it appears that more research evidence is required before a more definitive answer can be given to this question.

8. DO E-CIGARETTES NORMALISE SMOKING AND LEAD YOUNG PEOPLE TO TAKING IT UP?

Concerns have been voiced about the possible effect that e-cigarettes could have on promoting tobacco smoking. The debate centres on two key themes:

- The ‘Gateway Effect’, which refers to two potential circumstances:
  - the possibility that non-smokers will become addicted to nicotine through using e-cigarettes at a greater rate than if they did not exist in the first place
the possibility that non-smokers (especially children) will switch to tobacco cigarettes once addicted to nicotine through the use of e-cigarettes

- The ‘Normalisation Effect’ - the possibility that everything that makes e-cigarettes attractive to smokers may enhance the attractiveness of smoking itself and perpetuate tobacco smoking

WHO (2014, p 7) notes that, for these to effects to occur, requires a “complex interplay of individual, market and regulatory factors and is difficult to predict”. WHO states that such effects can only be assessed with empirical data, which it believes is, currently, very limited.

ASH Scotland (2014c) has considered the existing evidence base and has found that the ‘Gateway Effect’ is a difficult hypothesis to assess.Whilst research may indicate associations between the use of a nicotine product and young people then going on to take-up tobacco smoking, they may not be causal. A range of other factors may be responsible for influencing people’s behaviour. Surveys from the US appear to suggest that, if a gateway does exist, then it has not been sufficient to change overall reductions in tobacco cigarette prevalence. Meanwhile research in Korea has found that, whilst e-cigarette use amongst young people was associated with cigarette smoking and intentions to quit smoking, there was no association with abstaining from tobacco cigarettes.12

WHO (2014, p 7) contends that the existing evidence does not allow a view to be taken on the role of e-cigarettes in increasing nicotine addiction, let alone whether it leads to tobacco smoking. However, the Electronic Cigarette Industry Trade Association (ECITA) (2014d) asserts that the evidence is becoming clearer that, if there is a ‘gateway’, it goes away from smoking. Pointing to various sources showing that the phenomenon has not been proved, it believes there is a risk that, if e-cigarettes are too tightly regulated and restricted, people who may have used them may actually turn to smoking. ASH Scotland (2014c, p 8) considers that given the problems that have been identified in researching the phenomenon, more work is needed on coming up with a research approach that would be able to provide the right kind of evidence one way or another.

In terms of the ‘Normalisation Effect’ the study by ASH (2014b), already referred to above, found that most children using e-cigarettes had already smoked tobacco cigarettes. Another survey of 6,000 young people aged 14-17 in Cheshire and Merseyside found something similar (ASH Scotland, 2014c, p 7). WHO (2014, p 7) also reviewed such studies and noted that, although the UK has strong tobacco-control measures and has seen a decline in smoking rates, the use of e-cigarettes is still growing. So, in the UK at least it appears that normalisation is not occurring at present, though whether this would be true for other countries needs to be tested. Britton and Bogdanovica (2014, p 15) considered that the evidence thus far showed that the use of e-cigarettes in smoke free places was more likely to lead to a normalisation of nicotine devices than to smoking.

9. HOW SHOULD E-CIGARETTES BE REGULATED?

As outlined above, there is widespread debate about the likely risks and benefits posed by e-cigarettes. The main themes relate to:

- health and safety risks to e-cigarettes users and non-users (in particular under 18s);
- possible benefits in helping people to stop smoking; and
- whether e-cigarettes lead to a normalisation of smoking.

12 These studies have their limitations, and are discussed in greater detail in ASH Scotland (2014c, p 8-9).
This debate is an evolving one and, although new rules are in the pipeline (see below), there is currently little in the way of regulation at EU and UK level. In addition, there is currently little consensus as to how to regulate e-cigarettes. Instead, different approaches exist.

For example, certain medical bodies such as the BMA stress the need to set up a strong regulatory framework aimed at limiting e-cigarette use (BMA, 2013). This is also the approach taken by WHO (2014) which has recommended that governments should:

- impede the uptake of e-cigarettes by non-smokers, pregnant women and youth (and the promotion of e-cigarettes to these parties)
- minimise health risks to e-cigarette users and non-users (including prohibiting the use of e-cigarettes in public places)
- prohibit unproven health claims from being made about e-cigarettes
- protect existing tobacco control efforts from tobacco industry interests

Related arguments are that all e-cigarettes should be treated in a similar way to NRTs and should be required to have medicines licences. This approach was initially taken by the UK Medicines and Healthcare Products Regulatory Agency (MHRA), which is the UK body responsible for the licensing and regulation of medicines and medical devices in the UK (MHRA 2013). The MHRA’s approach has, however, largely been overtaken by events at EU level (for details see below).

Broadly speaking, the approaches mentioned above argue that the potential benefits of e-cigarettes are currently not quantifiable and that, in the absence of robust data, regulation should be focussed on minimising the risks to health. In contrast, other bodies argue that if regulation is too stringent and/or expensive (for example by requiring medicines licences), it could reduce the number of smokers who switch to e-cigarettes (See ECITA 2014d and Bates, 2013). There are also concerns that requiring medicines licences is not a suitable approach for a product which is not a medicine, and that treating e-cigarettes as consumer products may actually make them more effective as cessation devices (See ECITA 2014d and Bates, 2013).

