

## Tobacco suite: prevention, cessation and harm reduction (update)

### Consultation on draft scope Respondent comments table

14/05/2018 to 11/06/2018

Respondent	Page no.	Line no.	Comments	NICE comment
Please insert each new comment in a new row				
Imperial Brands PLC	10	11	<p>Imperial Brands strongly supports NICE's draft scope objective to recognise and promote the use of vaping products as an intervention tool to stop smoking and reduce the harm associated with it.</p> <p>The draft scope must take into account that most smokers choosing to switch to vaping as a cessation or harm reduction alternative are doing so through commercial products. There are currently no medically licensed vaping products on the market (cost and time makes this a much harder line for vaping companies to take). As such it is important that stop smoking services, NHS and pharmacy groups engage with vaping companies to ensure that their clients are given the best quality products to help them in their switch from smoking to vaping, and where wanted, a complete stop in the consumption of nicotine.</p>	<p>Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a>. Your comments have been reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.</p>
Imperial Brands PLC	10	19	<p>Imperial has trialled heated tobacco products ("HTPs") in some markets external to the UK. We believe that more evidence is needed before health bodies promote HTP products, especially as vaping products are proven to be 95% less harmful than tobacco. The UK Committee on Toxicity recently agreed with this position, citing the lack of independent studies and the variety of devices made the committee 'unable to assess the absolute risk of heat-not-burn tobacco products'<sup>1</sup></p>	<p>Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco</a></p>

<sup>1</sup> [https://cot.food.gov.uk/sites/default/files/heat\\_not\\_burn\\_tobacco\\_summary.pdf](https://cot.food.gov.uk/sites/default/files/heat_not_burn_tobacco_summary.pdf)

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			<p>As a global business, we are committed to offering our consumers choice and moving smoking consumers away from the harms of smoking cigarettes.</p> <p>Recently the UK HMRC placed HTPs within the tobacco excise category as a clear indication that as they contain tobacco they must be legislated as such. There is a growing body of evidence around harm reduction aspects of HTPs but much is produced by the manufacturers. Imperial hopes that NICE will use peer reviewed evidence in this space to ensure that the guidance it provides on harm reduction and cessation is founded on accurate study.</p>	<p><a href="#">organisations</a>. Your comments have been reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.</p>
Imperial Brands PLC	11	16 - 19	<p>We welcome the draft scopes inclusion of work place cessation policy. Vaping product growth and speed of development left legislators behind; as a result many workplace guidelines smoking have been expanded to include vaping. As evidence showing vaping to be a significantly less harmful alternative to smoking grows, it is increasingly apparent for that an updated central workplace guideline which educates on the differences between smoking and vaping is required. This gives employees the confidence to differentiate smoking and vaping and provides the necessary support for smokers looking to use vaping as a cessation tool.</p>	<p>Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a>. Your comments have been reviewed for factual inaccuracy claims. None have been identified. The</p>

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Imperial Brands PLC	4	16 - 18	<p>While the evidence cited in the draft scope is useful, it does not accurately reflect the most recent scientific progress.</p> <p>The vaping sector and the science underpinning vapour products is evolving at such a rapid rate it is imperative regulators understand, and take into consideration, the most up-to-date scientific evidence to ensure appropriate policy-making for the longer term. Data from Action on Smoking and Health (ASH) in 2017 shows there are approximately 2.9 million vapers in the UK, over half of whom (52%) have successfully quit smoking altogether. Furthermore, successful stop smoking quit attempts in the UK are at an all-time high<sup>2</sup>; UK smoking rates are at the lowest levels ever recorded (now the second lowest in Europe<sup>3</sup>, after Sweden, a country with a history of successful harm reduction through the use of smokeless tobacco products); and 1.4 million UK smokers are now tobacco free thanks to vaping products<sup>4</sup>.</p> <p>Imperial Brands and its subsidiary, Fontem Ventures, ensures all its published scientific research is peer reviewed and we strongly recommend that NICE also</p>	<p>Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a>. Your comments have been reviewed for factual inaccuracy claims. None have been identified. The</p>

<sup>2</sup> Action on Smoking and Health, "Use of e-cigarettes among adults in great Britain", <http://ash.org.uk/media-and-news/ash-daily-news/ash-daily-news-08-may-2017/>

<sup>3</sup> The Guardian, <https://www.theguardian.com/society/2017/sep/20/success-rates-for-people-quitting-smoking-hit-record-high>

<sup>4</sup> The Guardian, <https://www.theguardian.com/society/2017/jun/15/smoking-rate-in-uk-falls-to-second-lowest-in-europe>

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			ensures the evidence it uses is of a similar standard to ensure credibility of its guidance.	comments have not otherwise been considered.
Imperial Brands PLC	4	19 - 22	<p>Imperial Brands closely monitors all the scientific research around the theory and manifestation of gateway. To-date, official sources from the Office of National Statistics (ONS) and Action on Smoking and Health (ASH), through annual surveys, has found no evidence of vaping products forming a gateway into smoking. The most recent 2017 ONS figures show a year-on-year decline in the number of smokers across the country, from 17.8% of adults in 2015 to 16.1% in 2016, one of the most significant percentage drops in decades. The steepest decline occurred among young people aged 16 to 24, with smoking rates in this age group dropping from 23.6% in 2015 to 16.6% in 2016.</p> <p>According to ASH, regular vaping use among young people remains rare<sup>5</sup>. In 2018, only 4% of young people reported using a vaping device once a month or more. Amongst 'never smoking' youth, that figure decreased to 1%. This has remained consistent since ASH surveys began in 2012.</p> <p>Additionally, Imperial Brands has worked with independent researchers to investigate the likelihood of gateway materialising and, through the Centre of Substance Use Research, conducted two studies amongst young people. The studies demonstrated the availability of vaping products is actually contributing</p>	<p>Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a>. Your comments have been reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.</p>

<sup>5</sup> Action on Smoking and Health, press release: <http://ash.org.uk/media-and-news/press-releases-media-and-news/ash-welcomes-new-public-health-england-report-e-cigarettes/>

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			<p>to further denormalization and demonization of cigarettes due to the fact young people, including never-smokers, understand that vaping is a less harmful alternative to smoking<sup>6</sup>. Evidence therefore suggests that the availability of e-cigarettes is actually preventing the uptake of tobacco.</p> <p>Consistently, gateway studies have come under widespread criticism from scientists and academics in the UK for utilising flawed methodology (i.e. working from the foundation that an 'e-cigarette user' is someone, who, in the past 12 months, has used a vaping device; and, in addition, many of these studies have failed to recognise that youth experimentation with vaping often acts as a substitute to trial with the real thing (tobacco cigarettes) and is a consequence of typical adolescent 'risky behaviour' that entails experimentation with multiple substances<sup>7</sup>.</p> <p>Imperial Brands therefore recommends that NICE makes itself aware of the differentiations of gateway study methodologies to ensure its findings and conclusions are not misled by sensationalist headlines that don't accurately reflect the role vaping can – and already is - playing in the prevention of tobacco use amongst young people.</p>	

<sup>6</sup> The Scotsman, <https://www.scotsman.com/news/e-cigarettes-act-as-roadblock-to-teen-smoking-1-4160161>

<sup>7</sup> Science Media Centre, Expert reaction to e-cigarette studies: <http://www.sciencemediacentre.org/?s=e-cigarettes&cat=>

