

IMPERIAL BRANDS PLC

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# Response to the Science & Technology Committee E-cigarettes Inquiry

# **Imperial Brands**

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## **Responses to the Inquiry questions**

## **Introduction - Company background**

Imperial Brands PLC ("**IMB**") is a multinational consumer goods company, specialising in tobacco and non-tobacco brands. Our core business is built around a tobacco portfolio that offers a comprehensive range of cigarettes, fine cut and smokeless tobaccos, papers and cigars. Our tobacco brands are sold in 160 markets worldwide.

Imperial Brands is a FTSE 100 business headquartered in Bristol and directly employs over 1,070 people in the UK. Last year it collected in excess of £5.7 billion for the Exchequer in duties and other taxes.

Our PLC name reflects the breadth of our brands' focus across five distinct entities: Imperial Tobacco, Tabacalera, ITG Brands, Fontem Ventures and Logista. Imperial Tobacco Limited ("ITUK", with IMB "Imperial Tobacco") is the UK trading operation of IMB, distributing IMB's products to the UK market from its distribution facilities in Nottingham. ITUK currently holds approximately 41 per cent market share through brands including Lambert & Butler, JPS, Richmond, Embassy and Regal.

Through our Fontem Ventures business, we are also developing a portfolio of brands beyond tobacco. Fontem Ventures is dedicated to developing and growing a portfolio of innovative products including electronic cigarettes ("**e-cigarettes**", also referred to as E-Vapour Products ("**EVPs**")), and focuses on non-tobacco opportunities. Fontem Ventures produce devices and e-liquids for the UK under its brand, blu. The blu brand holds a current market share of 15.57% (based



on the value of products when sold in traditional retail outlets) in the UK market. ITUK is the distributor for Fontem's products in the UK.



## **Inquiry topics:**

# Health:

1) The impact on human health of e-cigarettes – themselves and relative to 'conventional' smoking – and any gaps in the science knowledge-base in this area.

The vast majority of scientific research into the health of e-cigarettes is based upon looking at their impact relative to conventional smoking. However, in the first investigation of its kind, a recent prospective 3.5-year study of regular daily e-cigarette users who have never smoked found no health concerns were associated with long-term use of e-cigarettes, although it could not be excluded that some harm may occur at later stages<sup>1</sup>.

Following a review of the available scientific evidence in 2015 comparing conventional smoking to e-cigarettes, Public Health England ("**PHE**") characterised e-cigarettes as being "around 95% less harmful than smoking"<sup>2</sup>. This view was subsequently supported by numerous other UK public health organisations including the British Lung Foundation, Cancer Research UK and the Royal Society of Public Health<sup>3</sup>. The following year, the UK Royal College of Physicians ("**RCP**") concluded the long-term health risks associated with e-cigarettes are "unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower"<sup>4</sup>.

A recently updated Cochrane Review<sup>5</sup>, whilst acknowledging the small number of published clinical studies currently available, concluded that e-cigarettes with nicotine can help smokers to replace

<sup>&</sup>lt;sup>1</sup> Polosa, R et al: "Health impact of E-cigarettes: a prospective 3.5-year study of regular daily users who have never smoked", Sci Rep, 2017. 7(1): p. 13825

<sup>&</sup>lt;sup>2</sup> https://www.gov.uk/government/news/e-cigarettes-around-95-less-harmful-than-tobacco-estimates-landmark-review

<sup>&</sup>lt;sup>3</sup> <u>https://www.gov.uk/government/publications/e-cigarettes-a-developing-public-health-consensus</u>

<sup>&</sup>lt;sup>4</sup> <u>https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0</u>

<sup>&</sup>lt;sup>5</sup> Cochrane Reviews are systematic reviews of primary research in human health care and health policy, and are internationally recognised as the highest standard in evidence-based health care resources.



conventional cigarettes with no increased health risks associated with short- to mid-term (up to two years) use<sup>6</sup>.

