I have worked in and around the e-cigarette industry since 2012. As Corporate Affairs, Business Development & Legal Director for E-Lites, the brand at the forefront of the UK industry’s explosive early growth, I was closely involved both in the emerging public and regulatory debate in Westminster and Brussels and the development of the E-Lites’ business which culminated in its’ sale to JT International in 2014. More recently I have been Head of Corporate and Legal Affairs for Europe at Nicopure Labs, a US based manufacturer of e-liquids. At present, while I have no financial interest in the industry, I remain an interested ‘industry observer’ with an eagerness to see the e-cigarette (and wider ‘new nicotine’ industry) realise its’ full potential.

Using the Parliamentary Office of Science and Technology’s Research Briefing on E-cigarettes (Postnote Number 533 August 2016 – updating POSTnote Number 455) as a ‘base-point’, it should be noted that:

Industry & Market Data/Information

1. Due to the nascency of the industry and the diverse and fragmented market place (e-cigarettes being sold online and on the high street, in convenience stores, supermarkets, pharmacies and specialist ‘vape’ shops), there is still limited robust evidence and quantitative data regarding the size and make-up of the UK market. Notwithstanding this, recent data and research has been presented to the effect that:

   a) **there are an estimated 4.5million e-cigarette users in the UK**, 1.5million of whom are exclusive users and 3million are dual-users (of both e-cigarettes and cigarettes)

   b) 2,500 businesses have notified an aggregate of 46,000 SKUs (stock keeping units) to the Medicines and Healthcare Products Regulatory Agency (MHRA);

   c) **UK sales of e-cigarettes (and other ‘new nicotine’ products) are now worth £1 billion**

2. On a global level it’s estimated that there are 55 million users of e-cigarettes (and other new nicotine products)

On Health

3. The public health consensus around e-cigarettes – building on Public Health England’s August 2015 report (and findings that e-cigs are at least 95% safer than cigarettes) – has continued to grow:

   a) ‘**Evidence is accumulating that vaping is unlikely to pose more than a small fraction of the risks of smoking, that it is helping large numbers of smokers to quit, that it holds no attraction for non-smokers who rarely progress beyond trying e-cigarettes once or twice, and that the prevalence of smoking, including the prevalence of smoking in young people, has been declining at an unprecedented rate.**’

   b) In April 2017 the Royal Society for Public Health called for all local stop smoking services to become ‘e-cigarette friendly’

   c) In October 2017 Public Health England’s Stoptober Campaign endorsed e-cigs as an aid to stop smoking – ‘**E-cigarettes are a great way to help combat nicotine cravings and carry a fraction of the risk of cigarettes...**’

4. It is the UK public health community (including for example Professor John Britton Univ of Nottingham), Professor Ann McNeill (Kings College), Professor Peter Hajek (Queen Mary Univ), Professor Robert West (UCL), Professor Gerry Stimson (Imperial College), Professor Linda Bauld (Univ of Sterling) and
Written evidence submitted by Charles Hamshaw-Thomas (ECG0083)

comprising some of the world’s leading nicotine and addiction scientists and experts, public health and tobacco control experts) who have been at the forefront of promoting the harm reduction approach – the promotion of safer alternatives to those who would otherwise choose to smoke – and the global advocacy of e-cigarettes as a substantially safer alternative to cigarettes and as an important tool in delivering the public health goal of reduced tobacco consumption.

The UK public health community has led the way at both the E-Cigarette Summit (London November 2016, Washington 2017, London November 2017) and the Global Forum on Nicotine (Warsaw June 2014, 2015, 2016 and 2017), each of which have witnessed escalating attention from public health experts across the globe in the opportunity that e-cigarettes present, both to the UK’s 9 million smokers and the approximately 1 billion smokers globally.

On Regulation

5. Prior to transposition into UK law (under the Tobacco and Related Product Regulations 2016 (‘TRPR’)) of Article 20 of the EU Tobacco Products Directive (‘TPD’), e-cigarettes were regulated by a patchwork of over 20 General Product Safety & Consumer Protection Laws & Regulations. Since the industry’s earliest days, the regulatory ‘debate’ (as proposals for future regulatory frameworks were tabled & discussed in both Westminster and Brussels) has been intense (and often very public) as amongst:

a) Parliamentarians and Regulators – whose initial mindset was that e-cigarettes were only bought/used by smokers to stop smoking and correspondingly that they would be best regulated as pharmaceutically ‘licensed’ nrt (‘nicotine replacement therapy’) products; the resulting ‘tensions’ that this created were ‘eased’ in 2014 with the UK Government’s endorsement of a twin-track regulatory regime for e-cigarettes, meaning ‘pharmaceutical’ regulation for products that carry health claims and ‘consumer/tobacco products’ regulation for those that do not;