Certain bodies have also made the case that, although there are risks, electronic cigarettes should have a place in reducing the harm caused by cigarettes. Public Health England has in particular noted that:

“Electronic cigarettes, and the various new generation nicotine devices in development, clearly have potential to reduce the prevalence of smoking in the UK. The challenges are to harness that potential, maximise the benefits, and minimise risks.” (Britton and Bogdanovica, 2014, p 13)

Increasingly, there are also suggestions that any regulation needs to take place in tandem with more research. For example in a press release in March 2014, BMA Scotland stated that, although it wished to see e-cigarettes banned in public places:

“… We now need to press for more research which looks at both the efficacy and health implications of e-cigarettes. It is really important that we find out if the hand to mouth use of e-cigarettes either breaks or reinforces smoking behaviours. We need to know if e-cigarettes actually help smokers quit." (BMA Scotland, 2014a)

Although WHO recommends the setting up of a strong regulatory framework, it also recognises that scientific evidence is evolving rapidly and that any regulations should be adaptable so that they can respond to change (WHO, 2014, para. 37).

The role of e-cigarette advertising has also become a key part of the debate. As outlined below, strict advertising rules are likely to come into force at EU level, while in the UK new e-cigarette specific advertising codes have recently been introduced. In addition, more general arguments have been made that much current e-cigarette packaging is designed to attract children or to resemble cigarette packaging, and that standardised forms of plain packaging should be
required (German Cancer Research Center, 2014). Examples of packaging which the German Cancer Research Center considers to be problematic include the following (please note that the text under each picture is taken from the German Cancer Research Center document itself):

![Image of packaging examples]

**Figure 8: Liquids with designs that are attractive to adolescents. Details from screenshots of the distributors. Sources: Shisha-world.com 2014™, Totally wicked 2014™, Puff King promotional flyer 2014, Photos: German Cancer Research Center, Unit Cancer Prevention, 2014**

![Image of packaging examples]

**Figure 3: Names and logos of liquids which recall known cigarette brands. Left: Colin’s Desert Wind and Camel cigarettes, Centre: Colin’s New Star and Lucky Strike cigarettes, right: MB Liquid by Liquid.de (detail from a Screenshot™) and Marlboro print advertisement from 2006. Photos: German Cancer Research Center, Unit Cancer Prevention, 2014**  

**Source: German Cancer Research Center (2014) pages 3 and 5**

### 10. WHAT REGULATION IS IN THE PIPELINE AT EU LEVEL?

The European Union (EU) looked at setting up a regulatory framework for e-cigarettes as part of its broader revision of the Tobacco Products Directive (TPD), which regulates tobacco products within the EU.

**What is the main principle in the TPD?**

The initial drafts of the TPD put forward by the European Council proposed that e-cigarettes should be regulated as medicines.

However, the European Parliament did not support this approach and the final version of the TPD allows e-cigarettes to be placed on the market **without a medicines licence** if the nicotine concentration does not exceed 20 mg/ml (ASTHO 2014, p. 10).

Above that 20 mg/ml nicotine level, or if companies voluntarily opt in or make health claims about products, an over the counter medicines licence will be necessary similar to those currently needed for NRTs such as nicotine gums and patches (MHRA 2005).
What are the other requirements in the TPD?

The TPD lays down other rules for e-cigarettes with a nicotine concentration of less than 20 mg/ml (see Article 20), including:

- A 10ml size limit for e-cigarette refill containers and 2ml for cartridges and tanks
- Compulsory consumer information on use/storage; addictiveness/toxicity; ingredients; nicotine content and delivery per dose; and health warnings, including warnings on nicotine content, covering 30% of the front and back of packs
- Rules requiring e-cigarettes to deliver nicotine doses at consistent levels
- Safety measures such as child-proof fastenings and an obligation that ingredients, other than nicotine, do not pose a risk to human health
- An obligation on manufacturers and importers of e-cigarettes to bear full responsibility for the quality and safety of products
- Rules prohibiting cross border advertising and sponsorship of e-cigarettes in line with those which already apply to tobacco products
- Rules allowing Member States to prohibit cross-border distance sales (for example internet sales)
- Rules requiring Member State authorities to monitor the market for any evidence that e-cigarettes lead to nicotine addiction or tobacco consumption and for the European Commission (Commission) to report on safety concerns and market developments.

What does the TPD not do?

The TPD does not harmonise rules\(^\text{13}\) in relation to:

- Smoke-free environments
- Domestic sales arrangements
- Domestic advertising (the definition of domestic advertising is a narrow one – see below)
- Age limits
- Flavourings\(^\text{14}\)

Therefore, Member States including the UK are free to introduce their own legislation on these matters (TPD, preamble, paras 47 and 48; ASTHO 2014, p. 11).

When does the TPD enter into force?

The TPD was published in the Official Journal on 29 April 2014, but in common with all EU Directives has first to be transposed by the Member States into national legislation (i.e. implemented) before it can have full effect. In this case Member States have to bring into force domestic measures to implement the directive by 20 May 2016 (Article 29).

