

CONSULTATION QUESTIONS

In addition to the responses below, please refer our general comments appended to this response ("**General Comments Section**"). blu (UK) is an e-cigarette company and our affiliated companies do not actively market or sell tobacco products outside the United States of America. Our responses are therefore restricted to the questions in the Consultation relating to e-cigarettes.

For the purpose of this response and the General Comments Section, we shall refer to individuals under the age of 18 as "**Underage Persons**".

References cited in this response and the General Comments Section appear at the end of the document.

Age restriction for e-cigarettes

1. Should the minimum age of sale for e-cigarette devices, refills (e-liquids) be set at 18?

Yes No

2. Should age of sale regulations apply to:

a. only e-cigarette devices and refills (e-liquids) that contain nicotine or are capable of containing nicotine, or

b. all devices / refills (e-liquids) regardless of whether they contain or are capable of containing nicotine?

a b

3. Whom should the offence apply to:

- a. the retailer selling the e-cigarette
- b. the young person attempting to purchase the e-cigarette
- c. both

a
b
c

4. Should sales of e-cigarettes devices and refills (e-liquids) from self-service vending machines be banned?

Yes No

The Scottish Government proposes that all sales of e-cigarettes and e-cigarette refills from self-service vending machines should be banned in line with tobacco sales regulations.

As discussed in the General Comments Section, e-cigarettes and refills are products that are distinct from tobacco products and do not bear the same health risks. Therefore, any regulation affecting e-cigarettes and refills should be considered in light of current scientific evidence relating to e-cigarettes and not tobacco products.

We consider that the sale of e-cigarette devices and refills (e-liquids) through self-service vending machines should be limited to establishments that ensure Underage Persons are prohibited from entering at any time.

5. Should a restriction be in place for other e-cigarette accessories?

Yes No

From the question it would appear that "e-cigarette accessories" are items other than the e-cigarette devices and e-liquids. However, neither the question nor the Consultation specifies what "e-cigarette accessories" are. The term "e-cigarette accessories" could apply to a wide range of items which are not solely used in connection with e-cigarettes.

If the term "e-cigarette accessories" relates solely to items that can only be used with e-cigarettes, then their purchase online or in retail outlets should also be restricted to those aged 18 or over. However, placing an age-restriction on items that are not solely used in connection with e-cigarettes would be disproportionate the Scottish Government's aims of building and maintaining a robust statutory and policy framework which supports its health policy objectives on tobacco control.

In respect of our business, a list of accessories relating to blu e-cigarettes is provided on our website, www.blucigs.co.uk. These include items such as clearomisers, USB chargers, mains chargers, adaptors and batteries. All of these items are specific for e-cigarettes sold by blu (UK) and can only be purchased through our website if the customer has verified that they are 18 years of age or over before entering the site and at the point of sale. Such accessories may

also be purchased in retail outlets. However, our agreements with retailers stipulate that these items can only be sold to individuals whose age has been verified by the retailer as being 18 or over.

6. If you answered “yes” to question 5, which products should have restrictions applied to them?

Please refer to the response to Question 5.

Proxy purchase for e-cigarettes

7. Should the Scottish Government introduce legislation to make it an offence to proxy purchase e-cigarettes?

Yes No

Domestic advertising and promotion of e-cigarettes

8. Should young people and adult non-smokers be protected from any form of advertising and promotion of e-cigarettes?

Yes No

Please refer to the General Comments Section.

9. In addition to the regulations that will be introduced by the Tobacco Products Directive do you believe that the Scottish Government should take further steps to regulate domestic advertising and promotion of e-cigarettes?

Yes No

Please refer to the General Comments Section.

10. If you believe that regulations are required, what types of domestic advertising and promotion should be regulated?

- | | |
|---|-----------------------------------|
| a. Bill boards | a <input type="checkbox"/> |
| b. Leafleting | b <input type="checkbox"/> |
| c. Brand-stretching (the process of using an existing brand name for new products or services that may not seem related) | c <input type="checkbox"/> |
| d. Free distribution (marketing a product by giving it away free) | d <input type="checkbox"/> |
| e. Nominal pricing (marketing a product by selling at a low price) | e <input type="checkbox"/> |
| f. Point of sale advertising (advertising for products and services at the places where they were bought) | f <input type="checkbox"/> |
| g. Events sponsorship with a domestic setting | g <input type="checkbox"/> |

We note that the Consultation states that the Tobacco Products Directive (Directive 2014/40/EU; “TPD”) encourages Member States to consider regulation within their own jurisdiction, providing a list of examples where this might apply, which are also set out in question 10 above. However, the current CAPⁱ Codes (which apply to the whole of the United Kingdom) already extend to the forms of advertising and promotion listed in (a) to (g) above. As such, we consider that there is no need for any further regulation to apply or for any further regulation of advertising and promotion of e-cigarettes in Scotland.

At blu (UK), we fully recognise our responsibility to consumers in relation to the manner in which we advertise our products. We believe that e-cigarettes and refills are not products suitable for Underage Persons and usage of the products in this group is unacceptable. We also consider that the targeting of advertisements for nicotine-containing e-cigarettes to non-smokers is unacceptable.

As a result, we have already developed and implemented advertising and marketing policies and guidelines to govern the advertising and marketing of our products in each type of advertising or promotional tool or media (including those set out in items (a) to (g) in Question 10 above). These policies are updated in accordance with the applicable laws and rules regulating the advertising and marketing of e-cigarettes, including the new CAP and BCAPⁱⁱ rules that came into effect on 10 November 2014. blu (UK) has therefore imposed on itself guidelines in this area. In many respects the guidelines mirror the new e-cigarette advertising codes in the United Kingdom, but in some they exceed what is required.

blu (UK) is willing to discuss its comments to the consultation run by CAP and BCAP on the new e-cigarette advertising rules with the Scottish Government if that might assist the consultation process. These are based on our strong belief that advertising of e-cigarettes should not target Underage Persons or non-smokers, but instead should be directed solely at adults who wish to use e-cigarettes in order to reduce their consumption of tobacco.

11. If you believe that domestic advertising and promotion should be regulated, what, if any, exemptions should apply?

As discussed in relation to Question 10 above, we consider the advertising laws and rules in place relating to the advertisement and promotion of e-cigarettes are sufficient and no further regulation is required.

Please also refer to the General Comments Section for further details.

ⁱ Committee of Advertising Practice

ⁱⁱ Broadcast Committee of Advertising Practice

12. Are you aware of any information or evidence that you think the Scottish Government should consider in relation to regulating domestic advertising in relation to impacts on children and adults (including smokers and non-smokers)?

As discussed in our response to Question 10, blu (UK)'s advertising and marketing policies are driven by our strong belief that advertising should not target Underage Persons or non-smokers, but should be directed solely at adults who wish to use e-cigarettes in order to reduce their consumption of tobacco.

The current scientific evidence suggests that there is no real support for the premise that e-cigarettes (i) are a gateway to smoking tobacco products in Underage Persons or (ii) cause the re-normalisation of smoking. Further, the current advertising framework in the United Kingdom seeks to minimise the risk of a gateway effect and re-normalisation. We have addressed these points below, but further details are provided in the General Comments Section.

1. The advertising framework

Partly due to concerns over advertising of e-cigarettes to Underage Persons and non-smokers, CAP and BCAP launched a consultation in February 2014 on proposed new advertising rules. The new rules were published in October 2014 and came into effect on 10 November 2014.¹ To assist advertisers with interpreting the new rules, CAP has recently published guidance.²

The new CAP and BCAP rules on e-cigarettes specify that e-cigarette advertisements must be responsible and must not (amongst other things):

- appeal to Underage Persons;
- feature people who are or seem to be under 25; and
- encourage non-smokers or non-nicotine users to use e-cigarettes.