b) elements of the public health and tobacco control community - who have been wary of accepting harm reduction as a third plank (alongside discouraging initiation (of smoking) and encouraging cessation) to UK public health & tobacco control policies and correspondingly reluctant to recognise the potential public health benefit of e-cigarettes; this wariness and reluctance has contributed to an ensuing confusion and obfuscation between ‘safe’ and ‘safer’ and seen continuing advocacy for ‘pharmaceutical’ and/or ‘restrictive’ regulation of e-cigarettes comparable to that for combustible tobacco products;

c) the e-cigarette industry, users and the growing number of scientists & public health experts (who have endorsed the role that e-cigarettes (and other ‘new nicotine’ products) can play in tobacco harm reduction) – who have advocated for ‘lighter regulation’ to ensure e-cigarettes are not regulated more onerously than cigarettes and that their potential public health benefit is maximised; and

d) an at times ‘sensationalist’ media, which in the opinion of many has amplified a seemingly ideologically based opposition to e-cigarettes (which escalated when the tobacco industry began investing significantly in the category) and contributed to the now widely recognised worsening understanding of the public health benefit of e-cigs for smokers.
6. Since 20 May 2017 all e-cigarette products - containing nicotine and that do not carry health claims must comply with Article 20 of the EU Tobacco Products Directive as transposed under the TRPR (‘Article 20’).

A number of limits and restrictions set out in Article 20 - on nicotine strengths, tank and e-liquid bottle sizes and advertising restrictions akin to those for cigarettes – have been identified and raised by e-cigarette manufacturers and retailers as areas of serious concern in terms of the risks of a potentially material and adverse impact on the continuing growth of (and innovation within) the e-cigarette market. The most significant of these restrictions (and notes regarding the manufacturers and retailers’ concerns) are summarised below:

I. A max 10ml bottle size
Prior to May 2017, 30ml was the market’s dominant product format for e-liquids. Limited scientific (or other) justification was provided for the 10ml limit. A 10ml limit:
- significantly precludes (because of the size of the bottle and the number of labelling requirements (incl health warnings)) the ability of manufacturers to build brands and trademarks
- inconveniences manufacturers & retailers (in disruption of processes, materials, costs and handling)
- inconveniences consumers (in use and price) and
- inconveniences the environment (in additional materials and waste).

Elsewhere under the TPD, the sale of cigarettes in small quantities (packets of 10) is banned. Counterintuitively therefore(?), e-cigarettes, which are at least 95% less harmful than cigarettes, can only be sold in small quantities, while the more harmful product it is designed to replace can only be sold in large quantities.

II. A limit of 20mg/ml nicotine
This limit appeared to ignore the evidence of vaping habits:
- Higher nicotine levels are recognised as important for smokers making the initial switch to e-cigarettes (and particularly for the more heavily dependent smokers)
- 20% of users initiated vaping with >20mg/ml nicotine concentration. Konstantinos Farsalinos has noted that “high nicotine-containing liquids are probably essential for initiating and maintaining smoking abstinence in a group of motivated vapers” and that “regulatory decisions should be adjusted in a way that would not restrict the availability of nicotine-containing liquids for this population”
- ASH UK report May 2017 suggested 6% of vapers use e-liquid containing over 20mg/ml, which poses the question of whether the 168,000 vapers, who have been denied access to a product which has enabled them to stop or reduce their smoking, have or will return to smoking

III. Max 2ml tank size
This limit means removal from the market of a large number of the second and third generation devices which were very popular devices with users. As with the
20mg/ml nicotine limit above, this poses the question of whether a large number of users, denied access to a product which has enabled them to stop or reduce their smoking, have returned (or will) to smoking.

IV. Advertising ‘ban’
'Tobacco-like’ restrictions on the advertising and promotion of vaping products prevents communication of the important message to smokers and the wider public that vaping is much less harmful than smoking. It is counterintuitive that Public Health England can inform smokers that vaping is at least 95% less harmful than smoking and that the use of vaping products can help smokers to stop or reduce their smoking habit, but the manufacturers and retailers of all the vaping products currently on the UK market are precluded from doing so.

Excessive ‘tobacco-like’ restrictions on advertising serve to fuel the perception that vaping is as harmful as smoking. While the scientific consensus regarding the relative safety of vaping has grown, the public perception has gone in the opposite direction. Action on Smoking and Health’s 2017 report found that many people are over-estimating the risk posed by vaping products. Only 13% of respondents recognised that vaping is a lot less harmful than smoking, with 26% thinking they are more or equally harmful.