On 29 November 2017 the BMA released a position statement stating that "The wide availability of e-cigarettes as an alternative to tobacco is likely, overall, to be playing a positive role in supporting tobacco-harm reduction, and consumer regulations will ensure a minimum standard of product quality."<sup>7</sup>

The public health potential of e-cigarettes must be considered in the context of the growing body of international clinical research that has emerged since publication of the above landmark reports. Recently published clinical research has shown that smokers who have switched to e-cigarettes have significantly lower exposure to carcinogens and toxicants found in cigarette smoke, with reductions largely indistinguishable from complete smoking cessation or use of licensed nicotine replacement products<sup>8,9,10</sup>.

Further research is required to augment the understanding of the impact of e-cigarette use on key physiological parameters associated with cardiovascular and respiratory function in smokers that switch. This information, together with the aforementioned emerging clinical evidence, will provide further insight as to whether reduced exposure to tobacco smoke carcinogens and toxicants with use of e-cigarettes results in improved cardiovascular and pulmonary health with short- and long-term e-cigarette use.

<sup>&</sup>lt;sup>6</sup> http://www.cochrane.org/CD010216/TOBACCO\_can-electronic-cigarettes-help-people-stop-smoking-and-are-they-safe-use-purpose

<sup>&</sup>lt;sup>7</sup>BMA position paper, released 29 November 2017 https://www.bma.org.uk/news/2017/november/use-of-e-cigarettes-must-be-balanced-against-risks <sup>8</sup> O'Connell, G et al: "Reductions in biomarkers of exposure to harmful or potentially harmful constituents following partial or complete substitution of cigarettes with electronic cigarettes in adult smokers", Toxicol Mech Methods, 2016

<sup>&</sup>lt;sup>9</sup> Goniewicz, M et al: "Exposure to Nicotine and Selected Toxicants in Cigarette Smokers Who Switched to Electronic Cigarettes", Nicotine & Tobacco Research, 2016

<sup>&</sup>lt;sup>10</sup> Shahab, L et al: "Nicotine, carcinogen, and toxin exposure in long-term e-cigarette and nicotine replacement therapy users", Annals of Internal Medicine, 2017



The scientific evidence to date indicates that the potential health risks associated with e-cigarette use are highly likely to be much lower than continued cigarette smoking. However, e-cigarettes have not been around long enough to generate epidemiological data, which looks at health impacts after decades of use, and we believe more research is needed into the long-term effects of their use.

## 2) The benefits and risks of e-cigarettes as a 'stop smoking' tool, any gaps in the knowledgebase on this, and whether any approaches are needed to tackle e-cigarette addiction.

### Benefits

Although 'consumer' e-cigarettes cannot currently be marketed as smoking cessation devices in the UK, the primary cited motivation for e-cigarette use in the UK is tobacco-harm reduction<sup>11</sup>. In May 2017 Action on Smoking and Health ("**ASH**") found that, for the first time since the survey started in 2012, more than 50% of the UK's 2.9 million e-cigarette users have stopped smoking altogether<sup>12</sup>. Success rates for quitting smoking are now at a record high in the UK, with almost 20% of attempts to quit successful in 2017 versus the past decade's average success rate of 15.7%<sup>13</sup>. The improvement in quitting success has been attributed to the increased prevalence of e-cigarettes in the UK, with Cancer Research UK commenting "*Research has shown that e-cigarettes are the most popular way to quit*"<sup>14</sup>. In 2015 alone, use of e-cigarettes resulted in an *additional* 18,000 long-term ex-smokers in England<sup>15</sup>.

<sup>&</sup>lt;sup>11</sup> Office for National Statistics (UK). E-cigarette use in Great Britain. 2016, June 2017. Table 3a Main reason for using e-cigarettes

<sup>&</sup>lt;sup>12</sup> http://ash.org.uk/information-and-resources/fact-sheets/use-of-electronic-cigarettes-vapourisers-among-adults-in-great-britain/

<sup>&</sup>lt;sup>13</sup> http://www.smokinginbritain.co.uk/read-paper/draft/8/Quit%20success%20rates%20in%20England%202007-2017

<sup>&</sup>lt;sup>14</sup> http://www.cancerresearchuk.org/about-us/cancer-news/news-report/2017-09-21-smoking-quit-rates-highest-in-10-years

<sup>&</sup>lt;sup>15</sup> Beard, E et al: "Association between electronic cigarette use and changes in quit attempts, success of quit attempts, use of smoking cessation pharmacotherapy, and use of stop smoking services in England: time series analysis of population trends", BMJ, 2016.