The advertisements must also make clear that the product being advertised is an e-cigarette and not a tobacco product.

The rules are enforced by the Advertising Standards Authority, which has the power to refer persistent offenders to the Office of Fair Trading. Safeguards are therefore currently in place to encourage responsible advertising of e-cigarettes.

We have considered available data from the United Kingdom that has examined the impact of e-cigarette advertising and promotion on Underage Persons and adult non-smokers with respect to concerns that e-cigarettes acting as a gateway to tobacco products and the re-

normalisation of smoking-like behaviours. These are discussed below.

2. Impact on advertising on Underage Persons

(a) Awareness of e-cigarettes in Underage Persons in the United Kingdom

The understanding and awareness of e-cigarettes in Underage Persons in Britain is generally high. According to ASH³, the majority of individuals aged 11 to 18 who had heard of e-cigarettes believed that they were less harmful than tobacco cigarettes to the user (66%) and those around them (73%). Further, more than two-thirds of 16 to 18 year olds (67%) who had heard of e-cigarettes believed that either all or some contained nicotine. Approximately, one third (34%) correctly reported that some e-cigarettes contain nicotine, but others do not.

Similar levels of awareness have been reported by ASH Scotland⁴ and ASH Wales⁵.

(b) Source of awareness

There is little information currently available about where Underage Persons in Britain had first heard of e-cigarettes. However, ASH Scotland's⁶ research has shown that the highest proportion (45%) of 17-18 year olds had heard of e-cigarettes through media (i.e. newspapers, magazines, TV or radio) compared to 29% of 15-16 year olds and 34% of 13-14 year olds. The comparable figures reported by ASH Wales are: 39% of 13 to 14 year olds, 41% of 15 to 16 year olds and 40% of 17 to 18 year olds.⁷

(c) Use of e-cigarettes in Underage Persons

Although there are limited studies examining the effect of e-cigarette advertising on Underage Persons, the studies conducted by ASH on Underage Persons in the United Kingdom⁸ show that even though a large proportion this group had heard of e-cigarettes, sustained use was rare and confined to those who currently smoked tobacco cigarettes or had previously smoked. A low percentage of sustained or regular use of e-cigarettes in non-smokers has also been reported by ASH Scotland⁹, the Scottish Schools Adolescent Lifestyle and Substance Use Survey¹⁰, ASH Wales¹¹ and Trading Standards (Cheshire and Merseyside).¹²

(d) Impact of advertising on Underage Persons

Although studies conducted by ASH Scotland and ASH Wales discussed above indicate that a significant proportion of Underage Persons have seen e-cigarette advertisements, there is no real evidence that they act as a gateway to smoking tobacco cigarettes or promote the re-normalisation of smoking behaviours. The evidence suggests that the use of e-cigarettes is largely restricted to current smokers or ex-smokers seeking to reduce tobacco use or quit altogether.

A study undertaken by the Trading Standards Institute on behalf of Public Health England¹³ examined the ease with which Underage Persons could purchase e-cigarettes and similar

products in England. The study showed that the majority of the products that were purchased by purchasers under the age of 18 were marked "*not to be sold to under 18s*". There is therefore a clear need for educating retailers and prohibiting the sale of e-cigarettes and refills to Underage Persons.

Summary

Like alcohol, it is difficult to completely restrict Underage Persons seeing advertisements for e-cigarettes and refills. It is therefore important that the regulatory framework permits responsible advertising which is effectively monitored, whilst restricting Underage Persons from purchasing or obtaining e-cigarettes and refills. As discussed above, we consider that the new CAP and BCAP Codes are sufficient to ensure responsible advertising; however, legislation may be required to reduce the availability of e-cigarettes to Underage Persons (e.g. direct sales and proxy sales).

3. Advertising impact on adults (smokers and non-smokers)

(a) General awareness in adults

Awareness of e-cigarettes has increased amongst British adults. A study commissioned by ASH in 2014¹⁴ showed that of those surveyed, 95% of smokers and 90% of non-smokers had heard of e-cigarettes. Further, the study showed that 35% of British adults surveyed believed that e-cigarettes were good for public health whereas 22% disagreed.

There is a high level of awareness of e-cigarettes amongst Scottish adults.¹⁵ Studies published in 2014 that were undertaken by YouGov for ASH Scotland showed that 31% of those surveyed either strongly agreed or agreed that e-cigarettes were good for public health (23% of people surveyed disagreed). Agreement amongst smokers was higher (55%). It therefore appears that the majority of adults who smoke consider e-cigarettes as good for public health.

(b) Use of e-cigarettes in adults

ASH estimates that there are currently 2.1 million adults in the United Kingdom that currently use e-cigarettes of which 700,000 are ex-smokers (approx. 33%) and 1.3 million are current smokers (approx. 62%).¹⁶

ASH has further shown that there has been a significant rise in the number of smokers who have tried e-cigarettes in the period of 2010 to 2014 and the number of ex-smokers who currently use e-cigarettes. However, no increase has been shown in non-smokers currently using e-cigarettes (this is less than 1% of those surveyed).¹⁷

These findings are further supported by the statistics published by Smoking in England¹⁸, the Office for National Statistics¹⁹, ASH Scotland and ASH Wales. Specifically, the use of e-

cigarettes by those who have never smoked or long-term ex-smokers was reported as extremely rare.

According to a study by ASH²⁰, the main reason given by ex-smokers for using e-cigarettes was to help them quit smoking entirely (71%) or to keep them off tobacco (48%). Amongst current smokers, the main reasons were to quit smoking entirely (36%) and to reduce the amount of tobacco smoked (48%). Therefore, the majority of ex-smokers and smokers successfully used e-cigarettes to help them stop smoking or keep them off tobacco, indicating that choice to use e-cigarettes was influenced by a desire to quit or reduce their tobacco use.

On 17 December 2014, the well-known Cochrane Collaboration published a report concluding that there was some evidence that e-cigarettes can help people to stop smoking.²¹ This report has already been cited by NHS Choices.²² We further note that earlier this year NHS Scotland included e-cigarettes for the first time in its official guidance aimed to help smokers quit.²³

The potential for harm reduction for smokers by using e-cigarettes is therefore being recognised by the NHS.

(c) Effect of advertising and promotion

Several factors have influenced the growth of the e-cigarette industry including consumer-led promotion and advertising. It is likely that the advertising and promotion of e-cigarettes by the e-cigarette industry has in part increased sales. However, the studies discussed above all appear to agree that the effect has been to increase their use in smokers and ex-smokers rather than non-smokers amongst the adult population.

ASH Scotland has considered the general visibility of e-cigarettes through various advertising channels and noted that similarities in the tone and technique of some e-cigarette advertising to conventional tobacco cigarette advertising from previous decades may make it plausible that widespread marketing of e-cigarettes might generate a degree of interest and trial in never smokers and Underage Persons.²⁴ However, as briefly summarised below and in the General Comments Section, there is no conclusive evidence that e-cigarettes form a gateway to tobacco cigarette smoking or re-normalise smoking-like behaviours in Underage Persons or adults.

Further, as summarised in the Scottish Parliament Information Centre Briefing on e-cigarettes (page 20)²⁵, the World Health Organization (WHO) accepts that the existing evidence does not allow a view to be taken on the role of e-cigarettes in increasing nicotine addiction or whether it leads to tobacco smoking. Further, the WHO also noted that although the United Kingdom has strong tobacco control measures and there has been a decline in smoking rates, the use of e-cigarettes was continuing to grow. The evidence pointed away from normalisation in the United Kingdom.

13. Are you aware of any information or evidence that you think the Scottish Government should consider in relation to regulating domestic advertising in relation to impacts on business, including retailers, distributors and manufacturers?