7. Regarding para 6 I above, a widespread practice has emerged across the e-cigarette industry since May 2017 whereby bottles of e-liquids (that have come to be known as ‘short-fills’ or ‘shake and vape’)) are being manufactured and sold (in 60ml and 100ml bottles) with the sole intention and purpose that the e-liquid then be mixed by users with high strength, non-flavoured nicotine ‘shots’ (sold in 10ml bottles) and subsequently be used for vaping. Because these ‘short-fills’ contain no nicotine, they are subject to none of the requirements of notification, provision of ingredient information and testing data and bottle size limits (10ml max) under the TPRP.

Short-fills (which I am advised by some suppliers could now represent over 30% of e-liquid sales in the UK) present serious public health and commercial implications.

From the public health perspective, there is growing evidence that there are now short-fills on the market which contain untested levels of ingredients and/or contain ingredients which are prohibited under the TRPR. I am aware of more than one e-cigarette supplier whose laboratories have recently tested a range of short-fills and found ingredients that are banned under TRPR. It cannot have been the intention of policy makers that ingredients banned in nicotine containing e-liquids should be being used in e-liquids that don’t contain nicotine.

It should be noted that:
- the presence in the market of large volumes of e-liquids, which are’nt subject to any notification or reporting requirements (solely because they don’t contain nicotine), cannot have been what the policy makers had intended;
- short-fills serve to encourage the consumption by e-cigarette users of larger quantities of e-liquid; and
- when Article 20 was being developed and debated in Brussels and Westminster, the DIY
mixing of e-liquids by users was a practice which public health and tobacco control groups were anxious to restrict (with the attenuant issues of adulteration/contamination, leakage, tamper resistance etc) and ensure was appropriately regulated - perversely, there is currently probably more DIY mixing of e-liquids being done by users now than there was before May 2017?

In terms of consumer protection and public health, the risks are self-evident. And as eloquently put to me recently by one of the UK’s leading manufacturer and retailer of e-cigarette products ‘.... the current situation regarding short-fills makes a mockery of Article 20 and the investment that businesses such as ours have made to ensure compliance with the new regulations .... and has only encouraged more unscrupulous businesses to enter the category and who have no interest in either the public health benefit that e-cigarettes offer or in safeguarding the future of the e-cigarette industry .... and whose motives are solely short-term sales and margin...’

From the commercial and financial perspective, short-fills are having the effect of driving retail prices down which is undermining the industry’s revenues and profitability. This has obvious ramifications for all those in the industry, and also other stakeholders (for example UK Government if they anticipate at some point in the future following other markets in levying additional excise or other taxes on e-cigarette products), who may have an interest in the longer-term growth, revenue and profit pool of the e-cigarette industry. Please also be aware that some ‘renegade’ suppliers of short-fills are infringing trademarks with their use of popular soft drink, energy drinks, confectionery and snack brands.

8. Regarding para 6 II and III above, while I do not currently have access to any tangible evidence, it is being widely reported within the industry that users who wish to use higher strength e-liquids or larger tanks are finding ways to access them, whether via the internet or otherwise.
9. A conclusion that could not unreasonably be drawn, from paras 7 and 8 above, is that since the implementation of Article 20, under the TRPR, there is a less ‘orderly’ market for e-liquids than there was before that implementation.

10. At the same time, it is conversely important to note that the UK is now widely recognised, relative to both its’ EU peers and in other markets (including the US which is the world’s largest market for e-cigarettes), as the most ‘e-cig friendly’ market in terms of both its’ interpretation of Article 20 and its’ more ‘accommodating’ and/or ‘benevolent’ approach to e-cigarettes generally. This is evidenced by:

   a) guidance provided by the MHRA regarding the 6 month notification period, as between notification of products to the MHRA and their launch into the market, as stipulated under Article 20. Such guidance allows UK suppliers to launch their products as soon as the notification has been completed and appears on the MHRA register. The presumption is that it was recognised that any such 6 month ‘waiting’ period would otherwise have a stifling effect on innovation within a dynamic and rapidly emerging new industry and in which the ‘product development cycle’ is still measurable in months as opposed to years.

   It may also be relevant to note that no such 6 month pre-market notification applies for any new combustible tobacco product – and it would presumably be similarly perverse (per the 10ml bottle limit issue above) if it was more difficult easier to place a new e-cigarette product on the market than it would be to launch a new cigarette, the more harmful product it is designed to replace.

   b) regarding 6 IV above and the advertising ‘ban’, the Committee of Advertising Practices has indicated that in early 2018 there may be an announcement regarding the possibilities for some ‘relaxation’ regarding the current UK advertising codes, subject to the provision of ‘robust evidence’, relating to the prohibition on health claims; for example claims that e-cigarettes are safer than tobacco\textsuperscript{11}.