The RCP noted in its 2016 report: "*E-cigarettes are marketed as consumer products and are proving much more popular than NRT as a substitute and competitor for tobacco cigarettes. E-cigarettes appear to be effective when used by smokers as an aid to quitting smoking"*<sup>16</sup>. Consistent with this, smokers using e-cigarettes to replace smoking are 60% more likely to succeed than those using traditional, over-the-counter medicinal NRT products or willpower alone<sup>17</sup>. There is also emerging evidence that e-cigarettes can also encourage reduced cigarette consumption and cessation, even among those smokers not intending to quit or rejecting other support<sup>18</sup>.

#### Risks

The major risk to the continued success of e-cigarettes, as a replacement for conventional cigarettes, is declining smoker confidence in the e-cigarette category, evidenced by a slowdown of growth in the UK market. When ASH conducted its 2017 survey, it found that perceptions of e-cigarettes among smokers is not improving, only 20% agreed that e-cigarettes are 'a lot less harmful' than conventional cigarettes, compared to 31% in 2015<sup>19</sup>.

Further, the number of UK vapers increased by just 4% from 2016 to 2017, compared to a rise of 86% in 2013, 62% in 2014, and 24% in 2015<sup>20</sup>. The stabilising of the upward trend in e-cigarette use by smokers over the years, plus declining consumer confidence is, in large parts, due to sensationalist media headlines, misinformation and misleading science. This is obscuring the

<sup>&</sup>lt;sup>16</sup> <u>https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0</u>

<sup>&</sup>lt;sup>17</sup> Brown, J et al: "Real-world effectiveness of e-cigarettes when used to aid smoking cessation", Addiction, 2014.

<sup>&</sup>lt;sup>18</sup> Polosa, R et al: "Success rates with nicotine personal vaporisers", BMC public health, 2014.

<sup>&</sup>lt;sup>19</sup> <u>http://ash.org.uk/stopping-smoking/ash-briefing-on-electronic-cigarettes-2/</u>

<sup>&</sup>lt;sup>20</sup> <u>http://ash.org.uk/stopping-smoking/ash-briefing-on-electronic-cigarettes-2/</u>



positive public health message regarding e-cigarettes<sup>21</sup> and remains a major communication challenge to be urgently addressed.

### Addiction

E-cigarettes do not contain tobacco and therefore do not produce tobacco smoke. They may, however, deliver nicotine.

Data from the UK shows a majority of current e-cigarette users sometimes or always use products that contain nicotine at strengths less than the 20 mg/mL maximum limit<sup>22</sup> specified by the EU Tobacco Products Directive ("**EUTPDII**").

A recent large USA survey of over 22,000 adults found that consumer behaviour is shifting rapidly towards a preference for low nicotine products; a stark contrast to purchasing behaviours five or more years ago when smokers typically initiated use of e-cigarettes through high-nicotine strength liquids<sup>23</sup>. Academic research on potential e-cigarette dependence is also emerging, with one study concluding e-cigarettes "*may be as or less addictive than nicotine gums, which themselves are not very addictive*"<sup>24</sup>. Data from another USA study, which surveyed over 25,000 e-cigarette users, found that e-cigarette users were less dependent on their respective e-cigarette than comparable cigarette smokers<sup>25</sup>. More research in this area would be informative.

<sup>&</sup>lt;sup>21</sup> APPG on E-cigarettes, State of the Vaping Nation report, 2017.

<sup>&</sup>lt;sup>22</sup> http://ash.org.uk/information-and-resources/fact-sheets/use-of-e-cigarettes-among-adults-in-great-britain-2017/

<sup>&</sup>lt;sup>23</sup> Russell, C. "Patterns of E-Cigarette Use Among 22,807 U.S. Adults" TSRC conference USA, 2016. In preparation for publication.