The e-cigarette business in the United Kingdom was estimated to reach £193m in 2013, which is an increase from £44m in 2012.²⁶ The growth of the industry is rapid with Nielsen estimating that value of the industry in the United Kingdom may reach around £340m in 2015.²⁷

This increase in growth is likely to be due to smokers and ex-smokers embracing this new technology to reduce their tobacco consumption, to quit smoking or to stay off cigarettes. Some analysts have further reported that e-cigarette sales will overtake tobacco cigarettes within 10 years.²⁸

We consider that regulating domestic advertising in Scotland may have the following impact on business.

1. Entry barriers and Market Share

The growth of the industry has been attributed to a number of factors. These include increased use of the products through consumer-led promotion by word of mouth, the mechanism of advertising and promotion (e.g. online sales, events in adult venues, sophisticated advertising campaigns). Advertising and marketing are therefore central to not only entry into the industry and establishing a market presence, but also maintaining or increasing market share.

Disproportionate restrictions on advertising and marketing activities would create unnecessarily high hurdles for new businesses entering the industry, especially SMEs that rely on low-cost advertising such as via the internet.

2. Consumer choice/Lack of competition

Disproportionate restrictions on the advertising of e-cigarettes could restrict consumer choice, due to the effect of creating high entry barriers for SMEs as described above. This is likely to drive up the cost of products already on the market by reducing the number of brands that are sold in Scotland.

3. Illicit trade/Quality & Safety of products

Disproportionate regulation may result in illicit trade and the increased import of products from outside the UK that may pose potentially serious risks to the British public. It may also promote more internet sales from non-UK manufacturers and suppliers. Products obtained from outside the European Union may not be CE-marked (a mechanism whereby manufacturers and importers attest to the safety of their products).

The risks to the British public would not only be limited to the quality and safety of the e-liquid,

but also the device itself.

4. Restricting innovation

It is widely recognised that e-cigarettes have the potential for significant public health gain by reducing tobacco consumption and helping people to quit and stay off conventional cigarettes.

The e-cigarette industry is still young but it is an innovation-driven market. New products are continually being launched, producing products that meet consumer needs. This attracts investment into the industry, which further promotes innovation and continual product improvement. The ability to advertise new products is an important aspect of the commercial decision to invest in product development.

Disproportionate regulation will stifle innovation and investment, which would effectively curtail product improvements.

5. Lack of harmonised approach in the United Kingdom

In an age where the majority of people's primary source of information is the internet, the divergence of advertising regulations across the four countries that make up the United Kingdom could lead to uncertainty for e-cigarette manufacturers, online retailers and distributors.

If the online advertiser would have to comply with different advertising legislation in Scotland compared to the other countries that make up the United Kingdom, this could lead to a confusing situation. This could also potentially affect the packaging of products, resulting in the product appearance differing depending on which country within the United Kingdom it is sold in. Not only will this affect British e-cigarette manufacturers and suppliers decision whether or not to sell products in Scotland, it will also influence cross-border trade between Member States of the European Union.

At a retail outlet level, the divergence could increase expenditure and create uncertainty for retailers having to comply with the Scottish regulations. This may pose particular issues for large retailers who have outlets across the United Kingdom.

Inclusion of electronic cigarettes on the Scottish Tobacco Retailer Register

14. Do you agree that retailers selling e-cigarettes and refills should be required to register on the Scottish Tobacco Retailers Register?

Yes No

15. Do you agree that the offences and penalties should reflect those already in place for the Scottish Tobacco Retailers Register?

Yes No

16. If you answered ‘no’, to question 15, what offences and penalties should be applied?

No comment.

E-cigarettes – use in enclosed public spaces

17. Do you believe that the Scottish Government should take action on the use of e-cigarettes in enclosed public spaces?

Yes No

18. If you answered ‘yes’ to Question 17, what action do you think the Scottish Government should take and what are your reasons for this?

19. If you answered, ‘no’ to Question 17, please give reasons for your answer.

The Consultation highlights two main areas of concern: (1) ‘passive vaping’ and (2) re-normalisation of smoking-like behaviours and proposes several options to address the issue of use of e-cigarettes in public places.

Each of the concerns and our suggested approach is addressed below.

1. Passive Vaping

As discussed in response to Question 20 below, the risks to health from exposure to second-hand vapour is very low based on current science. Further, bystanders exposed to second-hand vapour in enclosed public places are unlikely to be exposed for any length of time. The risk of developing long-term health problems from the use e-cigarettes by third parties in enclosed public places is therefore low.

Unlike tobacco cigarettes, e-cigarettes do not produce emissions between puffs. Therefore, passive smoking and passive ‘vaping’ are not comparable. As discussed in response to Question 20 below, the current evidence suggests that there is little or no harm to bystanders from passive vaping.

2. Re-normalisation

We note that the Scottish Government has suggested that there is some concern amongst experts that e-cigarettes may re-normalise smoking behaviours which have become unacceptable since the introduction of smoke-free laws in Scotland in 2006.

It is important to note, however, that this concern applies equally to e-cigarettes that are or will be licensed as medicinal products. In one context, e-cigarettes as licensed smoking cessation aids are viewed positively i.e. they will encourage smokers to move away from

tobacco cigarettes. Conversely, e-cigarettes that are placed on the market as consumer goods and used predominantly by smokers and ex-smokers are viewed negatively as promoting re-normalisation. As recognised in the Public Health England report²⁹, this approach is inconsistent.

The majority of e-cigarettes superficially resemble tobacco cigarettes, which may lead to confusion in the minds of some of the public where the products have been used in enclosed public places e.g. public transport. However, ASH has commented that *“given that the most distinctive feature of cigarette smoking is the smell of the smoke, which travels rapidly, and is absent from electronic cigarette use, it is not clear how any such confusion would be sustained.”*³⁰

Further (and as recognised by the Scottish Government)³¹, the WHO accepts that the existing evidence does not allow a view to be taken on the role of e-cigarettes in increasing nicotine addiction or whether it leads to tobacco smoking. Indeed, the WHO has said *“re-normalization as measured by prevalence of smoking is not occurring currently”* in the United Kingdom.³²

3. Welsh Government consultation

We note that limiting the use of e-cigarettes in enclosed public places was recently considered in the Welsh Government's consultation on proposals for a Public Health Bill. However, the proposal was opposed by those who responded (79%).³³

4. Designated Vaping Spaces

Several possible options have been proposed in the Consultation document. However, the Consultation recognises that the use of e-cigarettes in enclosed public places (including workplaces) is currently a matter for an individual organisation and whether they wish to have their own policies to restrict the use e-cigarettes. Indeed, as the Advisory, Conciliation and Arbitration Service (ACAS) has recognised, if employers wish to have e-cigarette policies, they may have rules for cigarette smokers and rules for e-cigarettes smokers.³⁴

ASH has also suggested that those wishing to quit are less likely to do so if they have to go to smoking area.³⁵

5. blu (UK)'s position

In summary, blu (UK) considers that there is no need for further regulation of the use of e-cigarettes in enclosed public places.

Employers and establishments should be entitled to adopt their own policies as to whether use on their premises should be restricted or prohibited. In addition, there is no real evidence that there are significant health risks from passive vaping or re-normalisation of tobacco cigarettes. Designated vaping areas may, however, be beneficial for those who wish

to quit smoking.

20. Are you aware of any evidence, relevant to the used of e-cigarettes in enclosed spaces, that you think the Scottish Government should consider?

Smoking tobacco cigarettes in public places has been banned in the United Kingdom since the amendments to the Health Act 2006. The effects of passive smoking were known for many years prior to the introduction of the ban, which was based on accepted scientific evidence.

The analogous term that would apply to e-cigarettes is passive 'vaping'. However, there are significant and relevant differences between tobacco cigarettes and e-cigarettes.