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Imperial Brands PLC	5	28 - 29	<p>Imperial Brands is pleased the draft scope recognises the need to provide guidance on work place cessation and harm reduction. Indeed, the current conflation between tobacco products and vaping products – as dictated by current legislation (i.e. the EU Tobacco Products Directive “<b>EUTPD</b>”) is perceived as hindering more widespread adoption of vaping products, and sending conflicting messages to consumers about the relative risk profile of vaping products when compared to smoking.</p> <p>Public Health England has gone to great effort to try and educate employers on appropriate workplace policies that could encourage and enable more smokers to switch to vaping products. However, this advice isn’t filtering down to individual workplaces and venues as current guidelines fail to adequately differentiate vaping from smoking and, in turn, help workplaces build the necessary confidence to promote vaping as a less harmful alternative.</p> <p>Imperial Brands therefore believes much more work needs to be done to educate both employers, employees, and others to equip more businesses to proactively assist smokers on their journey away from smoking. Imperial Brands has initiated contact with UK workplaces in an effort to brief them on Public Health England’s guidelines and to implement appropriate policies to advance staff wellbeing and smoking cessation.</p>	<p>Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a>. Your comments have been reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.</p>
Imperial Brands PLC	6	9	<p>Imperial Brands welcomes the addition of vaping manufacturers and retailers in the NICE guidance. However it should be noted that the vaping category has, to-date, been an entirely consumer-driven, private-sector phenomenon that has</p>	<p>Thank you for your comment. Your organisation</p>

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			<p>successfully developed with little to no involvement from the public sector and/or significant taxpayer burden.</p> <p>Furthermore, development in the industry has moved much more quickly than regulation. Imperial Brands believes in the importance of industry consultation as subject matter experts, which, if timely and transparent, can make a real and tangible contribution by helping to make significant advances towards “smoke-free” goals. In the absence of adequate funding and expertise from the public sector, responsible manufactures such as Imperial Brands, are investing heavily in long term clinical trials and peer-reviewed published research that can make a meaningful contribution to the growing body of scientific evidence around vaping products<sup>8</sup>. We presented a selection of our scientific evidence to date to the House of Commons Science and Technology Committee Inquiry into E-Cigarettes (Oral evidence <a href="#">here</a> and written evidence <a href="#">here</a>).</p>	<p>is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a>. Your comments have been reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.</p>
Imperial Brands PLC	7	10 - 12	<p>Imperial Brands welcomes the focus and recognition of this important demographic as its own priority group. We recognise that smoking rates amongst mental health patients remains a significant challenge for regulators and health care providers alike. We also understand the complexities and behavioural issues amongst this group that interact with entrenched smoking habits.</p>	<p>Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its</p>

<sup>8</sup> Fontem Ventures Science Website: <http://www.fontemscience.com>

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			To this end, we have worked successfully with various UK stop smoking services in an effort to build understanding of vaping products, educate service providers on the science of vaping, and also to directly engage with members of the public who remain fearful or apprehensive about vaping products <sup>9</sup> . Moreover, we recognise that this group may require enforced product standards to ensure devices are tamper proof and safe delivery mechanisms of e-liquids.	<a href="#">position statement on engaging with tobacco organisations</a> . Your comments have been reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.
Imperial Brands PLC	7	24 - 25	The draft scope rightly identifies NRT users as a specific group looking to reduce or quit smoking. However, many smokers are utilising the ease of vaping as their chosen method of quitting. Public Health England states that vaping is 95% less harmful than traditional tobacco products <sup>10</sup> , as such, those who choose to switch voluntarily using vaping should be given due consideration.	Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a> . Your

<sup>9</sup> Science of Vaping Tour Comes To Milton Keynes: <https://www.miltonkeynes.co.uk/news/science-of-vaping-tour-to-visit-milton-keynes-1-8019152>

<sup>10</sup> Public Health England: <https://www.gov.uk/government/news/e-cigarettes-around-95-less-harmful-than-tobacco-estimates-landmark-review>

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Imperial Brands PLC	9	12 - 15	<p>Imperial Brands welcomes the focus, consideration – and sheer necessity – of more widespread public health campaigns around EVPs. Public Health England<sup>11</sup>, Cancer Research UK<sup>12</sup>, and UK cities, such as Manchester<sup>13</sup>, have already stepped up momentum on this despite current legislation, recognising the public health benefits to be gained by informing smokers about less harmful alternatives. Imperial Brands, too, has orchestrated smoker education programmes involving direct interactions, local media campaigns, and partnerships with stop smoking services.</p> <p>Alarming, ASH 2017 data revealed that public perceptions of harm around vaping products have quadrupled due to misleading science and media headlines. To combat this growing trend, industry, regulators and the public</p>	

<sup>11</sup> Public Health England Stoptober Campaign: <https://campaignresources.phe.gov.uk/resources/campaigns/6-stoptober/overview>

<sup>12</sup> Cancer Research UK Manchester Campaign: [http://www.cancerresearchuk.org/sites/default/files/overview\\_briefing\\_external.pdf](http://www.cancerresearchuk.org/sites/default/files/overview_briefing_external.pdf)

<sup>13</sup> Make Smoking History Manchester Campaign: <http://www.gmhsc.org.uk/wp-content/uploads/2018/04/Tobacco-Free-Greater-Manchester-Strategy.pdf>

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			health community, need to work together to ensure smokers get access to the information they require to make better choices – whether complete smoking cessation, or alternative products.	
Imperial Brands PLC	9	16 - 19	We welcome the recommendation by NICE to use television, radio, online and social media to engage wider stakeholders. As vape companies are legally unable to use many of these channels (EUTPD article 20) to advertise or promote the health aspects of vaping to the wider smoking community it is important that health bodies are aware of the opportunities and use them effectively (post watershed) to target over 18 smokers who are looking to switch to something better.	Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a> . Your comments have been reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.

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Nicoventures Holdings Limited	10 18 18	11 – 18, 21 - 23 13 – 15 26 – 27	<p><b><u>Use of e-cigarettes to support cessation and harm reduction</u></b></p> <ul style="list-style-type: none"> <li>In the context of 'cessation and harm reduction', and in response to your request for evidence regarding interventions to stop smoking or reduce harm, including e-cigarettes (licensed or consumer), whilst Nicoventures does not market its products as 'cessation' devices (as claims relating to smoking cessation can only be made on products that have been licensed by the Medicines and Healthcare products Regulatory Agency (MHRA)), we are aware that there is a growing body of scientific evidence <sup>i ii iii</sup>, that supports the use of e-cigarettes in assisting smoking cessation, such as a recent study by Levy <sup>iv</sup> which, found both quit attempts and quit successes were positively associated with increased frequency of e-cigarette use. Further, Action on Smoking and Health (ASH) recently published figures showing that of the 2.9 million users of e-cigarette products, 1.5 million are people who have stopped smoking entirely.<sup>v</sup> We would also refer you to the Committee to the Submission by Associate Professor Colin Mendelsohn (2017),<sup>vi</sup> 'Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia', which addresses, inter alia, the evidence on using e-cigarettes to assist people to quit smoking.</li> <li>From a harm reduction perspective, a number of recent scientific studies have reinforced that e-cigarettes are likely to be significantly less hazardous than 'conventional' tobacco products. For example:</li> </ul>	<p>Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a>. Your comments have been reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.</p>