<sup>&</sup>lt;sup>24</sup> Etter, J. F et al: "Dependence levels in users of electronic cigarettes, nicotine gums and tobacco cigarettes", Drug Alcohol Depend, 2015

<sup>&</sup>lt;sup>25</sup> Liu, G et al: "A comparison of nicotine dependence among exclusive E-cigarette and cigarette users in the PATH study", Prev Med, 2017



# 3) The uptake of e-cigarettes among young people and evidence on whether e-cigarettes play a role in 're-normalising' smoking.

It has been suggested that e-cigarettes could act as a 'gateway' to smoking amongst non-smokers and young people who were not inclined to smoke, or that e-cigarette use could 're-normalise' the act of smoking. Current evidence indicates neither of these phenomena are occurring in the UK.

The largest ever analysis of available UK data recently showed that there is no evidence e-cigarettes are leading young people into smoking. The study, which analysed five large-scale surveys conducted in 2015-2017 involving over 60,000 11-16 year-olds, found among young people who had never smoked, regular use of e-cigarettes was negligible – between 0.1% and 0.5% across the five surveys<sup>26</sup>. Whilst there is some experimentation amongst young (U18) UK 'never smokers', there is no evidence of this group regularly using e-cigarettes; indeed, regular use is almost entirely concentrated in young (U18) people who had already smoked<sup>27</sup>. The RCP also concluded: "*E-cigarettes are not a gateway to smoking – in the UK, use of e-cigarettes is limited almost entirely to those who are already using, or have used, tobacco.*"<sup>28</sup> The World Health Organisation ("**WHO**") acknowledged in 2014: "At least for the United Kingdom, renormalization as measured by prevalence of e-cigarettes has increased, smoking rates among school children (7%)<sup>30</sup> and the wider population have reached the lowest level on record (15.8%)<sup>31</sup>.

<sup>&</sup>lt;sup>26</sup> Bauld, L et al: "Young People's Use of E-Cigarettes across the United Kingdom: Findings from Five Surveys 2015-2017", Int J Environ Res Public Health, 2017.

<sup>&</sup>lt;sup>27</sup> Bauld, L et al: "E-Cigarette Uptake Amongst UK Youth: Experimentation, but Little or No Regular Use in Nonsmokers", Nicotine & Tobacco Research, 2016.

<sup>&</sup>lt;sup>28</sup> <u>https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0</u>

<sup>&</sup>lt;sup>29</sup> http://apps.who.int/gb/fctc/PDF/cop6/FCTC\_COP6\_10Rev1-en.pdf

<sup>&</sup>lt;sup>30</sup> Smoking, Drinking and Drug Use among young people in England 2016. NHS Digital, September 2017. Chapter 2 tables – smoking prevalence.

<sup>&</sup>lt;sup>31</sup> Adult smoking habits in the UK: 2016. Office for National Statistics.



When behavioural researchers conducted qualitative interviews with young (U18) people across the UK in 2016, they discovered the overwhelming majority – who collectively represented current and former smokers, non-smokers, and e-cigarette users – believed e-cigarettes offered smokers an alternative<sup>32</sup>. Furthermore, participants viewed e-cigarettes as having reduced the possibility of both themselves and other people smoking<sup>33</sup>. Another UK study that explored non-smoker attitudes to e-cigarettes found that they most commonly interpret e-cigarette use for what it is: the actions of a current or former smoker seeking to reduce or replace smoking<sup>34</sup>. Non-smokers gave little indication that they themselves would be inclined to take up vaping as a result of seeing other people using e-cigarettes and their attitudes to smoking were more negative based on the logic that smokers now have access to a less harmful alternative in e-cigarettes<sup>35</sup>. This suggests that not only are non-smokers able to clearly distinguish e-cigarette use from smoking, but the denormalisation of e-cigarettes should be avoided.

<sup>&</sup>lt;sup>32</sup> McKeganey, N et al: "Vapers and vaping: E-cigarettes users views of vaping and smoking", Drugs: Education, Prevention and Policy, 2017

 <sup>&</sup>lt;sup>33</sup> McKeganey, N et al: "Vapers and vaping: E-cigarettes users views of vaping and smoking", Drugs: Education, Prevention and Policy, 2017
<sup>34</sup> McKeganey, N et al: "Visible Vaping: E-Cigarettes and the Further De-Normalization of Smoking", Int Arch Addict Res Med, 2016
<sup>35</sup> McKeganey, N et al: "Visible Vaping: E-Cigarettes and the Further De-Normalization of Smoking", Int Arch Addict Res Med, 2016



# **Regulation:**

1) Whether there is any regulatory variation between the EU and UK, and across UK nations, and the implications of Brexit on regulation in this area.