1. Passive Vaping

Passive vaping refers to bystanders breathing in exhaled e-cigarette aerosol/vapour (rather than exhaled cigarette smoke and emissions produced between puffs, as is the case in passive smoking in tobacco cigarettes). Indeed, a report on e-cigarettes by Professor John Britton and Dr Ilze Bogdanovica of the UK Centre for Tobacco and Alcohol Studies, University of Nottingham, commissioned by Public Health England (published May 2014) concluded³⁶:

*"Electronic cigarettes do not produce smoke so the well-documented effects of passive exposure of others to cigarette smoke are clearly not relevant. Exposure of non-smokers to electronic cigarette vapour poses a concern, though laboratory work suggests that electronic cigarette use in an enclosed space exposes others to nicotine at levels about one tenth generated by a cigarette, but little else³⁷. **The health risks of passive exposure to electronic cigarette vapour are therefore likely to be extremely low.**"*

A similar conclusion was reached in a paper produced by the National Centre for Smoking and Cessation and Training³⁸ in partnership with Public Health England:

*"Low levels of toxicants and carcinogens have been detected in electronic cigarette liquid and vapour although these are **much lower than those found in conventional cigarette smoke and are not considered to pose any passive inhalation risk.**"*

However, the WHO adopts a more cautious approach to the issue of potential health risks to bystanders exposed to e-cigarette vapour.³⁹

We note; however, Schripp *et al.* (2013)⁴⁰ reported that many parameters can affect passive vaping, including type of e-cigarette, length of puff, indoor climate, airflow conditions and

the age, sex, health status and diet of the user. It is therefore difficult to make any generalisations as to the risk posed by passive vaping as these studies have compared different products and the test conditions are not standardised.

However, Lorillard Inc. (blu (UK)'s ultimate parent), has conducted its own research and analysis on its blu e-cigarettes and e-liquids, which Lorillard Inc. has published in peer reviewed journals or on the US clinical trials database:

- *Toxicology assessment of the e-liquid and vapour of certain blu electronic cigarettes.*⁴¹ The assessment included 4 *in vitro* assays to test for genotoxicity, cytotoxicity, mutagenicity and inflammatory response and was based on traditional combustible cigarette analyses modified for e-cigarette use. The results showed that the blu e-liquids or the collected vapour tested did not produce any meaningful toxic effects in *in vitro* test systems, in which the conventional cigarette smoke preparations, at comparable exposures, are markedly cytotoxic and genotoxic.
- *Aerosol/Vapour testing.*⁴² Aerosol testing using a modified smoking machine to measure the level of certain constituents found in tobacco cigarette smoke in the aerosol/vapour produced of certain blu e-cigarettes.
- *Exhaled aerosol/vapour study.*⁴³ An exhaled vapour study with human subjects to test the level of harmful and potentially harmful constituents ("HPHCs")ⁱⁱⁱ in exhaled vapour of certain blu e-cigarettes as compared to the level of HPHCs in the smoke of a combustible cigarette.
- *Puffing topography study.* A puffing topography study with human subjects to assess the puffing profile (puff volume, duration and number of puffs) of certain blu e-cigarettes.
- *Second-hand exposure to vapour.* Lorillard has partnered with external parties to conduct a real-world vaping/environmental study to compare second-hand exposure from environmental tobacco smoke constituents from combustible cigarettes to environmental aerosol constituents from certain blu e-cigarettes.
- *Pharmacokinetics studies.*⁴⁴ Lorillard has partnered with an external party to conduct a randomised, partially single-blinded, six-period crossover clinical pharmacokinetics study to characterize nicotine exposure and urge-to-smoke following controlled administration and short-term use of certain blu e-cigarettes as compared to

ⁱⁱⁱ HPHCs are chemicals or chemical compounds in a tobacco product or tobacco smoke that cause, or could cause, harm to smokers or non-smokers, which are required to be reported to the US Food and Drug Administration under the US Family Smoking Prevention and Tobacco Control Act. There are currently 93 HPHCs that tobacco companies are required by law to report for every regulated tobacco product sold in the US (see: <http://www.fda.gov/TobaccoProducts/PublicHealthScienceResearch/HPHCs/default.htm#>).

combustible cigarettes.

2. Content of exhaled vapour

The WHO has advanced guidelines “for the protection of public health from risks due to a number of chemicals commonly present in indoor air” (WHO, 2010)⁴⁵. These chemicals include several that have been reported to be present in side-stream cigarette smoke emissions, such as benzene, carbon monoxide, formaldehyde and polycyclic aromatic hydrocarbons (“PAH”). These values are generally expressed as a time weighted average for an 8-hour work day.

Only four studies we are aware of have analysed the air in a room after a vaping session has occurred. These studies generally compared the levels of various components in room air after vaping with those after cigarette smoking, or with the air in a control room where no vaping or smoking has occurred (intended to represent the “normal” composition of indoor air).⁴⁶

This distinction between passive vaping studies and those that analyse the mainstream aerosol is significant, as Schripp *et al.* (2013)⁴⁷ notes that during “*inhalation of the e-cigarette vapor, the aerosol size distribution alters in the human lung and leads to an exhalation of smaller particles. This effect is caused by evaporation of the liquid particles in the lung and also in the environment after exhalation.*”

The passive vaping studies compared indoor air concentrations of PAHs, volatile organic compounds (VOCs), carbonyls and metals after vaping to those in a control setting and/or after conventional cigarette smoking. Some other parameters such as total organic carbon (TOC), particulate matter and carbon monoxide levels are sometimes reported.

Smoking in cars carrying children aged under 18

21. Do you agree that it should be an offence for an adult to smoke in a vehicle carrying someone under the age of 18?

Yes No

22. Do you agree that the offence should only apply to adults aged 18 and over?

Yes No

23. If you answered ‘no’ to Question 22, to whom should the offence apply?

24. Do you agree that Police Scotland should enforce this measure?

Yes No

25. If you answered 'no' to Question 24, who should be responsible for enforcing this measure?

26. Do you agree that there should be an exemption for vehicles which are also people's homes?

Yes No

27. If you think there are other categories of vehicle which should be exempted, please specify these?

28. If you believe that a defence should be permitted, what would a reasonable defence be?

Smoke-free (tobacco) NHS grounds

29. Should national legislation be introduced to make it an offence to smoke or allow smoking on NHS grounds?

Yes No

30. If you support national legislation to make it an offence to smoke on NHS grounds, where should this apply?

- a. All NHS grounds (including NHS offices, dentists, GP practices) a
- b. Only hospital grounds b
- c. Only within a designated perimeter around NHS buildings c
- d Other suggestions, including reasons, in the box below

31. If you support national legislation, what exemptions, if any, should apply (for example, grounds of mental health facilities and / or facilities where there are long-stay patients)?

32. If you support national legislation, who should enforce it?

33. If you support national legislation, what should the penalty be for non-compliance?

34. If you do not support national legislation, what non-legislative measures could be taken to support enforcement of, and compliance with, the existing smoke-free grounds policies?

Smoke-free (tobacco) children and family areas

35. Do you think more action needs to be taken to make children's outdoor areas tobacco free?

Yes No

36. If you answered 'yes' to Question 35, what action do you think is required:

a. Further voluntary measures at a local level to increase the number of smoke-free areas a

b. Introducing national legislation that defines smoke-free areas across Scotland b

c. That the Scottish Government ensures sufficient local powers to allow decisions at a local level as to what grounds should be smoke-free c

d. Other actions. Please specify in the box below

37. If you think action is required to make children's outdoor areas tobacco-free, what outdoor areas should that apply to?

Age verification policy ‘Challenge 25’ for the sale of tobacco and electronic cigarettes

38. Do you agree that retailers selling e-cigarettes, refills and tobacco should be required by law to challenge the age of anyone they believe to be under the age of 25?