How will the TPD be implemented in the UK?

As indicated, the MHRA’s initial intention was to require all e-cigarettes in the UK to have medicines licences from 2016 so that they meet, “appropriate standards of safety, quality and efficacy to help reduce the harms from smoking” (MHRA 2013). The MHRA’s approach has, however, been overtaken by the decision at EU level not to require medicines licences where e-cigarettes have a nicotine concentration of less than 20 mg/ml.

The UK government has not yet outlined its plans for implementing the TPD. However, it is highly likely that the specific approach in Article 20 of the TPD will appear in the UK’s

---

\(^\text{13}\) See TPD Preamble, para. 48

\(^\text{14}\) Any national prohibitions on flavoured e-cigarettes must be justified and notified to the European Commission in accordance with Directive 98/34/EC relating to technical standards and regulations (TPD, preamble, para 47)
implementing regulation since the general rule in the UK Government’s guidance on transposing European Directives (UK Government 2013) is that they should be “copied-out” as far as possible — in other words by using the same wording as in the Directive or by cross-referring to the relevant provisions (Department of Health 2014b).

On that basis, from 20 May 2016 only e-cigarettes with a nicotine concentration of more than 20 mg/ml (or which make health claims) will require a medicines licence in the UK. During the joint meeting of the Westminster All Party Pharmacy Group and the All Party Parliamentary Groups on Smoking and Health, and Heart Disease on June 10 2014, the UK Department of Health confirmed this, noting in a briefing that it:

“… will work with stakeholders on the transposition of the TPD. Following transposition of the revised directive in 2016, only electronic cigarettes which are licensed as medicines or meet the requirements of the TPD, will be allowed on the UK market.” (Department of Health 2014a).

Table 1, which was included in the Department of Health’s briefing, explains the Department’s view on the key practical differences between regulation under the TPD and under a medicines licence.

Table 1: Characteristics of regulation under MHRA and TPD

<table>
<thead>
<tr>
<th>Tobacco Products Directive regulation of electronic cigarettes</th>
<th>MHRA licenced Nicotine Containing Products (NCPs) including e-cigs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Products not available on prescription</td>
<td>Products available on prescription</td>
</tr>
<tr>
<td>20% VAT</td>
<td>5% VAT</td>
</tr>
<tr>
<td>Cross border advertising banned by 2016, up to MS to decide on domestic advertising (billboards, PoS, buses etc.)</td>
<td>Advertising allowed – under OTC rules so no celebrity endorsement, free samples and must be targeted at adult smokers etc.</td>
</tr>
<tr>
<td>Products widely available</td>
<td>Products available on general sale (GSL)</td>
</tr>
<tr>
<td>Can’t make health claims</td>
<td>Can make health claims</td>
</tr>
<tr>
<td>Upper limits for nicotine content will be set and likely to be in force by 2017.</td>
<td>MHRA regulation is flexible there are no upper limits.</td>
</tr>
<tr>
<td>30% health warning on packs about nicotine on front and back of packs</td>
<td>No health warnings on packs</td>
</tr>
<tr>
<td>Member States retain powers e.g. on flavours, domestic advertising.</td>
<td>Flavours require a marketing authorisation</td>
</tr>
<tr>
<td>Children and Families Bill allows for age of sale of 18 for nicotine products.</td>
<td>Age of sale 12 but can be varied by product so could be higher for e-cigs</td>
</tr>
</tbody>
</table>

Source: Department of Health 2014, page 2, Table 1

Legal challenge to the TPD

In July 2014, the e-cigarette company Totally Wicked brought a judicial review action in the English High Court of Justice against the Secretary of State for Health in England. The argument was that it would be unlawful for the UK government to implement the TPD (as required under Article 29), because its e-cigarette provisions breach EU law (for details of the legal arguments see Bates, 2014).

On 6 October 2014 the English High Court of Justice used the preliminary reference procedure (see European Union) to refer various questions on the compatibility of the TPD with EU law to the European Court of Justice (CJ(EU)) – i.e. the European Union’s highest court (Planet of the Vapes, 2014, Ross, 2014).

SPICe understands that the UK Secretary of State did not oppose the application for a judicial review. Whilst maintaining that the TPD is legal, the UK Secretary of State agreed that there
was room for argument in some specific areas and that these arguments were best made in the CJ (EU) as the UK courts do not have the power to rule on the legality of European legislation. SPICe also understands that the UK Secretary of State agreed the questions for reference to the European Court with TW’s counsel (Department of Health 2014b)

Based on normal waiting times, it appears that the ECJ will issue its judgment on these questions sometime in late 2015 or early 2016.

The ECJ’s preliminary ruling decisions are binding on both the national court which referred the matter and also on all other Member State courts (see European Union). The outcome of the Totally Wicked case could therefore have an impact beyond the UK and could lead to the TPD’s e-cigarette provisions being struck down or otherwise amended if they are found to be contrary to EU law.

11. HOW ARE E-CIGARETTES REGULATED IN THE UK/SCOTLAND?

Current regulation

Although e-cigarettes have to comply with various UK regulations and EU Directives, there is currently little regulation which is aimed specifically at e-cigarettes in the UK or Scotland.