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			<ul style="list-style-type: none"> <li>○ A study funded by <b>Cancer Research UK (2017)</b>,<sup>vii</sup> analysed the nicotine, carcinogen, and toxin exposure in long-term e-cigarette and nicotine replacement therapy users over a year. This study, which is the first long-term study of its kind, found that people who swapped smoking regular cigarettes for e-cigarettes or nicotine replacement therapy for at least six months, had much lower levels of toxic and cancer causing substances in their body than people who continued to use conventional cigarettes.</li> <li>○ A study by <b>Chen et al., (2017)</b><sup>viii</sup> conducted a comparative health risk assessment of e-cigarettes and conventional cigarettes and suggested the use of e-cigarettes could save lives. It stated that "...Using ECs to replace CCs as nicotine delivery products could lead to millions of lives saved and significant reductions in the burden of many smoking-related diseases."</li> <li>○ A study by <b>Levy et al., (2017)</b><sup>ix</sup> considered a strategy of switching cigarette smokers to e-cigarette use in the USA to accelerate tobacco control progress. The study found that "a hypothetical substitution of e-cigarette for cigarette use provides tremendous potential to avert premature deaths due to smoking, with only a relatively small amount of premature deaths due to e-cigarettes. Among those aged 15 years and above in 2016, almost 6.6 million fewer premature deaths and</li> </ul>	

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			<p>Please insert each new comment in a new row</p> <p><i>86.7 million fewer LYL [life years lost] due to cigarette use occur in the Optimistic Scenario."</i></p> <ul style="list-style-type: none"> <li>The recent systematic review of the scientific literature undertaken by the NASEM * also concluded, inter alia, that: <ul style="list-style-type: none"> <li>"There is conclusive evidence that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes."</li> <li>"There is substantial evidence that completely switching from regular use of combustible tobacco cigarettes to e-cigarettes results in reduced short-term adverse health outcomes in several organ systems"</li> <li>"Taken together, the evidence ... suggests that e-cigarette aerosol contains fewer numbers and lower levels of toxicants than smoke from combustible tobacco cigarettes."</li> <li>"The evidence about harm reduction suggests that across a range of studies and outcomes, e-cigarettes pose less risk to an individual than combustible tobacco cigarettes".</li> </ul> </li> <li>We are aware that some studies have pointed to the potential adverse health effects of e-cigarettes. For example, the USSGR Report (2016)<sup>xi</sup>,</li> </ul>	

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			<p>Please insert each new comment in a new row</p> <p>and WHO Report (2016)<sup>xii</sup> raise a number of concerns over the potential health risks of e-cigarettes. However, we note that both these reports have been heavily criticised (see Polosa et al., (2017)<sup>xiii</sup> and the UK Centre for Tobacco and Alcohol Studies).<sup>xiv</sup></p> <ul style="list-style-type: none"> <li>We acknowledge that e-cigarettes are not risk free and agree that more research is needed into the long-term effects of their use. However, based on the evidence to date, the risks of e-cigarettes that are manufactured to robust quality and safety standards are likely to be substantially less hazardous than traditional combustible products; and have a significant potential for harm reduction. E-cigarettes are able to deliver nicotine to consumers without the vast majority of hazardous constituents of tobacco smoke whilst simultaneously providing some of the behavioural and sensory aspects of the smoking ritual.</li> <li><b>Smoking Relapse.</b> In the context of interventions that may prevent a former smoker relapsing, it is worth noting a paper by Mendelson (2018)<sup>xv</sup> that concluded: "[t]here is growing evidence for the effectiveness of e-cigarettes as a quitting aid and, although not completely harmless, the scientific consensus is that they are substantially less harmful than smoking tobacco. More research is needed, but there is now sufficient empirical evidence and real-world experience over more than a decade to consider their use as a legitimate tobacco harm reduction tool for smokers who are unable or unwilling to quit with conventional strategies. Smokers should be advised that the highest success rates occur with daily use with</li> </ul>	

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			Please insert each new comment in a new row <i>nicotine e-liquid and newer e-cigarette models. After quitting smoking, it is preferable to aim ultimately to cease vaping if possible, but <u>long-term use of e-cigarettes is safer than relapsing to smoking.</u></i>	
Nicoventures Holdings Limited	16	28 - 31	<p><b><u>Children and Access to Cigarettes</u></b></p> <ul style="list-style-type: none"> <li>In the context of 'prevention and promotion', and in recognising that one of NICE's key issues concerns the illegal sale of tobacco to children and young people, we largely agree with the recommendations contained within Guidance PH14, but do not consider it necessary to restrict the tobacco industry's involvement in campaigns that support better enforcement of existing legislation strategies that aim to prevent children and young people under 18 from accessing cigarettes. Nicoventures support measures that prevent under-age access to tobacco and nicotine products.</li> <li>In addition to our strict requirement to only market our products to adult consumers, we expect youth access prevention activities to be carried out in all our markets where we directly distribute our products and where these activities are permitted by local legislation.</li> <li>Our commitment to only market our combustible tobacco products to adult smokers has long been supported by our global Youth Smoking Prevention (YSP) Guidance and activities for our operations worldwide.</li> </ul>	Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a> . Your comments have been reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.

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			<ul style="list-style-type: none"> <li>In 2017, we revised and strengthened our approach further by developing new Youth Access Prevention Guidelines for our operations to cover all product categories – from conventional cigarettes to vapour products and THPs. For further information, please see: <a href="http://www.bat.com/group/sites/UK_9D9KCY.nsf/vwPagesWebLive/D052ANVW">http://www.bat.com/group/sites/UK_9D9KCY.nsf/vwPagesWebLive/D052ANVW</a></li> <li>We are also broadening the scope of our YAP activities to include markets where our products are distributed through third parties.</li> <li>Our global approach requires all our operations wherever possible to: <ul style="list-style-type: none"> <li>Work directly with retailers to uphold minimum age laws and our own internal standards;</li> <li>Support distributors in providing training and point-of-sale materials for use by retailers; and</li> <li>Engage with governments in markets where there is no minimum age law of 18 to see one introduced.</li> </ul> </li> <li>The support we provide to our operations and to distributors includes training and point-of-sale materials for retailers to help them uphold minimum age laws.</li> </ul>	

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Nicoventures Holdings Limited	2 9 17	20 - 21 29 - 30 11 - 13	<p><b><u>Children and e-cigarettes</u></b></p> <p>In the context of 'prevention and promotion', and in response to your request for evidence regarding e-cigarettes and their impact on smoking behaviour among children and young people who currently do not smoke, we should like to highlight the following:</p> <p><b>'Gateway Effect'</b></p> <ul style="list-style-type: none"> <li>The overall weight of the evidence does not support the proposition that e-cigarettes have a 'gateway effect' on youth smoking.<sup>xvi</sup> Rather, the evidence suggests that "[u]se of the devices is confined to current and ex-smokers and use amongst never smokers remains very low," and that "regular use of electronic cigarettes amongst children and young people is rare and is confined almost entirely to those who currently or have previously smoked."<sup>xvii</sup> For example: <ul style="list-style-type: none"> <li>A recent systematic review of the evidence conducted by the University of Victoria, Canada (2017)<sup>xviii</sup>, concluded that: "[t]here is no evidence of any gateway effect whereby youth who experiment with vapour devices are, as a result, more likely to take up tobacco use. The available evidence is that tobacco use by youth has been declining while use of vapour devices has been increasing".<sup>xix</sup></li> </ul> </li> </ul>	<p>Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a>. Your comments have been reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.</p>