Yes No

39. Do you agree that the penalties should be the same as those which are already in place for selling tobacco to someone under the age of 18?

Yes No

Unauthorised sales by under 18 year olds for tobacco and electronic cigarettes

40. Do you agree that young people under the age of 18 should be prohibited from selling tobacco and non-medicinal e-cigarettes and refills unless authorised by an adult?

Yes No

41. Who should be able to authorise an under 18 year old to make the sale, for example, the person who has registered the premises, manager or another adult working in the store?

As with alcohol, Underage Persons should be permitted to sell e-cigarettes provided they have received adequate training and that the sale is authorised by a responsible person who is over 18 years of age. The person authorising the sale should be a store manager or someone authorised by the store manager.

The regulation should be similar to the provisions for alcohol under the Licensing (Scotland) Act 2005.

42. Do you agree with the anticipated offence, in regard to:

a. the penalty

a

b. the enforcement arrangements

b

Equality Considerations

43. What issues or opportunities do the proposed changes raise for people with protected characteristics (age; disability; gender reassignment; race; religion or belief; sex; pregnancy and maternity; and sexual orientation)?

We are not aware of any issues or opportunities that the proposed changes will raise for people with protected characteristics.

44. If the proposed measures are likely to have a substantial negative implication for equality, how might this be minimised or avoided?

Please refer to our response to Question 43.

45. Do you have any other comments on or suggestions relevant to the proposals in regard to equality considerations?

We have no further comments or suggestions relevant to the proposals in regard to the equality considerations. However, we reiterate our position that the proposals would adversely affect the ability of smokers to use e-cigarettes as a means to reduce their tobacco consumption or quit smoking. We consider the proposed regulations will unduly hinder the potential harm reduction opportunity to smokers presented by e-cigarettes.

Business and Regulatory Impacts Considerations

46. What is your assessment of the likely financial implications, or other impacts (if any), of the introduction of each of these proposals on you or your organisation?

Please refer to the response to Question 13.

47. What (if any) other significant financial implications are likely to arise?

In addition to the issues summarised in the response to Question 13, we consider that it is likely that the retailer compliance training that will be required in light of the proposed regulation of e-cigarettes will represent an additional cost of doing business to retailers.

48. What lead-in time should be allowed prior to implementation of these measures and how should the public be informed?

Without prejudice to whether or not we agree to the implementation of the measures, we consider that the lead in period should be sufficiently long for businesses to adapt to the necessary changes within an appropriate timeframe whilst minimising disruption to

business and having regard to implementation of the Tobacco Products Directive. We consider that a period of 2 years would be sufficient.

49. Do you have any other comments on or suggestions relevant to the proposals in regard to business and regulatory impacts?

We note that the Scottish Government has had discussions with business around e-cigarettes and strengthening tobacco control as part of the Ministerial Working Group on Tobacco Control and during the development of *Creating a Tobacco-Free Generation*.

blu (UK) welcomes the Scottish Government's willingness to engage with business. blu (UK) has its headquarters in Edinburgh, so the regulatory framework in Scotland is very important to its business and future plans. Together with its sister company, LOEC, Inc., (maker of the best-selling e-cigarette brand in the United States of America), blu (UK) is a major global player in the e-cigarette industry. Accordingly, it would be happy to engage with the Scottish Government directly to discuss the issues surrounding e-cigarettes and is in the process of arranging a meeting with the Tobacco Policy Control Team in 2015.

As a party to the World Health Organization's Framework Convention on Tobacco Control (FCTC), Scotland has an obligation to protect the development of public health policy from the vested interests of the tobacco industry. To meet this obligation, we ask all respondents to disclose whether they have any direct or indirect links to, or receive funding from, the tobacco industry. We will still carefully consider all consultation responses from the tobacco industry and from those with links to the tobacco industry and include them in the published summary of consultation responses.

blu (UK) and its sister company, LOEC, Inc. (hereinafter referred to as "**blu (US)**") are wholly-owned subsidiaries of Lorillard, Inc. ("**Lorillard**").

1. About Lorillard

Lorillard is listed on the New York Stock Exchange (NYSE: LO). With its business originally founded in 1760, it is the oldest continuously operating tobacco business in the US.

Through its Lorillard Tobacco Company subsidiary, it is also the third largest manufacturer of tobacco cigarettes in the US. None of its current tobacco cigarette brands are actively marketed in Europe.

On 15 July 2014, Lorillard entered into a transaction with Reynolds American Inc. and Imperial Tobacco Group PLC (both of which are tobacco companies) whereby Imperial Tobacco Group PLC would ultimately acquire certain assets owned by Lorillard and its

subsidiaries (including blu (US) and blu (UK)). The asset purchase includes the blu e-cigarette brand and related assets. Completion of this transaction is pending approval from the US Federal Trade Commission.

2. About blu (UK)

In April 2012, Lorillard acquired the brand name, other intellectual property rights and the manufacture, distribution, research and development capabilities of blu eCigs, the leading e-cigarette company in the US at the time. As of August 2014, blu eCigs had approximately 40.9% share of the US retail market for e-cigarettes.

The blu eCigs acquisition in the US was followed in October 2013 with the purchase of the assets and operations of a British e-cigarette company (then doing business as SKYCIG) through blu (UK). The SKYCIG brand was the leading premium brand of e-cigarettes sold in the United Kingdom at the time of the acquisition. In May 2014, the SKYCIG product was rebranded as blu eCigs. The blu eCig business in the United Kingdom is operated through blu (UK).

blu (UK) is thus a subsidiary of Lorillard and is one of the main players in the e-cigarette industry both in the United Kingdom, and together with blu (US), globally.

blu (UK) is also actively involved in the e-cigarette industry through its membership of the Electronic Cigarette Industry Trade Association ("ECITA")^{iv}. ECITA was formed in 2010 with members comprising e-cigarette vendors and manufacturers who are committed to the excellence, quality and safety of their products.

^{iv} See: <http://www.ecita.org.uk/>

ANNEX
GENERAL COMMENTS ON THE CONSULTATION

1. Introduction

blu (UK) acknowledges the Scottish Government's desire for clear regulation of e-cigarettes in Scotland. In particular, there has been a debate about their potential for normalising smoking and questions over whether they may act as a gateway to nicotine or tobacco for Underage Persons or non-smokers. We comment on that below, but will first address our suggested principles that the regulation of advertising, promotion and sales of e-cigarettes in Scotland should be (i) distinct from the framework applicable to tobacco cigarettes based on the different characteristics and risk profiles of the products, (ii) proportionate (as required by the principles of better regulation to which the Scottish Government adheres) and (iii) based on evidence from the scientific and healthcare communities.

We submit that, given the potential for population level harm reduction associated with the availability of quality e-cigarettes, the regulatory framework should aim to allow consumers appropriate access (and opportunities for use of) e-cigarettes, while at the same time encouraging the gathering of further information on the use of the products, promoting innovation and supporting the on-going development of quality products.

2. Electronic Cigarettes – Product description and history of development

The modern e-cigarette was pioneered and launched initially in China in the early 2000s.⁴⁸ Since their introduction into the European market around 2005, e-cigarettes have become increasingly popular with a number of brands available to consumers.

The available e-cigarettes can differ in appearance. Some superficially resemble a traditional tobacco cigarette in shape and size and others are larger in size and are usually described as personal vaporisers. E-cigarettes have largely been adopted by adult smokers and ex-smokers who use the devices as an alternative source of nicotine either to reduce their consumption of tobacco products, to help them quit or to keep off tobacco products altogether.⁴⁹ This trend has been supported by responsible marketing and promotional policies adopted by many e-cigarette manufacturers, including age verification at point of sale, marketing to adult audiences (smokers) and limiting promotional events to adult events and adult-only spaces in those events.