The UK-wide regulation which exists is of a more general nature and largely treats e-cigarettes as normal consumer products. This means that they must be fit for purpose, of a satisfactory quality and fit their description. In addition, they also have to comply with UK product safety legislation, for example in relation to: general product safety, electrical safety, chemical safety, battery safety, packaging etc. (see Sheffield Trading Standards). However, the rules do not deal directly with the public health matters outlined above, and it has also been argued that they do not impose specific nicotine purity standards or (Britton and Bogdanovica, page 20).

According to the trade body ECITA, efforts are underway to draw up a Publicly Available Specification (PAS) with the British Standards Institute which would provide product safety, quality, labelling and packaging instructions for the importation and sale of e-cigarettes in the UK (ECITA 2014g).

Unlike tobacco, there are also no specific UK taxes associated with e-cigarettes.

There are currently also no statutory rules which set age limits for using e-cigarettes or restrict e-cigarette use in public places. Specific rules do, however, exist which regulate the advertising of e-cigarettes in the UK (see below for details).

Future regulation

UK

Although there is currently little regulation aimed specifically at e-cigarettes in the UK, changes are in the pipeline. Many of these changes will result from the implementation of the TPD by the UK government. However, other proposed changes are also likely based on specific national legislation in areas which are not governed by the TPD.

---

15 ECITA indicates in its press release on this matter that, “British Standards documents do not contain legal requirements; the assumption is made that any and all legal requirements will be complied with, as a matter of course, so this PAS – as with all other British Standards – is a ‘best practice’ model.”
In Scotland, the Scottish Government recently published a ‘Consultation on Electronic Cigarettes and Strengthening Tobacco Control in Scotland’ (Scottish Government, 2014a).

The consultation recognises that there is much debate amongst academics about the potential benefits and risk of e-cigarettes and indicates that, “it will take some time before we can properly understand the impacts of their use on health.” However, it also stresses that, there is widespread agreement that e-cigarettes present, “much less risk for users and bystanders” whilst noting that, “it is not possible to say that they are risk free” (Scottish Government, 2014a, p.9).

Much of the focus of the consultation is on the perceived need to protect young people from nicotine addiction. In this light one of the main proposals in the consultation is to make it an offence to sell e-cigarettes to those under 18.

The consultation also raises the issue that the TPD does not cover purely domestic forms of advertising (such as billboards, leaflets and posters) and invites view on what forms of domestic advertising and promotion, if any, should be regulated in Scotland.

In addition, while the document notes that the Scottish Government has no current plans to legislate on the use of e-cigarettes in public places, it asks for views, suggestions and evidence which should be considered for any longer term policy development in this area.

The Scottish Government’s proposals and other English and Welsh proposals are dealt with in more detail below.

**Power to regulate in the UK/Scotland**

As outlined above, the TPD will place certain limits on the type of e-cigarette regulation which can be introduced by Member States, including the UK.

In addition, under section 29 of the Scotland Act 1998 (Scotland Act) the Scottish Parliament's power to pass legislation on e-cigarettes is limited in particular to matters which:

- are not reserved to the UK Parliament; and
- do not breach EU law

As regards reserved powers, The Scottish Parliament does have the general competence to legislate in relation to public health. However, other areas of policy are reserved to Westminster including:

- The regulation of medicines and medical devices (Scotland Act, Schedule 5, section J4)
- Consumer protection and “misleading and comparative advertising, except regulation specifically in relation to food, tobacco and tobacco products” (Scotland Act, Schedule 5, section C7).
- The regulation of “product standards, safety and liability” (Scotland Act, Schedule 5, Section C8).

Therefore, depending on its scope, issues could potentially arise as to whether Scottish e-cigarette legislation falls within the Scottish Parliament’s devolved powers. SPICe understands, however, that it is not the intention of the Scottish Government to touch on the reserved powers listed in any e-cigarette legislation (Scottish Government 2014b).
12. IS THERE AN AGE LIMIT FOR USING E-CIGARETTES?

**UK**

There is currently no statutory age limits in any part of the UK for using e-cigarettes and no age limits are set at EU level under the TPD. However, many e-cigarette manufacturers in the UK include a general warning on their packaging indicating that the product is not for sale to those under 18.

The UK Trading Standards Institute recently carried out research into the workings of this voluntary regime. This involved under 18 year olds making test purchases in various English shops. Its report, published on July 2 2014, concluded that, despite the presence of health warnings, “there is a degree of confusion around the age at which these products may be supplied”, in particular as regards sales from market stalls and independent pharmacies (Trading Standards Institute 2014)\(^{16}\). The table below summarises this research.