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			<p>Please insert each new comment in a new row</p> <ul style="list-style-type: none"> <li>○ A UK study by Bauld et al., (2017)<sup>xx</sup> which assessed recent trends in ever and regular use of e-cigarettes and tobacco among 11-16 year olds, similarly found that their <i>"findings indicate that there is no evidence of e-cigarettes driving smoking prevalence upwards. This is important, and suggests that fears about e-cigarettes as a gateway to more youth becoming smokers are not currently justified, at least in the UK."</i></li> <li>○ A US study published by Kozlowski et al., (2017)<sup>xxi</sup> also concluded that <i>"risks for youth posed by e-cigarettes likely fall far short of those feared by the products' opponents"</i> and that, currently <i>"youth use of e-cigarettes is unlikely to increase the ranks of future cigarette smokers."</i></li> <li>• Studies that purport to show that e-cigarettes have a gateway effect among youth, fail to establish that it is the use of e-cigarettes that leads to smoking. For example: <ul style="list-style-type: none"> <li>○ a study by Conner et al., (2017)<sup>xxii</sup> which, concluded that e-cigarette use among adolescents is associated with smoking initiation. However, the authors acknowledged the study's limitations, stating that <i>"there is no direct evidence yet to suggest that ever use of e-cigarettes normalises cigarette use"</i> and that <i>"given the limited numbers escalating their cigarette use in this study and lack of support in other studies, these</i></li> </ul> </li> </ul>	

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			<p>Please insert each new comment in a new row</p> <p>findings should be treated cautiously." Moreover, this study has been criticised by experts, such as Professor Linda Bauld who noted that the study does not provide evidence that using e-cigarettes causes young people to become smokers;</p> <ul style="list-style-type: none"> <li>○ a study by Soneji et al., (2017)<sup>xxiii</sup> which, found that results from nine longitudinal studies were consistent in finding that e-cigarette use is associated with an increased risk of future cigarette smoking initiation, and current cigarette smoking, was critiqued by various experts, with Professor Ann McNeill, Professor of Tobacco Addiction at the National Addiction Centre, finding that "[w]hether using e-cigarettes causes a young never smoker to go on to smoke tobacco cigarettes is important. This review does not find this. It cannot rule out the alternative explanation that young people who are interested in trying e-cigarettes are also interested in trying tobacco cigarettes..."<sup>xxiv</sup></li> <li>○ Whilst the recent systematic review of the scientific literature undertaken by the National Academies of Sciences, Engineering, and Medicine ("NASEM") for the US Food and Drug Administration, concluded that there is substantial evidence that e-cigarette use by youth and young adults increases their risk of ever using conventional cigarettes, this is not a finding of causation. Maciej Goniewicz, a member of the NAS committee which conducted the study, stated: "[t]he</li> </ul>	

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			<p>Please insert each new comment in a new row</p> <p>relationship is just correlation. We did not make any conclusion that electronic cigarettes cause smoking..."<sup>xxv</sup> Public Health England in its 2018 report also notes that the studies which suggest that e-cigarette use is associated with subsequent smoking in young people "all ... face similar limitations which need to be understood before assuming that this relationship is causal."</p> <ul style="list-style-type: none"> <li>Furthermore, in relation to adult smokers, e-cigarettes have provided a gateway out of smoking for millions of smokers (see section below titled 'Use of e-cigarettes to support cessation and harm reduction'). Indeed, a recent report notes that in the UK, the adult smoking rate barely moved after the smoking ban was introduced in 2007, but once e-cigarettes became mainstream consumer products it went onto sharp decline, falling from 20.4 per cent in 2012 to just 15.8 per cent in 2016, and that the UK now has the second lowest smoking prevalence rate in the EU.<sup>xxvi</sup></li> </ul>	

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			<p><b>'Re-normalisation'</b></p> <ul style="list-style-type: none"> <li>There is increasing agreement amongst health experts that e-cigarettes 're-normalise' smoking. To supplement PHE's review of the available evidence in 2015, which concluded that "[s]ince EC were introduced to the market, smoking prevalence among adults and youth has declined. Hence there is no evidence to date that EC are renormalizing smoking, instead it's possible that their presence has contributed to further declines in smoking, or denormalisation of smoking"<sup>xxvii</sup>, there are additional studies that also contradict renormalisation concerns and indicate that e-cigarettes may contribute to lower smoking prevalence rates. For example: <ul style="list-style-type: none"> <li>a study by ASH (2017)<sup>xxviii</sup>, found that for the first time there were more ex-smokers than current smokers using e-cigarettes<sup>xxix</sup>;</li> <li>data from the US Center for Disease Control and Prevention ('CDC') National Health Interview Survey (2016), suggests that the decline in smoking prevalence in the United States has accelerated since e-cigarettes became popular in 2010, whereas it had previously flat-lined for 6 years.<sup>xxx</sup></li> </ul> </li> </ul>	

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Nicoventures Holdings Limited	General	General	<p><b><u>Response Overview</u></b></p> <ul style="list-style-type: none"> <li>There is increasing agreement amongst health experts that exclusive use of Electronic Nicotine Delivery Systems ('ENDS') (including e-cigarettes), that are manufactured to robust quality and safety standards, are likely to confer reduced risks of harm as compared to smoking conventional cigarettes. ENDS do not contain tobacco, they do not rely on combustion and, as a consequence, no smoke is formed when the e-liquid is 'vaped'.</li> <li>Tobacco Heating Products ('THPs'), also known as Heat-not-Burn products, are electronic devices which heat tobacco, rather than burn it, to create an inhalable aerosol. THPs also offer the potential to contribute to tobacco harm reduction and should be considered in the scope of the NICE review.</li> <li>E-cigarettes have provided an exit out of smoking for millions of smokers. The overall weight of the evidence does not support concerns about the possible effect on re-normalisation of and 'gateway' into smoking.</li> <li>Given the increasing evidence supporting the potential for ENDS, THPs and other non-combustible/smokeless nicotine and tobacco products as a reduced risk alternative to cigarettes, it is crucial that smokers are</li> </ul>	<p>Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a>. Your comments have been reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.</p>

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			<p>Please insert each new comment in a new row</p> <p>given full and accurate information on the use of and access to such products.</p> <ul style="list-style-type: none"> <li>NICE Guideline PH45 (which is within the scope of this update), largely restricts its recommendations to licensed nicotine containing products (i.e. raising awareness of such products, promoting their benefits, and where and how they should be made available). Given that at the date of its publication the guidance anticipated changes in the law that did not materialise, i.e. that the EU Tobacco Products Directive would introduce a requirement that ENDS would be required to have a medicines licence prior to being placed on the market, the recommendations made within Guidance PH45 should now extend to all ENDS, whether licensed or not. This is particularly important given that traditional licenced products have not been seen as a satisfactory alternative by many smokers.</li> <li>We have identified below (both by way of general comments and evidence pertaining to specific matters), information that we believe informs the scope of NICE's update of various guidelines relating to tobacco use, prevention and promotion, cessation and harm reduction.</li> </ul>	
Nicoventures Holdings Limited	General	General	<p><b><u>Tobacco Heating Products</u></b></p> <ul style="list-style-type: none"> <li>With regard to question 1 (on page 1) above and NICE considering whether, or not to include heat not burn products within the scope of</li> </ul>	Thank you for your comment. Your organisation is treated as a respondent

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			<p>Please insert each new comment in a new row</p> <p>the guidelines, our view is that heat not burn products should be included.</p> <ul style="list-style-type: none"> <li> <b>Cigarettes and THPs are fundamentally different products:</b>  Consumption of THPs involves no combustion. The scientific community widely agrees that it is the combustion and the resulting toxicants in cigarette smoke that primarily cause tobacco-related diseases, not nicotine.<sup>xxxii</sup> The tobacco in THPs is heated through a heating element which produces an aerosol. The aerosol is mainly made up of water, glycerine, flavours and nicotine which the consumer inhales. </li> <li> <b>THPs offer the potential to contribute to tobacco harm reduction:</b>  Given the reduced risk potential of THPs, compared to conventional cigarettes, adult consumers should be made aware of their availability and have ready access to them. They cannot deliver on their potential to contribute to tobacco harm reduction unless adult consumers are made aware of them and they are readily accessible. </li> <li> Adding on to the findings of Public Health England regarding its conclusions that "<i>the available evidence suggests that heated tobacco products may be considerably less harmful than tobacco cigarettes</i>"<sup>xxxii</sup> and that "<i>Compared with cigarettes, heated tobacco products are likely to expose users and bystanders to lower levels of particulate matter and harmful and potentially harmful compounds (HPHC)</i>"<sup>xxxiii</sup>, but noting </li> </ul>	<p>rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a>. Your comments have been reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.</p>