There is considerable variability in the appearance and quality of e-cigarettes sold in the United Kingdom (either through the internet or in retail outlets). However, e-cigarettes generally comprise a battery, an atomiser or heating element and a fluid-filled cartridge, which may or may not contain nicotine (as an 'e-liquid'). The cartridge and atomiser can

also be combined into one element known as a 'clearomiser'. The products are electronic vaporisers and do not involve the process of combustion.

By inhaling on the mouthpiece of the e-cigarette, the user triggers an electronic airflow or pressure sensor, which automatically activates the atomiser heating the e-liquid. This in turn creates the vapour which is inhaled by the user. Accordingly, the e-cigarette is only active when the user puffs on the device.

E-cigarettes are not tobacco products. Furthermore, a portion of e-cigarettes or e-liquids on the market do not contain nicotine and thus do not raise the same issues as nicotine-containing e-cigarettes.

3. Comparison with tobacco products

As a general observation, certain commentators advocate the same restrictions on e-cigarettes as those that apply to tobacco cigarettes. E-cigarettes and tobacco products are, however, very different, and should be considered independently. A 'one size fits all' approach to regulation would be inappropriate.

E-cigarettes do not rely on the combustion of tobacco nor do they contain the same harmful components as tobacco cigarettes. A major difference is that e-cigarettes do not contain tar, a mixture of chemicals which can contribute towards lung cancer in smokers. In addition, there are over 5,000 chemicals present in tobacco cigarettes of which many are known to be carcinogenic.⁵⁰

In comparison to tobacco cigarettes, the ingredients found in e-cigarettes are relatively few. E-cigarettes may include distilled water, nicotine (when applicable), glycerine, propylene glycol and flavourings. Likewise, in comparison to the smoke generated by combustion of tobacco cigarettes, the vapour emitted by e-cigarettes contains very few constituents.

In addition, the mechanism of delivery of nicotine from tobacco cigarettes and nicotine-containing e-cigarettes appears to be different. Smoke generated by a tobacco cigarette delivers nicotine through the respiratory system, with the majority of absorption taking place through the systemic venous circulation from the large airways and the pulmonary circulation via the smaller airways and alveoli in the lungs. Absorption through the pulmonary circulation permits a rapid increase in arterial nicotine levels and thus rapid delivery to the brain⁵¹. According to the literature summarised in the Public Health England report on e-cigarettes⁵², absorption of nicotine from e-cigarette vapour appears to be primarily absorbed into the systemic venous circulation (e.g. in the upper airways) and its rate of absorption appears to be slower than nicotine in tobacco cigarette smoke.

4. Overview of Scientific Evidence and Harm Reduction Potential

There is a substantial body of scientific evidence that has grown in volume since the 1950s that shows the public health risks associated with smoking tobacco cigarettes. Although the e-cigarette market is younger, there is a growing body of scientific data on the use of e-cigarettes, their safety and efficacy and their potential effect on smokers, non-smokers and Underage Persons. The main findings emerging from the scientific community are summarised below.

4.1 E-cigarette vapour and e-liquids generally contain less toxicants than tobacco cigarette smoke

Multiple studies have compared the level of toxicants (including harmful or potentially harmful constituents) in e-liquids, vapour and indoor air after vaping, to the levels in cigarette smoke, as well as the *in vitro* effects, including inflammatory response, mutagenicity, genotoxicity and cytotoxicity. However, it is difficult to generalise the results of the chemical and toxicology testing of e-liquids and vapour due to the number of brands available, the rapidly evolving e-cigarette designs, and the lack of standard testing protocols. For example, it has been recently reported that there are over 460 brands of e-cigarettes and 7700 flavours available over the internet.⁵³

Despite these limitations, the analyses available generally suggests that the level of toxicants in e-cigarettes is significantly lower than those found in tobacco cigarette smoke and that e-liquid and vapour are substantially less cytotoxic than tobacco cigarette smoke.

While there is limited information available on *in vitro* inflammatory, mutagenic and genotoxic properties of e-cigarettes, the information available suggests few effects.^{54,55,56,57,58,59,60} The few studies on “passive vaping” also suggest that the amount of harmful constituents is generally similar to that in indoor air and does not present additional risks to human health.^{61,62,63,64}

Although research on e-cigarettes will continue, many harm reduction proponents appear to agree that the current available scientific evidence is sufficient to conclude “[e]-cigs might be the most promising product for harm reduction to date.”⁶⁵ The current weight of the scientific evidence regarding safety is that the vapour from e-cigarettes only exposes users to toxic chemicals comparable to the exposure from use of therapeutic nicotine replacement products already on the market. A recent study comparing e-cigarette vapour to tobacco cigarette smoke reported that the “levels of potential toxic compounds in e-cigarette vapour are 9-450-fold lower than those in the smoke of conventional cigarettes, and in many cases comparable to the trace amount present in pharmaceutical preparations.”⁶⁶ The authors of the study also stated “[o]ur findings support the idea that substituting tobacco cigarettes with electronic cigarettes may substantially reduce exposure to tobacco-specific toxicants.”

Another recent review of the state of the science also concluded that “[t]he available evidence indicates that e-cigarettes do not raise serious health concerns and can be considered a much safer alternative to conventional smoking.”⁶⁷

4.2 E-Cigarettes are not likely to be a pathway to nicotine addiction and dependence.

Concern that e-cigarettes are a pathway to nicotine addiction and dependence are speculative and not supported by the available literature.

A number of large surveys have consistently reported that very few never-smokers have tried, or use, e-cigarettes. For example, research conducted in the United Kingdom by the Office for National Statistics published for Q1 2014 has shown that 11.8% of cigarette smokers have also used e-cigarettes compared to 4.8% of ex-smokers and only 0.14% of people who have never smoked^{68,69}. These findings are supported by research conducted by ASH⁷⁰ and other demographic studies conducted in the United Kingdom.

No studies have evaluated whether e-cigarettes contribute to smoking relapse and existing data on this issue are too limited to draw any conclusions. However, there is some evidence that points the other way: e-cigarettes may help smokers with a documented history of recurring relapses.⁷¹

Importantly, Polosa *et al.* also stated that “[t]here is no evidence that large numbers of non-smokers are purchasing or will purchase [electronic cigarettes] and become addicted to nicotine”.⁷²

4.3 Nicotine addiction potential could be less for e-Cigarettes than for conventional tobacco cigarettes.

While nicotine, whether delivered by e-cigarettes or conventional tobacco cigarettes or any other product that contains nicotine, is addictive, the available surveys and studies on the nicotine addiction potential of e-cigarettes suggest that users may be less dependent on e-cigarettes than on conventional tobacco cigarettes.

Surveys of e-cigarette users suggest that users tend to decrease the levels of nicotine they use over time. The studies have also evaluated various aspects of dependence on e-cigarettes as compared to conventional tobacco cigarettes and found lower levels of dependence for e-cigarettes on the measured criteria for dependence.^{73,74} A further clinical study of the "abuse liability" of e-cigarettes showed that the devices appeared to have a lower potential for abuse than conventional tobacco cigarettes.⁷⁵

4.4 E-cigarettes can deliver adequate nicotine to suppress cigarette withdrawal symptoms and help smokers reduce smoking, but the evidence is inconclusive on cessation.

The available clinical studies examining nicotine delivery of e-cigarettes have consistently noted that experienced e-cigarette users are able to obtain adequate nicotine levels to relieve withdrawal symptoms and craving.^{76,77,78}

The controlled trials and intervention studies that have been conducted on smoking reduction and cessation have observed that e-cigarette use results in statistically significant reductions in smoking for both smokers who wanted to quit and those who did not intend to quit. The clinical data regarding smoking cessation have been less consistent. Observational epidemiology studies assessing various cessation measures generally have found some evidence that e-cigarette users were more likely to have attempted to quit smoking, but were not more likely to have been successful at doing so.⁷⁹

In addition, although much of the evidence is anecdotal regarding the effectiveness of e-cigarettes as a substitute for smoking, recent clinical trials report promising results. Two large clinical trials provide evidence that e-cigarettes help smokers reduce or quit smoking, even those smokers who did not intend to quit.^{80,81} Several additional smaller clinical trials report similar results.