**Table 2: Results of Trading Standards Institute research into e-cigarette purchasing**

<table>
<thead>
<tr>
<th>Premise Type</th>
<th>Total attempts to purchase</th>
<th>Total refusals</th>
<th>Total purchases made</th>
<th>Proportion of visits resulting in purchases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialist E-cigarette supplier</td>
<td>69</td>
<td>29</td>
<td>40</td>
<td>58%</td>
</tr>
<tr>
<td>Large retailer</td>
<td>81</td>
<td>61</td>
<td>20</td>
<td>25%</td>
</tr>
<tr>
<td>Small retailer</td>
<td>117</td>
<td>82</td>
<td>35</td>
<td>33%</td>
</tr>
<tr>
<td>National newsagent</td>
<td>30</td>
<td>23</td>
<td>7</td>
<td>23%</td>
</tr>
<tr>
<td>Independent newsagent</td>
<td>111</td>
<td>60</td>
<td>51</td>
<td>46%</td>
</tr>
<tr>
<td>Pharmacy National chain</td>
<td>37</td>
<td>20</td>
<td>17</td>
<td>46%</td>
</tr>
<tr>
<td>Pharmacy Independent</td>
<td>19</td>
<td>5</td>
<td>14</td>
<td>74%</td>
</tr>
<tr>
<td>Market stall/car boot sale</td>
<td>20</td>
<td>4</td>
<td>16</td>
<td>80%</td>
</tr>
<tr>
<td>Off licence</td>
<td>57</td>
<td>41</td>
<td>16</td>
<td>28%</td>
</tr>
<tr>
<td>Other</td>
<td>36</td>
<td>25</td>
<td>11</td>
<td>31%</td>
</tr>
</tbody>
</table>

Source: Trading Standards Institute 2014, page 8, Table 3

**England and Wales**

Section 92 of the UK Children and Families Act 2014, which only applies to England and Wales, and which was given Royal Assent on 13 March 2014, gives the UK Secretary of State the power to make regulations prohibiting the sale of e-cigarettes to those under 18. The regulations will be subject to consultation and, as of the date of this briefing, have yet to be made. It is, however, expected that an age limit will be introduced in England and Wales in the near future.

---

\(^{16}\) The report admits that the research has certain limitations, including a limited timeframe and small sample sizes for market stalls and independent pharmacies (for details see Trading Standards 2014, para, 5.5)
Scotland

As outlined above, the Scottish Government has recently proposed making it an offence to sell e-cigarettes to those under 18 in line with tobacco legislation. The Scottish Government’s main argument is that, “the addictive nature of nicotine and the risk of promoting smoking behaviours” makes it, “appropriate to introduce legislation that will restrict children and young people’s access to e-cigarettes and refills” (Scottish Government 2014a, p. 11).

Other elements of the proposals include:

- Making the proof of age requirements for e-cigarettes the same as for other age-restricted products. In other words, those who appear to be under 18, but are not, would have to show a passport, driving licence or other applicable photographic identity card when buying e-cigarettes
- Prohibiting sales of e-cigarettes from vending machines (this is because proof of age cannot be verified)
- Giving Local Authority Trading Standards Officers the role of enforcing the rules
- Making it an offence for someone to buy e-cigarettes and supply them to those under 18 (i.e. so-called “proxy purchases”)
- Requiring e-cigarette retailers to register on the Scottish Tobacco Retailers Register in the same way as tobacco retailers. The aim is to allow e-cigarette retailers to be clearly identified and to make it easier for Trading Standards officers to stop illegal sales

The proposals also indicate that limited exemptions to these rules may apply to e-cigarettes which are licensed as medicinal products (in other words potentially allowing for them to be used by under 18s), but that this would be a matter for the MHRA.

13. WHAT ARE THE RULES ON ADVERTISING?

EU

It is important to stress that the TPD takes a restrictive approach to the advertising of e-cigarettes arguing that harmonised EU rules are needed which provide for a high level of health protection and which limit the risk of e-cigarettes acting as, “a gateway to nicotine addiction and … traditional tobacco consumption” (TPD Preamble, para. 43).

The TPD’s prohibition of cross-border advertising and sponsorship of e-cigarettes which will come into force in May 2016 is therefore a wide one and covers most forms of media (see Article 20(5)). In effect, it aims to mimic the current ban on tobacco advertising and sponsorship in the EU. Specifically, it includes a ban on e-cigarette advertising/promotion in relation to:

- Telecommunications (communication over a distance by cable, telegraph, telephone or broadcasting)
- Radio
- The internet

17 The Scottish Government’s consultation also indicates that it intends to extend the alcohol age verification policy known as “Challenge 25” to e-cigarettes and tobacco (Scottish Government 2014a) It is not yet clear what the legal basis for this policy will be, although SPICe understands that this will be clarified on the basis of the consultation responses and consultation with stakeholders
18 See amendment 170 to the original European Council draft TPD which notes that, “the limitations on advertising, sponsorship, audiovisual, commercial communication and product placement for tobacco products as set out in Directive 2003/33/EC and Directive 2010/13/EC shall apply to nicotine-containing products.”
• Most printed publications (including newspapers)
• Events marketing with a cross border effect (e.g. televised sporting events) (see Scottish Government 2014a)

Once the TPD enters into force in May 2016, Members States will, therefore, have less scope to regulate the advertising/sponsorship of e-cigarettes at national level. Certain forms of advertising will, however, be regarded as “domestic advertising” under the TPD and will remain under Member State competence.

UK

UK Advertising Codes

E-cigarette advertising in the UK is currently dealt with under the general UK Advertising Codes. The UK Advertising Standards Agency (ASA) enforces the rules in response to complaints from the public. There are two sets of codes:

• The CAP Code for all non-broadcast marketing which is written and maintained by the Committee of Advertising Practice (CAP)
• The BCAP Code for broadcast marketing (i.e. TV and radio) which is written and maintained by the Broadcasting Committee of Advertising Practice (BCAP).