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			<p>Please insert each new comment in a new row</p> <p>that further research is required, we would like to draw to NICE's attention to our peer-reviewed scientific research on our glo™ THP:</p> <ul style="list-style-type: none"> <li>○ Analysis of the aerosol from glo™ has found a <b>90-95% reduction as compared to smoke from a conventional reference cigarette, in the emission of nine harmful toxicants that the World Health Organization recommends to reduce in cigarette smoke.</b><sup>xxxiv</sup> Because glo™ aerosol has lower level of toxicants than cigarette smoke, it should in principle expose consumers to much less toxicants compared to smoke.<sup>xxxv</sup></li> <li>○ Analysis of indoor air quality and odour found that glo™ <b>had significantly less impact on indoor air quality</b>, and that the emissions from glo™ are significantly less odorous than those from conventional cigarettes. For glo™, most test analytes were below detectable levels or did not exceed baseline levels. For those that were measurable the levels were <b>typically more than 90% lower than those from cigarette smoke.</b><sup>xxxvi</sup></li> <li>● Consumers needs in the tobacco and nicotine space are evolving and it is important that the market can respond to consumer demand. Many consumers are seeking something other than e-cigarettes as an alternative to smoking. The wider the choice that is available in terms of different variants of e-cigarettes and other potential alternatives to smoking, the more consumers may be encouraged to switch. There is</li> </ul>	

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			Please insert each new comment in a new row no single solution for all consumers and consumer choice must be at the heart of both category innovation and policy.	
Nicoventures Holdings Limited	General 17	General 26 - 29	<p><b><u>Harm Reduction</u></b></p> <p>We note that the concept of 'Harm Reduction' is a common theme throughout the scope document. We acknowledge that the only way to avoid the health risks inherent in smoking is not to smoke, but many people continue to smoke, which is why developing and commercialising potentially less risky products is so important.</p> <p>Consumer tastes in the tobacco and nicotine space are fragmenting and evolving and it is only by making available a wide range of product choices that it is possible to address the many and varied preferences of today's more demanding consumers.</p> <p>At Nicoventures, we are committed to making a range of high-quality, innovative products as widely available as we practically can to address the varied needs of these consumers. We believe that by doing this, and working with regulators to establish supportive regulatory regimes, many millions of smokers will increasingly make the choice to switch.</p> <p>NICE Guideline PH45 - '<i>Smoking Harm Reduction</i>' - largely restricts its recommendations to licensed nicotine containing products (i.e. raising awareness of such products, promoting their benefits, and where and how they should be made available). It is noted that at the time of publication of Guideline</p>	<p>Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a>. Your comments have been reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.</p>

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			<p>PH45 (June 2013), the Tobacco Products Directive 2014 (as transposed into UK law by The Tobacco and Related Products Regulation 2016), was not yet in force, and further that it was anticipated at the time of release of the Guideline that ENDS would, when the Directive came into force, require a medicines licence. When the Directive/Regulation did come into force, it did not make such requirement – it in fact allowed ENDS on the EU market subject to certain requirements to help ensure safety however, licensing was not a requirement. Provided that such products comply with these safety requirements, they should be promoted and made available to adult smokers and the revised Guideline should recognise this.</p> <p>A criticism levelled at traditional NRTs is that while they provide a substitute for cigarettes in terms of delivering nicotine, they do not substitute the social, ritualistic or behavioural aspects of smoking. For this reason e-cigarettes have been viewed as a potential means of supporting smoking cessation for individuals for whom traditional NRTs have been ineffective. This has been acknowledged for example, by the American Cancer Society, which states in its position statement on Electronic Cigarettes: "[t]he ACS recommends that clinicians support all attempts to quit the use of combustible tobacco and work with smokers to eventually stop using any tobacco product, including e-cigarettes. Some smokers, despite firm clinician advice, will not attempt to quit smoking cigarettes and will not use FDA approved cessation medications. These individuals should be encouraged to switch to the least harmful form of tobacco product possible; switching to the exclusive use of e-cigarettes is preferable to continuing to smoke combustible products. Of course, these individuals should be regularly advised to completely quit using all tobacco</p>	

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			<i>products.</i> <sup>xxxvii</sup>	
Nicoventures Holdings Limited	General 9	General 12 - 19	<p><b><u>Communications</u></b></p> <p>In the context of ‘prevention and promotion’, and recognising that NICE will consider making new recommendations or updating existing recommendations in respect of the use of mass media, point of sale and supply measures (including consumer and retailer education), we would encourage NICE to recognise the fact that the potential role of e-cigarettes as part of a public health strategy, together with their relatively novel status in the market, means that it is vital that they are distinguished from conventional cigarettes as a product category both in regulation and public perception, and that consumers are able to readily access objective and factual information about the products. This has been recognised by NGOs including ASH, which have found that “[o]f particular concern is the worsening understanding among smokers... Research has shown that perceptions of harm may be inhibiting some smokers’ use of electronic cigarettes”.<sup>xxxviii</sup> We note that the need to correct public misperceptions about different nicotine products was also highlighted in the recent review of the evidence by Public Health England (2018), which stated that “[m]isperceptions of nicotine and different nicotine-containing products need to be addressed. These have deteriorated further since the PHE report in 2015 which called for clear and accurate information on relative harms.”<sup>xxxix</sup></p> <p>As the evidence continues to mount in support of the potential benefits of e-cigarettes educational campaigns from government, state agencies, charities and other not-for-profit groups could provide vital support. As both the UK</p>	<p>Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a>. Your comments have been reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.</p>

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			Government has endorsed the use of e-cigarettes as part of their tobacco control strategy, and recently NHS Scotland has stated its support of e-cigarettes as an alternative to smoking there is a benefit and need for these organisations to share these views widely in easily accessible media (including on-line) among consumers.	
Philip Morris Limited	10	19 - 20	We support NICE reviewing the evidence on heat not burn products as a means of harm reduction (compared with other interventions or no intervention). We believe that there is sufficient evidence to support heat not burn being considered as a reduced harm alternative to smoking. Please see comment 12 below for further details of the independent peer reviewed evidence underpinning this.	Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a> . Your comments have been reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.