## **Regulation of Tobacco-Free Products - E-Vapour Products**

We support evidence-based regulation of e-cigarettes that is proportionate to their public health potential and that clearly sets them apart from tobacco products. We believe e-cigarette regulation should not be modelled on tobacco product regulation, as this does not consider the important role e-cigarettes can play in harm reduction, but should instead be based on compliance with robust product quality, manufacturing and safety standards.

In order to remove the confusion around various next generation products and their regulatory/excise implications, regulators must establish a clear differentiation between tobacco-based and tobacco-free products.

Since e-cigarettes do not contain tobacco, they should be excluded from all existing and future tobacco regulation, including excise. E-cigarettes should be regulated as a consumer product in a separate category that assures product safety and quality. Regulators should seek to inform smokers of the benefits of e-cigarettes over traditional cigarettes, especially considering the endorsement by Public Health Bodies of e-cigarettes as a less harmful product that can play a significant role in helping achieve public health objectives.



### **Regulation of Tobacco-Based Products - Heated Tobacco Products**

In contrast, we encourage regulators to regulate new tobacco-based products, such as the emerging category of heated tobacco products, in the same way as tobacco. Strict enforcement of existing tobacco regulatory and excise frameworks is necessary in this area and no labelling or marketing exemptions should be granted. In addition, all heated tobacco products should be excised as tobacco products at a rate comparable to their traditional equivalents. HM Treasury is consulting separately on the excise treatment of heated tobacco products.

### EUTPDII

The EUTPDII legislation imposes: marketing; sales channels and product restrictions; a lengthy notification process prior to product launch; and, other requirements for e-cigarette manufacturers and retailers to comply with. A proportion of the restrictions corresponds in many instances with restrictions on conventional cigarettes, where some Member States have 'gold-plated' national legislation.

In England, the Department of Health has taken a pragmatic approach to implementation of the EUTPDII and has not restricted advertising any further than is required by the legislation. However, there has been a suggestion that the Scottish Government may soon seek to implement further restrictions to domestic e-cigarette advertising and promotion over and above the rest of the UK. *Table 1* shows the regulatory variations across the UK.



## Table 1: E-cigarette regulations across UK

Policy	England	Scotland	Wales	Northern Ireland
Public place vaping	Permitted <sup>36</sup>	Permitted	Permitted	Permitted
Marketing & advertising restrictions	One-to-one transposition of EUTPDII. The following options are permitted: outdoor advertising, cinema, leaflets and hard copy direct mail, feature products on own websites and only factual information, and sponsorship if it has no cross border effects.	The Health (Tobacco, Nicotine etc. and Care) Scotland Act includes both nicotine and non- nicotine e- cigarette products within its scope. This Act also contains powers to make regulations to ban advertising of e- cigarettes beyond the scope of the EUTPDII.	One-to-one transposition of EUTPDII	One-to-one transposition of EUTPDII
Age of sale	Over 18 only	Over 18 only	Over 18 only	Under consultation
Proxy purchase	Prohibited	Prohibited	Prohibited	Under consultation
Flavour	Not regulated	Not regulated	Not regulated	Not regulated
Sales channels	Distance sales permitted; subject to certain constraints.	The Scottish Act prohibits vending sales, and extends the existing tobacco vendors' register to sellers of e-cigarettes.	The Public Health (Wales) Act imposes a registration scheme for e- cigarette retailers.	Distance sales permitted; subject to certain constraints.