4.5 Scientific evidence does not suggest negative effects from dual use of conventional tobacco cigarettes and e-cigarettes.

Dual use of conventional and e-cigarettes has not been studied extensively although it is our understanding that there are studies planned that intend to evaluate the health effects of dual use. The prevalence of dual use is currently not well understood. Smoking cessation studies, as stated above, however, have reported statistically significant reductions in tobacco cigarette use among dual users. The reduction in cigarette consumption may lead to health benefits as experts have estimated that the potential harm of e-cigarettes to be a small percentage of the maximum relative harm of conventional cigarettes. Furthermore, surveys of smokers who have reduced smoking with e-cigarette use have generally reported improvements in health after initiating e-cigarette use.

Further, we note that the authors of the report on e-cigarettes commissioned by Public Health England⁸² stated:

“It has been suggested that there is a risk of sustained dual use among smokers who might otherwise have quit smoking completely, representing missed opportunities to achieve complete cessation. This concern clearly applies equally to NRT [Nicotine Replacement Therapy], which is licensed for what is in effect dual use and recommended on the grounds that dual use is likely to increase

quit attempts. The concern is therefore inconsistent; if dual use is good as a pathway to quitting, that surely applies to dual use involving either NRT or electronic cigarettes.”

A recent study examining relapse amongst dual users showed that only 6% of former smokers who used e-cigarettes relapsed to smoking after one month, and only 6% after one year, and nearly a half of dual users stopped smoking after one year.⁸³ This highlights the potential use of e-cigarettes in helping people to quit smoking. As discussed in our Response Form, this is beginning to be recognised by some NHS bodies.

Further and as reported by ASH, the Smoking Toolkit Study carried out in England has also found that an increasing number of smokers were using e-cigarettes as an aid to quitting, overtaking use of medicinal nicotine products such as patches and gum.⁸⁴

4.6 Scientific evidence does not suggest that e-cigarettes are a path to youth nicotine addiction or initiation of smoking.

Several public health bodies have raised concerns about adolescent use of e-cigarettes, whether e-cigarettes are a gateway to smoking or nicotine addiction and whether adolescents are uniquely susceptible to nicotine addiction. Indeed, this was a factor considered by the European legislators in respect of the TPD.

As discussed in the Response Form, the available literature on adolescent use of e-cigarettes in Scotland or other parts of the United Kingdom does not suggest that e-cigarettes are a gateway to later tobacco use. A longitudinal study that provides data on the temporal relationship between e-cigarette use and later smoking did not find a significant relationship.⁸⁵ While there are analyses of cross-sectional surveys that have concluded that e-cigarettes may encourage use of tobacco cigarettes or inhibit cessation, their conclusions are flawed because cross-sectional data do not address order of use and have been criticised for inferring a result that is not supported by data.

The available literature does not suggest that e-cigarettes are a path to nicotine addiction for Underage Persons, but instead suggests that the prevalence of e-cigarette use among such persons who have never smoked is very low.

As reported by ASH, the leader of the Smoking Toolkit Study⁸⁶, Professor Robert West, commented on the study as follows:

“Despite claims that use of electronic cigarettes risks renormalizing smoking, we found no evidence to support this view. On the contrary, electronic cigarettes may be helping to reduce smoking as more people use them as an aid to quitting.”

5. Regulation of domestic advertising and marketing

The regulation of advertising and marketing of e-cigarettes and refills must be approached from two levels: (i) advertising rules and guidance that promote the responsible advertising of e-cigarettes and (ii) restricting sales of e-cigarettes and refills to individuals over 18 years old. As discussed below, we fully support the restriction of sales of e-cigarettes and refills to individuals who are over 18 years of age.

Taking alcohol as an example, advertisements promoting alcohol are often on television at times when Underage Persons may be viewing. ⁸⁷ There are also numerous billboard and other advertisements (particularly around Christmas) in public places where they are frequently seen by Underage Persons (e.g. London underground stations, bus shelters, etc.). The effect of alcohol on social behaviour and health is well documented; however, the major factor in limiting Underage Persons' exposure to alcohol is the ability to procure it.

A fair balance needs to be struck between the need to protect vulnerable people and the legitimate business needs of e-cigarette manufacturers. As discussed below, the TPD presents an extreme position. Pending its implementation, we consider that the new CAP and BCAP advertising codes for e-cigarettes and refills that have recently come into effect in the United Kingdom⁸⁸ are sufficient and no further regulation of advertising is required.

5.1 The Tobacco Products Directive – Advertising restrictions

We consider that the advertising restrictions to be introduced following the implementation of the TPD in the United Kingdom presents a severe restriction on e-cigarette manufacturers' freedom to conduct a business and are disproportionate to the issues they address.

Article 20(5) of the TPD concerns the advertising and promotion of e-cigarettes. Its effect is to ban all forms of advertising and promotion of e-cigarettes which are not classified as medicinal products, save for a few specific exceptions (e.g. publications that are intended exclusively for professionals in the trade of e-cigarettes or refill containers and for publications which are printed and published in third countries, where those publications are not principally intended for the European Union). The restrictions imposed would therefore be aligned with those for tobacco products.

The overall effect of Article 20(5) of the TPD would be an effective ban of advertising of e-cigarettes that are not regulated as medicinal products in the United Kingdom. The e-cigarette industry is in its infancy and has not had the benefit of years of advertising campaigns that have allowed companies in other industries to establish their place in a crowded market.

Any new company entering an industry relies on advertising to increase sales, promote brand recognition and establish market presence. Advertising is also important in maintaining a market presence once it is established. The effective ban on advertising would therefore severely restrict a growing industry, an industry that has the potential to significantly reduce the consumption of tobacco cigarettes in the United Kingdom.

As the Scottish Government is aware, the lawfulness of Article 20 of the TPD has been challenged by way of judicial review in England by an e-cigarette manufacturer, Pillbox 38 (UK) Limited (trading as Totally Wicked). We understand that the issue of the validity of Article 20 of the TPD is pending a preliminary ruling from the Court of Justice of the European Union ("CJEU") following a reference from the English High Court on 6 October 2014.⁸⁹

The regulatory framework affecting e-cigarettes is therefore in a state of flux. Pending the implementation of the TPD or the ruling from the CJEU (whichever is earliest), we consider that the current regulatory framework applying to the advertising and promotion of e-cigarettes to be sufficient as discussed below.

5.2 The current advertising and promotion framework

The advertising and promotion of e-cigarettes currently falls within the scope of various legislation including (amongst others) the Directive on Consumer Rights (Directive 2011/83/EC), the E-Commerce Directive (Directive 2000/31/EC), Misleading and Comparative Advertising Directive (Directive 2006/114/EC) and the Unfair Commercial Practices Directive (Directive 2005/29/EC). Further, advertisements whose purpose it is to promote tobacco products or whose effect is to do so are prohibited under the Tobacco Advertising and Promotions Act 2002.

In addition to the legislative framework, the advertising of e-cigarettes is subject to self-regulation under the advertising codes issued by CAP and BCAP. Indeed, specific advertising rules concerning e-cigarettes were issued by CAP and BCAP on 9 October 2014 following a public consultation.⁹⁰ The new codes, which are applicable to the whole of the United Kingdom, have been enforced by the Advertising Standards Authority from 10 November 2014. As the Scottish Government is aware, the Advertising Standards Authority may refer companies who repeatedly breach the advertising codes to the Office of Fair Trading, which has the power to impose fines and take appropriate legal action.