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Philip Morris Limited	17	28 - 29	<p>Smoke-free products are a highly effective, and cost effective, means of harm reduction.</p> <p>The Department of Health's 2017 Tobacco Control Plan for England ("the TCP")<sup>14</sup> estimated that 2 million former smokers had quit smoking using e-cigarettes. As no licensed e-cigarette has been placed on the UK market, this means that this reduction in smoking has been achieved at zero cost to the Government. Consequently, e-cigarettes compare very favourably as a cost-effective means of harm reduction compared to licensed nicotine replacement therapy.</p> <p>As yet there are far fewer consumers of heat not burn tobacco products in the UK than e-cigarettes. However, based on registered user data, PMI has found that more than half of UK adult smokers who try PMI's heat not burn tobacco product IQOS convert to the product in place of smoking (conversion defined as at least 95% of individual tobacco consumption coming in the form of IQOS). We estimate that this is more than double the approximately 25% of smokers who successfully convert to e-cigarettes (based on ASH data).<sup>15</sup></p>	<p>Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a>. Your comments have been reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.</p>

<sup>14</sup> See [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/630217/Towards\\_a\\_Smoke\\_free\\_Generation\\_-\\_A\\_Tobacco\\_Control\\_Plan\\_for\\_England\\_2017-2022\\_2\\_.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/630217/Towards_a_Smoke_free_Generation_-_A_Tobacco_Control_Plan_for_England_2017-2022_2_.pdf)

<sup>15</sup> ASH's 2017 survey of e-cigarette usage in Great Britain estimated that 60% of UK smokers had tried an e-cigarette, which equates to approximately 4.56 million smokers (based on an Office of National Statistics estimate of 7.6 million smokers across the whole UK in 2016). The same ASH survey estimated that there were approximately 1.5 million vapers who are ex-smokers and use e-cigarettes. ASH's 2017 survey is available at <http://ash.org.uk/information-and-resources/fact-sheets/use-of-e-cigarettes-among-adults-in-great-britain-2017/> and the Office of National Statistics estimate of 7.6 million smokers comes from 'Adult Smoking Habits in the UK' (2016) available at <https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandlifeexpectancies/bulletins/adultsmokinghabitsingreatbritain/2016>

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			Please insert each new comment in a new row	
			The UK conversion rate for IQOS is consistent with international trends, which have seen more than 5 million smokers convert to IQOS worldwide. We are confident that heat not burn has the potential to convert many more UK smokers away from combustible tobacco, reducing the societal harm from smoking, and helping to achieve the Government's ambition of creating a smoke-free generation, at no cost to the Government or the NHS.	
Philip Morris Limited	18	1 - 2	<p>ASH's annual survey of e-cigarette usage in Great Britain<sup>16</sup> provides insights into what influences the acceptability of e-cigarettes among UK smokers – see for example Figure 6 on page 7 of the 2017 report.</p> <p>When asked what would prompt them to try e-cigarettes again, performance, price and perceptions were among the factors smokers cited, however, it was also clear that a significant number of smokers were not prepared to try e-cigarettes again:</p> <ul style="list-style-type: none"> <li>• 28% of smokers replied “if it felt more like smoking”. This was the most popular answer.</li> <li>• 24% also replied “nothing would encourage me to try an e-cigarette again.”</li> <li>• 23% said that they would use them again if they were “trying to quit smoking”.</li> <li>• 18% replied “if they helped me to deal with my nicotine cravings better”.</li> </ul>	<p>Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a>. Your comments have been reviewed for factual inaccuracy claims. None have been identified. The</p>

<sup>16</sup> Use of e-cigarettes (vapourisers) among adults in Great Britain, 2017 as above [the 2018 survey was not published at the time of writing].

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			<ul style="list-style-type: none"> <li>18% cited price.</li> <li>16% said “if I had confidence they were safe to use”.</li> </ul>	comments have not otherwise been considered.
Philip Morris Limited	18	3 - 8	E-cigarettes are not risk-free, and they should not be used by non-smokers or children. However, as PHE have concluded, e-cigarettes are a much safer alternative than continuing to smoke. Despite this clear endorsement by PHE, evidence indicates that there is considerable public confusion about the relative safety of nicotine containing products, and this is discouraging some smokers from switching (see, for example, ASH’s annual survey of e-cigarette usage in Great Britain). <sup>17</sup> Health professionals can and should play an important role in correcting misperceptions, and we therefore consider it important that the updated NICE guidance fully reflects the advice of PHE as well as the policies of the Government towards e-cigarettes and harm reduction generally.	Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a> . Your comments have been reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.

<sup>17</sup> <http://ash.org.uk/information-and-resources/fact-sheets/use-of-e-cigarettes-among-adults-in-great-britain-2017/>

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Philip Morris Limited	18	9 - 12	<p>Pharmacokinetic (“PK”) studies constitute a critical element in the development program of alternatives to cigarettes. Single product use PK/PD<sup>18</sup> clinical studies generate data that can indicate adult smoker acceptance of the product through measures such as nicotine PK, urge to smoke, and product satisfaction. Allowing smokers to achieve nicotine levels at a similar rate as seen for cigarettes is key in successfully switching smokers to alternatives.</p> <p>Nicotine is important because the nicotine delivery profile and the rewarding subjective effects of tobacco products are critical components of product satisfaction and its actual use. It is one thing to develop a tobacco product that is less hazardous than cigarettes or smoking; it is quite another to make the product acceptable and appealing so that adult smokers will want to switch to it from cigarettes. Less harm without appeal will generate little in the way of public health benefits.</p> <p><b>E-cigarettes</b></p> <p>It has been demonstrated that first generation e-cigarettes did not deliver nicotine in a comparable way to cigarettes.<sup>19</sup> However, other studies have shown that second and third generation e-cigarettes deliver nicotine more efficiently than first generation ‘cigalike’ products, and may deliver comparable</p>	<p>Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a>. Your comments have been reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.</p>

<sup>18</sup> Pharmacokinetic/pharmacodynamic.

<sup>19</sup> See for example: ‘E-cigarettes in smoking cessation: a harm reduction perspective’, Chris Bullen, Carla López-Núñez and [Oliver Knight-West](#), available at <https://www.pharmaceutical-journal.com/research/perspective-article/e-cigarettes-in-smoking-cessation-a-harm-reduction-perspective/20200851.article>

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			<p>amounts of nicotine to a combustible cigarette. For example, P Hajek concluded:  <i>"EC [e-cigarette] brands we tested do not deliver nicotine as efficiently as cigarettes, but newer EC products deliver nicotine more efficiently than cig-a-like brands."</i><sup>20</sup></p> <p>Wagener et. al. looking into second and third generation e-cigarette delivery concluded:  <i>"Under normal use conditions, both Gen2 and Gen3 devices deliver cigarette-like amounts of nicotine, but G3 devices matched the amount and speed of nicotine delivery of a conventional cigarette. Compared with cigarettes, Gen2 and Gen3 e-cigarettes resulted in significantly lower levels of exposure to a potent lung carcinogen and cardiovascular toxicant. These findings have significant implications for understanding the addiction potential of these devices and their viability/suitability as aids to smoking cessation."</i><sup>21</sup></p> <p><b>Heat not burn tobacco</b></p> <p>Results from PK/PD studies conducted for PMI's heat not burn product IQOS show that the product offers a comparable experience to that of cigarettes across various measures, including nicotine absorption, product consumption and</p>	

<sup>20</sup> 'Nicotine delivery to users from cigarettes and from different types of e-cigarettes', available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5306435/>

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			subjective effects. <sup>22</sup> Across most of the subjective effect parameters, the product received comparable scores to cigarettes either at baseline or by the end of the study period (e.g. 90 days), suggesting that, as intended, adults smokers will find the product to be an acceptable substitute for conventional cigarettes.	
Philip Morris Limited	19	14 - 16	<p>We recommend that 'Smoking: harm reduction' (2015) NICE quality standard 92<sup>23</sup> is revised and updated when the new guidelines are published, in order to reflect new evidence and policy developments since 2015, and to give greater clarity around non-licensed alternatives to smoking such as e-cigarettes and heat not burn tobacco.</p> <p>NICE's quality standard QS92 on Smoking: Harm Reduction was checked in 2017, and determined to be 'up to date',<sup>24</sup> even though its definition of 'Harm reduction approach' would appear to be inconsistent with the Government's support for harm reduction (as reflected in the TCP as well as the annual evidence reviews of PHE since 2015). Despite (at page 28) acknowledging as "important that the quality standard is considered alongside current policy</p>	<p>Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a>. Your comments have been</p>