A recent study explored how different regulatory environments may influence the effectiveness of

e-cigarettes as an alternative to conventional cigarettes. The researchers found use of e-cigarettes

<sup>&</sup>lt;sup>36</sup> Public Health England published guidance on public-vaping policies in 2016 recommending to allow e-cigarette use even where smoking is forbidden: <u>https://www.gov.uk/government/uploads/system/uploads/attachment\_data/file/534586/PHE-advice-on-use-of-e-cigarettes-in-public-places-and-workplaces.PDF</u>



in the real world "...appears only effective for sustaining smoking abstinence in a less restrictive [ecigarette] environment suggesting that the benefits of [e-cigarettes] for smoking cessation are likely highly dependent on the regulatory environment."<sup>37</sup> This underscores the need for careful consideration on how best to regulate e-cigarettes so that the public health benefits can be maximised.

PHE acknowledged in 2015 that the EUTPDII "certainly raises the barrier for bringing [e-cigarette] products to market or continuing to market existing products, and will undoubtedly constrain the [e-cigarette] market. Understanding any unintended consequences of the EU TPD as well as intended ones will be important. For example, the cap on nicotine concentrations introduced by the TPD will take high nicotine [e-cigarette] and refill liquids off the market, potentially affecting heavier smokers seeking higher nicotine delivery products"<sup>38</sup>.

To that end, Brexit provides an opportunity to re-appraise current UK e-cigarette regulation and to create a regulatory regime that supports the public health potential of e-cigarettes based on product quality, manufacturing and safety standards. As noted in the Government's 2017 Tobacco Control Plan for England<sup>39</sup>, we welcome the identification of de-regulatory measures for e-cigarettes following Brexit, which should include:

- i. reviewing the restrictions on advertising and promotion of e-cigarettes;
- ii. reducing the lengthy and costly notification process, which slows innovation and the bringing of high quality products to market; and,

<sup>&</sup>lt;sup>37</sup> Yong, H.H et al: "Does the regulatory environment for e-cigarettes influence the effectiveness of e-cigarettes for smoking cessation?: Longitudinal findings from the ITC Four Country Survey", Nicotine Tob Res, 2017.

 <sup>&</sup>lt;sup>38</sup> <u>https://www.gov.uk/government/news/e-cigarettes-around-95-less-harmful-than-tobacco-estimates-landmark-review</u>
<sup>39</sup> Department of Health (2017) Towards a Smokefree Generation: A Tobacco Control Plan for England



### iii. removing the arbitrary restrictions on nicotine strengths and bottle sizes.

### 1) The effectiveness of regulation on the advertising and marketing of e-cigarettes.

We believe that advertising and marketing via TV, radio, internet, print and outdoor media, and through sampling activities, should be permitted. As non-tobacco products, e-cigarettes should be regulated as consumer goods while minimising the targeting of - and impact on - under 18s and non-smokers, in line with UK regulation for other adult consumer products e.g. alcohol. Current restrictions, imposed by the EUTPDII, fail to provide a clear distinction between conventional cigarettes and e-cigarettes, and do not acknowledge the growing independent evidence base to support e-cigarettes as a less harmful alternative to cigarettes.

Tobacco-style advertising and marketing restrictions can reduce the ability of e-cigarettes to compete with established conventional cigarette brands and diminish the means to communicate the value proposition to smokers and e-cigarette users. Current regulations also prevent companies from encouraging smokers to switch to e-cigarettes thereby reducing competition with conventional cigarettes and making it harder to communicate product innovations, ease of use and experience, relative to smoking. Such restrictions also limit companies' ability to create trusted brands and higher quality products which in turn reduces consumer confidence in the category.

While this does not detract from concerns about under 18s and non-smokers entering the category, UK data shows that e-cigarette use is overwhelmingly confined to current and former smokers. In light of this, a balance must be struck: e-cigarette advertising and marketing should be freely permitted across multiple channels providing that: it only targets adult smokers and e-cigarette



users; does not feature images, characters or flavour descriptors that appeal directly to under 18s; and, only features individuals who are - and appear to be - over 25. Further, advertising should include a visible disclaimer advising that e-cigarettes should only be used by people over 18 years of age.

# 2) The impact to date of the Tobacco and Related Products Regulations on the vaping industry and on the prevalence of e-cigarettes.

As we are only six months post-implementation of the Tobacco and Related Products Regulations ("**TRPR**"), it is difficult to assess their full impact at this stage. However, we remain concerned that the TRPR e-cigarette regulations were bolted onto tobacco legislation, rather than acknowledging that e-cigarettes are a separate category.