The new codes promote advertisements that are socially responsible and do not encourage non-smokers or non-nicotine users to use e-cigarettes. E-cigarette advertisements must also avoid features and characters that relate to youth culture or appeal to Underage Persons. People appearing in the adverts must be or appear to be over 25 years old. There are also

certain requirements as to the audience of print media or timings of e-cigarette adverts in broadcast media to minimise exposure to Underage Persons.

Under the new rules, an e-cigarette advert must also be clear that it is an advertisement for an e-cigarette and must not contain anything that might be seen as promoting a tobacco brand or show the use of a tobacco product in a positive light.

The new rules appear to be an attempt to strike a balance between the e-cigarette industry's legitimate business interests and the need to protect Underage Persons and non-smokers. The new rules are subject to monitoring by CAP, who will undertake a formal review 12 months after their coming into effect.

6. The need for harmonised regulation across the United Kingdom

Separate Scottish regulation of advertising and promotion of e-cigarettes is likely to promote a lack of harmonisation within the United Kingdom.

The majority of e-cigarette manufacturers domiciled in the United Kingdom are small or mid-sized companies who depend on sales through their websites. The advertisements and promotions appearing on their websites may potentially be subject to separate advertising regulation in Scotland, England, Wales and Northern Ireland. What is lawful in one country may not be lawful in another if local advertising rules differ. This has the potential for causing great uncertainty for e-cigarette manufacturers and distributors.

Further, the implementation deadline for the TPD is 19 May 2016. However, there has not yet been a public consultation as to its implementation in the United Kingdom. We understand that the Department of Health may be launching a public consultation on the implementation of the TPD in early 2015.

Any additional regulation in Scotland in the interim period may ultimately need to be revised following the passing of legislation implementing the TPD. This again may cause uncertainty not only for e-cigarette manufacturers, distributors and retailers, but also members of the public, and goes against the Scottish Government's aims of achieving consistency and transparency of regulations.

7. blu (UK)'s approach to the e-cigarette business

blu (UK) is committed to developing and manufacturing a consistent product, including the development of responsible quality control and product stewardship policies.

Lorillard, blu (UK)'s parent company, has also committed to advancing scientific research into the safety and efficacy profile of e-cigarettes, including their potential to be safer than

combustible cigarettes or as effective as nicotine replacement therapy. Regardless of the harm reduction potential for blu (UK) products or e-cigarettes more generally, blu (UK) is scrupulous about marketing its products only as an alternative to tobacco products, not as reduced harm or reduced risk products. Moreover, blu (UK) responsibly markets its products only to adult smokers and takes significant steps to limit the exposure of Underage Persons to its marketing or promotional activities. The company's commitment to quality and integrity manifests itself through a number of key activities summarised below.

7.1 blu's (UK)'s commitment to quality manufacturing and stewardship

blu (UK) and blu (US) have voluntarily implemented a product stewardship program that focuses on (among other things):

1. integrity of product design;
2. product performance testing;
3. working with responsible audited or certified suppliers;
4. obtaining quality ingredients from suppliers; and
5. manufacturing under strict corporate quality standards.

As part of its stewardship and quality programs, blu (UK) invests significant resources in quality control testing of its ingredients. For example, Lorillard requires approved formulas and ingredient suppliers for blu e-liquids and will require a qualification process that includes sample and batch testing against blu-established specifications (including nicotine, propylene glycol, glycerine and water content, certain detectable metals, viscosity, flashpoint, pH and specific gravity). The company requires further validation testing prior to manufacturing of the finished product. Manufacturers will be required to provide Certificates of Analysis (COAs) with each lot of production and blu (UK) plans to perform verification testing of the COAs. In addition, blu (UK) has contracted with an independent laboratory for testing verification upon receipt.

For manufacturing of the finished product, blu (UK) has implemented robust quality controls for the manufacturing process. As an initial matter, blu (UK) selects contract manufacturers based on their eventual ability to comply with pharmaceutical and medical device GMPs or quality system regulations (QSRs). For example, blu (UK) requires traceability by lot number, incoming quality testing on key components, sample testing of each shipment of products that leaves the contract manufacturer and performs additional production monitoring on finished products. The company also conducts scheduled quarterly audits and unscheduled audits of the factories, reviews any corrective actions and maintains weekly manufacturing oversight through a third-party management company.

blu (UK) also has a complaint process whereby safety-related complaints regarding blu products are referred to appropriate personnel for investigation and resolution, as necessary.

7.2 blu (UK) is committed to research regarding the safety of its products

Lorillard, on behalf of blu (UK), has conducted various toxicological, environmental and clinical testing of blu products to assess product safety. The results of these studies suggest that the safety profile of blu e-cigarettes is more favourable than that of combustible cigarettes and comparable to smokeless tobacco products, which is consistent with the larger body of literature that has been published. These studies are discussed in response to Question 20.

7.3 blu (UK) is committed to continued innovation

blu (UK) is committed to future development and innovation of its e-cigarettes to improve further the safety profile of its products.

7.4 blu (UK) is committed to responsible marketing practices

blu (UK) believes that e-cigarettes are not a product for Underage Persons and that any use by such individuals is unacceptable. Furthermore, although e-cigarettes show promise as a safer alternative to combustible cigarettes, the company has taken significant steps to avoid claims that its products are safer than traditional combustible products. Therefore, blu (UK) has adopted internal guidelines that require its advertising and promotion to be directed to adults, by the means of various age-related restrictions, and to avoid any claims, implied or express, that e-cigarettes are healthy or safer than combustible cigarettes, or that they may help consumers quit smoking.

For each of these advertising and promotional tools, blu (UK) has implemented guidelines in line with the CAP and BCAP codes to limit exposure of Underage Persons to e-cigarettes.

7.5 blu (UK) is committed to responsible sales practices

blu (UK) sells its products primarily to consumers through retail and online sales.

blu (UK)'s sales agreements with retailers include a condition that all products, including accessories, should be sold only to persons 18 years old and over. Subject to that, the retailers themselves determine their own policies on their age restrictions, e.g. whether the age limit should be 18 or 21.

For online sales, blu (UK) sells its products only through its website, www.blucigs.co.uk, and employs a two-stage age-screening process to screen out Underage Persons. A consumer seeking to access the site must certify that he or she is 18 years of age or older. Then, prior to the purchase of any product, the consumer must provide personal information, including name, address and date of birth, which is verified against third-party systems (e.g. Experian

and Aristotle) for identity and age. Only age-verified adult consumers are permitted to complete the sales transaction.

8. Concluding Remarks

blu (UK) welcomes the opportunity to comment on the Consultation. As a leading e-cigarette manufacturer and vendor, blu (UK) fully supports any proposal that would provide clear and proportionate regulation based on substantiated science and public health considerations for e-cigarettes in Scotland.

Accordingly, blu (UK) would welcome an opportunity to meet with the Scottish Government and other stakeholders to assist in the finalisation of any measures which the Scottish Government decides to implement.

REFERENCES

- ¹ New UK advertising rules for e-cigarettes, 9 October 2014 (See: <http://www.cap.org.uk/News-reports/Media-Centre/2014/New-ecig-ad-rules.aspx>.) Section 22 of the CAP Code is available online at <http://www.cap.org.uk/Advertising-Codes/Non-Broadcast/CodeItem.aspx?cscid={49028fdc-fc22-4d8a-ba5b-ba7ccc3df99a}>. BCAP Codes relating to e-cigarette advertising are available at <http://www.cap.org.uk/News-reports/Consultations/Closed-consultations/~media/Files/CAP/Consultations/ecig%20consultation/BCAP%20E-cigarette%20Rules.ashx>.
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