<sup>23</sup> <https://www.nice.org.uk/guidance/qs92>

<sup>24</sup> <https://www.nice.org.uk/guidance/qs92>

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			<p><i>documents</i>", the policy documents listed in QS92 appear outdated (citing for example PHE's 2014 review of e-cigarettes, but not subsequent annual reviews; the Royal College of Physicians' 2007 report 'Harm reduction in nicotine addiction: helping people who can't quit' but not the more recent 2016 report 'Nicotine without smoke: Tobacco harm reduction', and also omitting the Government's TCP, published in 2017.)<sup>25</sup></p> <p>The TCP supports harm reduction, and in particular the use of e-cigarettes. This support for e-cigarettes is not limited to licensed products (indeed, no licensed product is commercially available in the UK). The TCP noted that an estimated 2 million consumers in England had used (non-licensed) e-cigarettes and completely stopped smoking, and another 470,000 were using them as an aid to stop smoking.<sup>26</sup> Although stopping smoking is the best thing that a smoker can do for their health, the TCP added that <i>"the evidence is increasingly clear that e-cigarettes are significantly less harmful to health than smoking tobacco. The government will seek to support consumers in stopping smoking and adopting the use of less harmful nicotine products."</i><sup>27</sup> Further, the 2017-22 delivery plan for the TCP included as key programmes and activity providing smokers, the public, and health professionals with evidence based information and guidance.<sup>28</sup></p>	reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.

<sup>25</sup> <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0>

<sup>26</sup> See page 15 of the Department of Health's Tobacco Control Plan for England, 2017, available at

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/630217/Towards\\_a\\_Smoke\\_free\\_Generation\\_-\\_A\\_Tobacco\\_Control\\_Plan\\_for\\_England\\_2017-2022\\_\\_2\\_.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/630217/Towards_a_Smoke_free_Generation_-_A_Tobacco_Control_Plan_for_England_2017-2022__2_.pdf)

<sup>27</sup> See page 15, *ibid*.

<sup>28</sup> See [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/714365/tobacco-control-delivery-plan-2017-to-2022.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/714365/tobacco-control-delivery-plan-2017-to-2022.pdf) at 2.3.3 and 2.3.4.

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			<p>In its 2018 annual evidence review, PHE clearly endorsed the health benefits of smokers switching to e-cigarettes regardless of whether or not the e-cigarettes are medically licensed:  <i>“Vaping poses only a small fraction of the risks of smoking and switching completely from smoking to vaping conveys substantial health benefits over continued smoking”.</i><sup>29</sup></p> <p>PHE further noted the potential of heat not burn tobacco:  <i>“The available evidence suggests that heated tobacco products may be considerably less harmful than tobacco cigarettes and more harmful than e-cigarettes”.</i><sup>30</sup></p> <p>By contrast, QS 92’s definition of ‘harm reduction approach’ makes no specific mention of e-cigarettes (or heat not burn tobacco). The quality statement acknowledges the role of harm reduction approaches, however, the three approaches it describes are cutting down before stopping smoking, smoking reduction, and temporary abstinence from smoking. For each approach, it distinguishes between using and not using licensed nicotine containing products, without any specific reference to e-cigarettes (or heat not burn tobacco). In light of public health campaigns such as PHE’s ‘Stoptober’ in 2018, which recommended smokers switch to (unlicensed) e-cigarettes, a ‘harm</p>	

<sup>29</sup> <https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review/evidence-review-of-e-cigarettes-and-heated-tobacco-products-2018-executive-summary>

<sup>30</sup> <https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review/evidence-review-of-e-cigarettes-and-heated-tobacco-products-2018-executive-summary>

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			reduction approach' more focused on measures such as temporary abstinence and cutting down seems in need of revision.	
Philip Morris Limited	21	7: Table – PH5	<p>No evidence review and the retention of all recommendations are proposed for PH5 (Smoking: workplace interventions).</p> <p>We consider that these recommendations should be reviewed to take account of PHE's 2016 advice 'Use of e-cigarettes in public places and workplaces – Advice to inform evidence based policy making'.<sup>31</sup> The Government highlighted this advice in the TCP, and it would appear particularly pertinent to recommendation 1, aimed at employers.</p> <p>PHE advises, for example, that: “e-cigarette use is not covered by smokefree legislation and should not routinely be included in the requirements of an organisation's smokefree policy,” and “when communicating an organisation's policy on e-cigarette use, make clear the distinction between vaping and smoking, and the evidence on the relative risks for users and bystanders.”<sup>32</sup></p> <p>The TCP stated that the Government wants all employers to “make good use of information and momentum generated by national campaigns such as ‘Stoptober’”.<sup>33</sup> Since ‘Stoptober’ promoted switching to e-cigarettes in 2017, it</p>	<p>Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a>. Your comments have been reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.</p>

<sup>31</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/534586/PHE-advice-on-use-of-e-cigarettes-in-public-places-and-workplaces.PDF](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/534586/PHE-advice-on-use-of-e-cigarettes-in-public-places-and-workplaces.PDF)

<sup>32</sup> See pages 7-8.

<sup>33</sup> See page 17.

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			would seem inconsistent for NICE guidance to omit any reference to vaping in its recommendation to employers.	
Philip Morris Limited	23	Table – PH48	<p>No evidence review and the retention of all recommendations are proposed for PH48 (Smoking: acute, maternity and mental health services).</p> <p>We consider that these recommendations should be reviewed to take account of PHE's 2016 advice 'Use of e-cigarettes in public places and workplaces – Advice to inform evidence based policy making'.<sup>34</sup></p>	<p>Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a>. Your comments have been reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.</p>

<sup>34</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/534586/PHE-advice-on-use-of-e-cigarettes-in-public-places-and-workplaces.PDF](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/534586/PHE-advice-on-use-of-e-cigarettes-in-public-places-and-workplaces.PDF)

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Philip Morris Limited	24	Table – NG92	<p>It is proposed to revise some recommendations in NG92 if they are affected by other evidence being reviewed.</p> <p>We would support revision, particularly of recommendations 1.4 (Engaging with people who smoke) and 1.7 (If a person who smokes is not ready to quit) to place greater emphasis on encouraging smokers who would otherwise continue to smoke to switch instead to e-cigarettes or heat not burn tobacco. This would be consistent with both government policy (as set out in the TCP) and PHE advice (reflected in the 2018 annual evidence review and public health campaigns such as ‘Stoptober’).</p>	<p>Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a>. Your comments have been reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.</p>
Philip Morris Limited	24	Table – PH45	<p>In line with the comments above, we would support recommendations in PH45 (Smoking: harm reduction) being updated to reflect the Government support for “<i>stopping smoking and adopting the use of less harmful nicotine products</i>” contained in the TCP (see page 15), and the advice of PHE.</p>	<p>Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its</p>

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			This would also be consistent with developments in other countries. For example, in New Zealand recently, a District Court concluded that the sale of IQOS/Heets was not prohibited under the Smoke-Free Environments Act 1990 because “ <i>while it may have associated risks in itself, [it] is not as harmful or potentially harmful as ordinary cigarette use</i> ”. <sup>35</sup>	<a href="#">position statement on engaging with tobacco organisations</a> . Your comments have been reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.
Philip Morris Limited	24	Table (Final line)	<p>We would like to draw the Committee’s attention to the following independent evidence with respect to PMI’s heat not burn product, IQOS.</p> <p><b>Aerosol Chemistry:</b> Farsalinos et al., Nicotine Delivery to the Aerosol of a Heat-Not-Burn Tobacco Product: Comparison With a Tobacco Cigarette and E-Cigarettes, Nicotine &amp; Tobacco Research, 16 June 2017<sup>36</sup></p> <p><b>Formation:</b></p>	<p>Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco</a></p>