The system is a mixture of self-regulation for non-broadcast advertising (i.e. the system is paid for by industry members who draft the rules) and co-regulation with the statutory regulator Ofcom for broadcast advertising (see ASA 2014a and ASA 2014b). It is a licence requirement for broadcast services that advertisements aired comply with the BCAP Code.

Up until recently, neither of the Codes contained specific rules on e-cigarettes. Instead, e-cigarette advertising had to comply with the general rule that advertising should not be misleading (CAP rule 3.1; BCAP rule 3.1). Any health/smoking cessation claims also had to be substantiated (CAP rules 3.7, 12.1 and 12.11; BCAP rule 3.9). In addition, drawing on BCAP rule 10.4 which prohibits advertisements for non-tobacco products from promoting smoking, the position of the BCAP was that, during television broadcasts, e-cigarette manufacturers “may advertise their product and make verbal or written references to it, but may not show them” (Committees of Advertising Practice 2014c, page 8).

New rules specifically dealing with e-cigarettes have, however, recently been adopted following a public consultation (Committees of Advertising Practice 2014c, Annex 2). These are set out in CAP and BCAP’s Joint Regulatory Statement entitled “New rules for the marketing of e-cigarettes” (CAP and BCAP 2014). They will come into force on 10 November 2014.

The new non-broadcasting rules will be contained in CAP rule 22 and include provisions which require e-cigarette advertisements (see Committees of Advertising Practice, 2014b):

• To be socially responsible (Rule 22.1)
• Not to promote any design, imagery or logo that might be associated with a tobacco brand (Rule 22.2)
• Not to promote the use of a tobacco product or show the use of a tobacco product in a positive light (Rule 22.3)
• To make clear that the product is an e-cigarette and not a tobacco product (Rule 22.4)
• Not to undermine the message that quitting tobacco use is the best option for health (Rule 22.5).
• Not to encourage non-smokers or non-nicotine users to use e-cigarettes (Rule 22.8)
• Not to feature characters likely to resonate with youth culture or to appeal to under 18s (Rule 22.10).
The online CAP guidance also contains information on health claims, noting that:

“Ads must not contain health or medicinal claims unless the product is authorised for those purposes by the MHRA. Claims that smoking e-cigarettes containing vaporised nicotine is healthier than smoking tobacco, risk free, or harmless are likely therefore to be problematic. Endorsements by health professionals are not permitted.” (Committees of Advertising Practice, 2014b)

Equivalent rules will apply in relation to broadcast advertising as the aim of the BCAP and CAP is to deliberately harmonise both sets of content rules so that they are the same in both Codes (CAP and BCAP 2014, p. 5). Specific broadcasting rules will, however, also be introduced. These include:

- Updating the rules prohibiting non-tobacco products from promoting smoking so that they do not apply to e-cigarettes. One result is that from 10 November 2014 e-cigarettes can be shown in television advertisements (subject to the above rules)20

- A broadcasting scheduling restriction aimed at limiting under-18s exposure to e-cigarette advertisements

According to the two committees, the new rules apply a level of protection that is fair and proportionate, “balancing the need to protect consumers with the need to allow marketers freedom of commercial speech” (CAP and BCAP, 2014, p. 2). It would appear, however, that the CAP and BCAP’s guidance that advertisements may not claim that smoking e-cigarettes is safer than smoking tobacco is likely to be a contentious one given the general view outlined above that the health risks associated with e-cigarettes are less than those linked to tobacco.

**Impact of the TPD – new UK rules serve as an interim measure**

As indicated above, the various prohibitions on cross-border e-cigarette advertising which will be introduced by the TPD are very wide-ranging and arguably cut across the new rules in the UK Advertising Codes. This point appears to be accepted by the CAP and BCAP who note in their Joint Regulatory Statement that the new rules:

“…do not pre-empt the requirements of the Directive but serve as an interim measure. When more is known about the application of the Directive in the UK, CAP will clarify what role its Code will have after the new law has been given effect.” (CAP and BCAP, 2014, p. 19)

Based on this statement, it therefore seems likely that the e-cigarette rules in the UK Advertising Codes will change once the TPD comes into force.

**Scotland**

**Consultation**

There are currently no specific Scottish advertising rules on e-cigarettes. However, in its Consultation on Electronic Cigarettes, the Scottish Government notes that the TPD allows Member States to regulate domestic advertising and suggests that this could include:

- Bill boards
- Leafleting
- Brand-stretching (using an existing brand name for new products or services)
- Free distribution (marketing a product by giving it away free)
- Nominal pricing (marketing a product by selling it at a low price)21

---

20 It would appear that the first broadcasting advertisement showing an e-cigarette was aired on ITV on the evening of 10 November (BBC News 2014b)
- Point of sale advertising (i.e. advertising in places where services/products are bought)
- Events sponsorship within a purely domestic setting

(Scottish Government 2014a, p.15)

The consultation does not take a view on which forms of regulation would be appropriate and notes that there are contrasting standpoints on the need for regulations. In particular it indicates that, although there would appear to be broad consensus that the advertising of e-cigarettes should not be aimed at young people, there are also views suggesting that distinguishing between advertisements aimed at young people and adults would be unworkable. It also explains that arguments have been made that a total ban on advertising could restrict the availability of information about e-cigarettes, thus reducing the likelihood that current smokers will use them as a cessation aid (Scottish Government 2014a, p.15).