11. By way of opinion, it should be noted that Article 20 is widely recognised within the industry as being helpful in terms of bringing some clarity to important minimum quality & safety issues (eg disclosure of product information, provision of testing and emissions data etc). However there continue to be a number of anomalies – as outlined above re advertising bans, 10ml bottle limits, tank and nicotine strength limits, a 6 month pre-market notification, zero nicotine strengths - which are viewed as having limited justification from either a public health or scientific perspective. Accordingly, the curious juxtaposition of such restrictive, ‘tobacco-like’(?), regulations side-by-side proposed pharmaceutical regulation (for substantially similar products) is puzzling and the anomalies, viewed by some as indicative of ill-conceived regulations developed in Brussels, are arguably more protective of incumbent nrt and combustible tobacco businesses than ‘constructive’ in terms of delivering the benefits that tobacco harm reduction policies (viz. the promotion of safer alternatives) can.

12. Regarding para 10 above and what is widely recognised as the UK’s more ‘accommodating’ and/or ‘benevolent’ approach towards the regulation of e-cigarettes, unarguably a function of the leadership which UK public health has shown (per para 4 above), it may be considered helpful to consider the evidence as to whether this approach has had an impact on levels of
cigarette consumption. From the data below (European Commission’s Releases for Consumption of Cigarettes 2002-2016\textsuperscript{12}) it can be noted that cigarette consumption in the UK has declined significantly more rapidly in the UK in the period 2011-2016 than in any of the other largest Western European cigarette markets.

<table>
<thead>
<tr>
<th></th>
<th>Cigarette volumes (sticks)\textsuperscript{12}</th>
<th>Cigarette volumes (sticks)\textsuperscript{12}</th>
<th>%age change</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2011</td>
<td>2016</td>
<td></td>
</tr>
<tr>
<td>Germany</td>
<td>87.6 bn</td>
<td>75 bn</td>
<td>-14.3%</td>
</tr>
<tr>
<td>Italy</td>
<td>85.5 bn</td>
<td>72 bn</td>
<td>-15.7%</td>
</tr>
<tr>
<td>Spain</td>
<td>60.3 bn</td>
<td>47.5 bn</td>
<td>-21.2%</td>
</tr>
<tr>
<td>France</td>
<td>54.1 bn</td>
<td>44.9 bn</td>
<td>-17%</td>
</tr>
<tr>
<td>UK</td>
<td>42 bn</td>
<td>30 bn</td>
<td>-28.5%</td>
</tr>
</tbody>
</table>

On Finance
13. UK public health attributes a value of £74,000 to every smoker who stops smoking\textsuperscript{13}. If there are already 1.5million e-cig users who describe themselves as former smokers, the financial value that e-cigs have already delivered is enormous.

The above seeks to identify some relevant evidence facts in terms of providing an update to the Parliamentary Office of Science and Technology’s August 2016 Research Briefing\textsuperscript{1}. By way of opinion, I would urge the Committee to reflect on:

- what is the true disruptive potential of e-cigarettes – Goldman Sachs’ August 2013 note The Search for Creative Destruction identified e-cigarettes as one of the world’s potentially most disruptive technologies: ‘... e-cigarettes can alter the status quo of the US tobacco market ...’

- what are viewed by many as two absolutely critical issues if the potentially huge public health prize that e-cigarettes offer is to be realised:
  - the failure of the public health message – and a continuing mismatch between the scientific consensus regarding e-cigarettes and the understanding of the public and wider society; and
  - ‘tobacco-like’ regulations for e-cigarettes – which are currently serving to fuel this mismatch.
I trust that the above is helpful for you in your examination of the impact of e-cigarettes on human health (including their effectiveness as a stop-smoking tool), the suitability of regulations guiding their use, and the financial implications of a growing market on both business and the NHS.

December 2017

1. [http://researchbriefings.parliament.uk/ResearchBriefing/Summary/POST-PN_0533#fullreport](http://researchbriefings.parliament.uk/ResearchBriefing/Summary/POST-PN_0533#fullreport)

2. At the Next Generation Delivery Conference 2007 (in London 14/15 November)


4. Professor Peter Hajek, Wolfson Institute of Preventative Medicine & Queen Mary University of London in The All Party Parliamentary Group’s ‘State of the Vaping Nation’ November 2017

5. Royal Society for Public Health, E-Cigarettes Position Paper, April 2017

6. Public Health England ‘Stoptober’ October 2017 [https://www.nhs.uk/oneyou/stoptober/home#6tOe008xJjl5T7g7](https://www.nhs.uk/oneyou/stoptober/home#6tOe008xJjl5T7g7)


8. Global Forum on Nicotine [https://gfn.net.co/conference-archives](https://gfn.net.co/conference-archives)


13. All-Party Parliamentary Group on Smoking and Health - *Burning Injustice Reducing tobacco-driven harm and inequality - Recommendations to the Government, local authorities and the NHS* - page 8