We support evidence-based regulation of all e-cigarettes that is proportionate to their public health potential, and that clearly sets them apart from tobacco products. A bespoke regulatory framework for e-cigarettes that encourages product innovation and focuses on implementing robust product quality and manufacturing standards, alongside a responsible marketing approach should be considered. This will ensure UK consumers can access consistently high quality e-cigarette products.

#### 3) The safety of e-cigarette devices, and any safety regulation requirements.

We believe e-cigarette regulation should be based on robust product quality, manufacturing and safety standards to limit any thermal, mechanical, chemical or electrical risks. High quality standards will ensure consumer safety, boost consumer trust in the category, and give smokers access to high quality products and information they can trust. Only if e-cigarettes are of the



highest quality with regard to manufacture, ingredients and electronic functioning, and provide smokers with the satisfaction they are looking for in a less harmful way, can the category offer a real alternative to smoking. Recognising the importance of product quality standards, the RCP commented: *"Technological developments and improved production standards could reduce the long-term hazard of e-cigarettes"*<sup>40</sup>.

We believe the sector is sufficiently regulated in certain areas. For example, there are a number of applicable EU directives (for example, General Product Safety Directive (2001) (as amended in 2004)); Low Voltage Directive (2006); RoHS2 (2011) and the Comparative and Misleading Marketing Directive (2006)(MCAD)), together with the introduction of minimum standards for the safety and quality of all nicotine-containing e-cigarettes in the UK as set out in the EUTPDII.

However, consistent enforcement of all applicable regulations is required to ensure that manufacturers are compliant and that consumers are protected. Without effective enforcement of product safety regulations there is the possibility of sub-standard products remaining on the market which are damaging to public perception of the category and have a negative impact on the public health message regarding e-cigarettes.

In addition, we believe that the EUTPDII regulations should apply to all devices and refills (e-liquids) regardless of whether they contain or are capable of containing nicotine. The current regulations only apply to nicotine-containing products, which has resulted in the phenomena of unregulated (via EUTPDII) "shortfills" hitting the UK market. These are non-nicotine flavoured e-liquids, sold in

<sup>&</sup>lt;sup>40</sup> https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0



larger bottles filled to 80% capacity by manufacturers, to allow space for a "shot" of nicotine to be added. If this loophole in the law is not addressed, it could pose a risk to consumers given these liquids are not required to comply with EUTPDII in the UK, in particular the prohibition of carcinogens, mutagens or reproductive toxins (CMRs) in nicotine-containing e-liquids.

## **Conclusion**

## **Regulation of Tobacco-Free Products - E-Vapour Products**

We support evidence-based regulation of e-cigarettes that is proportionate to their public health potential and clearly sets them apart from tobacco products. We believe e-cigarette regulation should not be modelled on tobacco product regulation, as this does not consider the important role e-cigarettes can play in harm reduction, but should be based on compliance with robust product quality, manufacturing and safety standards. Brexit may provide an opportunity to achieve this.

As noted in the Government's 2017 Tobacco Control Plan for England<sup>41</sup>, we welcome the identification of de-regulatory measures for e-cigarettes following Brexit, which should include:

- i. reviewing the restrictions on advertising and promotion of e-cigarettes;
- ii. reducing the lengthy and costly notification process which slows innovation and the bringing of high quality products to market; and,
- iii. removing the arbitrary restrictions on nicotine strengths and bottle sizes.

<sup>&</sup>lt;sup>41</sup> Department of Health (2017) Towards a Smokefree Generation: A Tobacco Control Plan for England



In order to remove the confusion around various next generation products and their regulatory/excise implications, we believe regulators must establish a clear differentiation between tobacco-based and tobacco-free products.

Since e-cigarettes do not contain tobacco, they should be excluded from all existing and future tobacco regulation, including excise. E-cigarettes should be regulated as a consumer product in an entirely separate category that assures product safety and quality. Regulators should seek to inform smokers on the benefits of e-cigarettes over traditional cigarettes, especially given the endorsement by Public Health Bodies.

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