The consultation therefore invites views on what forms of domestic advertising and promotion, if any, should be regulated in Scotland.

14. CAN E-CIGARETTES BE USED IN PUBLIC PLACES?

In contrast to tobacco products, there are currently no general statutory limits on the use of e-cigarettes in public places in the UK.

Voluntary bans

Various organisations and businesses have, however, voluntarily banned the use of e-cigarettes on their premises/grounds on a precautionary basis, including: the Scottish Parliament (Scottish Parliament, 2014c); BBC (BMA, 2014b); Scotrail (Scotrail, 2014); the pub chain JD Wetherspoon (Wetherspoon, 2014); and various parts of NHS Scotland following a recommendation by the Scottish Directors of Public Health Group (Scottish Directors of Public Health Group, 2013).

The BMA have also argued for the need for a more general ban on using e-cigarettes in workplaces and public places in order to:

“… limit second-hand exposure to the vapour exhaled by the user, and to ensure their use does not undermine smoking prevention and cessation by reinforcing the normalcy of cigarette use.” (BMA, 2013, pages 1 and 5)

ASH have published guidance on whether business should go down the route of implementing a voluntary ban (ASH, 2014c). It stresses that any voluntary policy should be clear about what it is trying to achieve (and which types of products are covered) and should also be good for health, by helping and not hindering smokers who are trying to quit to reduce the harm caused by smoking.

Future plans in the UK

Scotland

On 15 May 2014, the Scottish Minister for Public Health, Michael Matheson, responded to a parliamentary question by indicating that there are “currently no plans to amend the Smoking,

21 Minimum pricing legislation in the field of alcohol, i.e. the Alcohol (Minimum Pricing) (Scotland) Act 2012, has been challenged as being in breach of EU law. The Court of Session has referred the case to the European Court of Justice (see Scottish Whisky Association v Lord Advocate [2014] CSIH 38).

22 The Tobacco and Primary Medical Services (Scotland) Act 2010 prohibits the display of tobacco products in shops and bans tobacco vending machines. A legal challenge claiming that the legislation was outside the Scottish Parliament’s powers was not successful (see Imperial Tobacco Ltd v Lord Advocate (Scotland) [2012] UKSC 61).
Health and Social Care (Scotland) Act 2005 to cover e-cigarettes” – i.e. the Scottish Act banning smoking in enclosed public spaces (Scottish Parliament, 2014b).

The Scottish Government’s consultation confirms this point, indicating that, “we are clear that there are no plans to legislate at this time” (Scottish Government, 2014, p. 18). However, the consultation also recognises that there are many views on whether to legislate in this area and therefore invites views on longer term policy development. In particular, it asks for views on the following possible options:

- No action
- Scottish Government support for individual organisations to agree their own policies on the restriction of e-cigarettes
- Scottish Government consultation with organisations to develop national guidance
- Amending current smoke-free legislation to include e-cigarettes
- Banning e-cigarette use in designated public spaces (for example, those frequented most by children and families)
- Banning the use of certain e-cigarette products in enclosed public spaces (for example, those which include tobacco or look and behave most like traditional tobacco products)

**England**

On 1 May 2014 Jane Ellison, the UK Parliamentary Under-Secretary of State for Health, indicated in response to a parliamentary question that, “there are no current plans to restrict the use of electronic cigarettes in public places in England” (Hansard, 2014). In England there would, therefore, also appear to be no immediate plans to limit e-cigarette use in public places.

**Wales**

In contrast, the Welsh Government announced in April 2014, in a consultation on proposals for a new Public Health Bill, that it is, “seeking views and evidence on introducing legislation to ban the use of e-cigarettes in enclosed and substantially enclosed public places (including work places) in Wales” (Welsh Government, 2014, para. 2.34). This consultation closed on 24 June 2014 and, as of the date of this briefing, it is not yet known what the outcome is.

### 15. HOW ARE E-CIGARETTES TAXED?

In the UK, tobacco products are subject to a specific tax, Tobacco Products Duty, which has to be paid on products manufactured in or imported into the UK (HMRC, 2014a). The tax is a valuable source of revenue and also has a public health goal by pushing up the retail price of tobacco (HMRC 2014b).

There are no specific taxes associated with e-cigarettes in the UK, although general import duties may apply as well as VAT. The VAT rate will normally be the standard 20% rate, unless the product is a licensed medicine in which case a 5% rate will apply (Department of Health, 2014, page 2, Table 1).

Although there do not appear to be any moves in the UK to establish a specific e-cigarette tax, it would seem that certain other countries and jurisdictions have done so or are considering doing so. For example, in the USA, it would appear that Minnesota taxes e-cigarettes in the same way as tobacco (Minnesota Revenue, 2014), whereas in North Carolina liquid nicotine is taxed at 5 US cents per millilitre (National Conference of State Legislators, 2014). In Europe, claims have also been made that taxation levels could be set at low levels for e-cigarettes which clearly function as tobacco cessation devices and at higher levels for other more lifestyle based...
products so as to discourage adolescents and non-smokers from using them (German Cancer Research Center, 2014, p 6).  

16. HOW ARE E-CIGARETTES REGULATED ELSEWHERE IN THE WORLD?

It is not possible to provide an exhaustive account of regulation worldwide as the position is a fluid one, which is subject to constant change. Certain websites do, however, claim to contain overviews of worldwide e-cigarette legislation (e.g. E-Cigarette Politics), although the accuracy of such information cannot be vouched for.

USA

In the USA, the US Food and Drug Administration (FDA) published a proposed rule on April 25 2014 which would extend the agency’s tobacco authority to cover additional tobacco products, including e-cigarettes (U.S. Food and Drug Administration 2014). This would mean that manufacturers of e-cigarettes would have to register with the FDA and only market new tobacco products after FDA review. Claims of reduced risk could also only be made if the FDA confirms that they are supported by scientific evidence and that public health will benefit.

The proposed rule would also include:

- Minimum age and identification restrictions to prevent sales to underage youth
- Health warnings
- A prohibition on vending machine sales, unless in a facility that never admits youth
- A prohibition on free samples

The rule is currently subject to consultation and, as of November 2014, it is not yet clear what the outcome will be.

Individual U.S. states have also been creating or amending their own state legislation with, for example, the City of New York extending its own smoke-free laws on 29 April 2014 to include e-cigarettes (New York City, 2014). The US National Conference of State Legislators has recently carried out research outlining how e-cigarettes are regulated in each US state. This provides a usual overview of US state legislation on e-cigarettes (for details see National Conference of State Legislators, 2014).

WHO survey

As part of its recent report, WHO carried out a survey on world e-cigarette regulation which was sent to all WHO Member States. The WHO’s summary of the survey’s results is outlined in Table 3, below. Note that the first figure is the number of countries which responded to the specific survey question and that the figure in brackets indicates the percentage of the world population living in those countries.

According to WHO the survey also shows that:

- The sale of e-cigarettes with nicotine is banned in 13 of the 59 countries that regulate them, although the majority of these countries report that they are available to the public, through illicit trade and cross-border internet sales
- Comprehensive advertising, promotion and sponsorship bans are in place in 39 countries (in which 31% of the world’s population live)

---

23 This of course assumes that such a distinction would be possible from both a regulatory and scientific perspective.
• Use of e-cigarettes in enclosed public places is banned in 30 countries (35%)
• Premarket review is required by 19 countries (5%)
• Vendor licences are required by nine countries (4%)
• Policies on sales to minors were confirmed by 29 countries (8%). Where specified, the minimum required age for purchase ranged from 18 to 21 years

Table 3: WHO Survey into regulation of e-cigarettes by its Member States

<table>
<thead>
<tr>
<th>Type of e-cigarette</th>
<th>E-cigarettes regulated as</th>
<th>Not regulated or unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Consumer product</td>
<td>Therapeutic product</td>
</tr>
<tr>
<td>With nicotine</td>
<td>14 (27%)</td>
<td>12 (6%)</td>
</tr>
<tr>
<td>Without nicotine</td>
<td>23 (35%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

Source: WHO 2014, para. 30, Table 1
SOURCES


Department of Health (2014b) Personal communication. [Unpublished]


Hansard. (2014) HC Deb, 1 May 2014, c770W. Available at: http://www.publications.parliament.uk/pa/cm201314/cmdeb/cm140501/text/140501w0001.htm#140501w0001.htm_wqn25


Minnesota Revenue (2014) E-cigarettes. [Online]. Available at: http://www.revenue.state.mn.us/businesses/tobacco/Pages/e-Cig.aspx


Robert West Blog. [Online]. Available at: http://www.rjwest.co.uk/blog.php

Ross, G. (2014). Totally Wicked vs. the EU’s tobacco directive. [Online]. Available at: https://www.theparliamentmagazine.eu/blog/totally-wicked-vs-eus-tobacco-directive


Scottish Government. (2014b) Personal communication. [Unpublished].


Scottish Parliament Information Centre (SPICe) Briefings are compiled for the benefit of the Members of the Parliament and their personal staff. Authors are available to discuss the contents of these papers with MSPs and their staff who should contact either Angus Evans on Ext 85356 / angus.evans@scottish.parliament.uk or Jude Payne on Ext 85364 / email jude.payne@scottish.parliament.uk. Members of the public or external organisations may comment on this briefing by emailing us at SPICe@scottish.parliament.uk. However, researchers are unable to enter into personal discussion in relation to SPICe Briefing Papers. If you have any general questions about the work of the Parliament you can email the Parliament’s Public Information Service at sp.info@scottish.parliament.uk.

Every effort is made to ensure that the information contained in SPICe briefings is correct at the time of publication. Readers should be aware however that briefings are not necessarily updated or otherwise amended to reflect subsequent changes.

Published by the Scottish Parliament Information Centre (SPICe), The Scottish Parliament, Edinburgh, EH 99 1SP

www.scottish.parliament.uk