<sup>35</sup> <http://www.districtcourts.govt.nz/assets/unsecure/2018-03-27/2018-NZDC-4478-MOH-v-Morris.pdf>

<sup>36</sup> <https://academic.oup.com/ntr/advance-article-abstract/doi/10.1093/ntr/ntx138/3868870?redirectedFrom=fulltext>

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			<p>Li et al., Chemical Analysis and Simulated Pyrolysis of Tobacco Heating System 2.2 Compared to Conventional Cigarettes, Nicotine &amp; Tobacco Research, 8 January 2018<sup>37</sup></p> <p>Bekki et al., Comparison of Chemicals in Mainstream Smoke in Heat-not-burn Tobacco and Combustion Cigarettes, National Institute of Public Health (Japan), September 2017<sup>38</sup></p> <p>Farsalinos, Toxicant exposure: Heated tobacco products vs. e-cigarettes, Presentation at Global Forum on Nicotine 2017, 16 June 2017<sup>39</sup></p> <p>Mallock et al. (German Federal Risk Assessment Institute (BfR)), Levels of selected analytes in the emissions of “heat not burn” tobacco products that are relevant to assess human health risks, Archives of Toxicology, 5 May 2018<sup>40</sup></p> <p>US FDA’s Southeast Tobacco Laboratory (STL), October 2017<sup>41</sup></p> <p>Setyan, A., et al. (Swiss EMPA Institute), Physico-chemical characterization of particles and volatile organic compounds emitted by electronic cigarettes and heat-not-burn products, compared to a reference tobacco cigarette, 2018, Abstract<sup>42</sup></p>	<p><a href="#">organisations</a>. Your comments have been reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.</p>

<sup>37</sup> <https://academic.oup.com/ntr/advance-article-abstract/doi/10.1093/ntr/nty005/4793230?redirectedFrom=fulltext>

<sup>38</sup> [https://www.jstage.jst.go.jp/article/juoeh/39/3/39\\_201/\\_pdf](https://www.jstage.jst.go.jp/article/juoeh/39/3/39_201/_pdf)

<sup>39</sup> [https://gfn.net.co/downloads/Presentations\\_2017\\_/Dr%20Konstantinos%20Farsalinos.pdf](https://gfn.net.co/downloads/Presentations_2017_/Dr%20Konstantinos%20Farsalinos.pdf)

<sup>40</sup> [https://link.springer.com/epdf/10.1007/s00204-018-2215-y?author\\_access\\_token=m2gTAWzR8IN1XHHPyz2Egve4RwIQNchNByi7wbcMAY7B4pkXqsqfUkMAYl6dba736gw-jhsRtWkgMZmizReyYRn3AHhuAnBgK4UpddlBpl4gRJGOIPhap-GNK2mdVKfcekelyaEoSfu4eZEE5gztXA%3D%3D](https://link.springer.com/epdf/10.1007/s00204-018-2215-y?author_access_token=m2gTAWzR8IN1XHHPyz2Egve4RwIQNchNByi7wbcMAY7B4pkXqsqfUkMAYl6dba736gw-jhsRtWkgMZmizReyYRn3AHhuAnBgK4UpddlBpl4gRJGOIPhap-GNK2mdVKfcekelyaEoSfu4eZEE5gztXA%3D%3D)

<sup>41</sup> US FDA’s Southeast Tobacco Laboratory (STL), October 2017

<sup>42</sup> Setyan, A., et al. (Swiss EMPA Institute), Physico-chemical characterization of particles and volatile organic compounds emitted by electronic cigarettes and heat-not-burn products, compared to a reference tobacco cigarette, 2018, Abstract

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			<p>The All-Russia Scientific Research Institute for Tobacco and Tobacco Products (study conducted by request of Russian Government)</p> <p>Talih, S., et al., Is IQOS designed to convert combustible cigarette users? Investigation of Free-Base and Total Nicotine, and Reactive Oxygen Species, Poster 5-118 at SRNT 2018</p> <p>Dutch National Institute for Public Health and the Environment (RIVM). "Factsheet on novel tobacco products that are heated." May, 2018<sup>43</sup></p> <p><b>Indoor air quality and risk to bystanders:</b></p> <p>Protano, C., et al., Second-hand smoke exposure generated by new electronic devices (IQOS and e-cigs) and traditional cigarettes: submicron particle behavior in human respiratory system, Ann Ig, 2016<sup>44</sup></p> <p>Ruprecht, A.A., et al., Environmental pollution and emission factors of electronic cigarettes, heat-not-burn tobacco products, and conventional cigarettes, Aerosol Science and Technology, 21 March 2017<sup>45</sup></p> <p>Prodanchuk et al., Potential risk assessment of the electrically heated tobacco system (EHTS) use, Modern Problems of Toxicology Food and Chemical Safety, October 2017<sup>46</sup></p>	

<sup>43</sup> <https://www.rivm.nl/dsresource?objectid=e1ce3c72-1436-444f-a4d0-e9f93dc30da6&type=pdf&disposition=inline>

<sup>44</sup> [http://www.seu-roma.it/riviste/annali\\_igiene/open\\_access/articoli/73492f053274d293f3db764cbfac1134.pdf](http://www.seu-roma.it/riviste/annali_igiene/open_access/articoli/73492f053274d293f3db764cbfac1134.pdf)

<sup>45</sup> <https://www.tandfonline.com/doi/abs/10.1080/02786826.2017.1300231>

<sup>46</sup> <http://protox.medved.kiev.ua/index.php/en/issues/2017/1-2/item/517-potential-risk-assessment-of-the-electrically-heated-tobacco-system-ehts-use/517-potential-risk-assessment-of-the-electrically-heated-tobacco-system-ehts-use>

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## NICE guideline on tobacco suite: prevention, cessation and harm reduction (update)

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			<b>Toxicity:</b> Leigh et al., Cytotoxic Effects Of A Tobacco Heat-Not-Burn System On Human Bronchial Epithelial Cells, Abstract presented at SRNT 2018 <sup>47</sup>	
Philip Morris Limited	General	General	<p>Philip Morris Limited ("PML") is the U.K. and Ireland subsidiary of Philip Morris International ("PMI"). In 2016, PMI announced its ambition to replace cigarettes with smoke-free products that are likely to be much less harmful to human health than cigarette smoking. Our goal is to switch all smokers who would otherwise continue using cigarettes to smoke-free products. These include e-cigarettes and novel smokeless tobacco products such as heat not burn. It is important to note that PML is not a member of the Tobacco Manufacturers Association ("the TMA") and the views expressed by the TMA do not represent the views of PMI or PML.</p> <p>PML recognises that heat not burn products are not risk free, and that the best way for smokers to reduce smoking-related health risks is to quit. However, many smokers try to quit and find it difficult. Despite the clear health risks associated with smoking, there were still approximately 7.3 million smokers in England in 2015, as noted in the consultation on draft scope (at page 3). Consequently, harm reduction strategies can play an important role in reducing the risks from smoking and complement measures to prevent initiation and promote cessation.</p>	<p>Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a>. Your comments have been reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.</p>

<sup>47</sup> [https://c.ymcdn.com/sites/www.srnt.org/resource/resmgr/conferences/2018\\_Annual\\_Meeting/65388\\_SRNT\\_2018\\_Abstract\\_fin.pdf](https://c.ymcdn.com/sites/www.srnt.org/resource/resmgr/conferences/2018_Annual_Meeting/65388_SRNT_2018_Abstract_fin.pdf)

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			<p>PML believes that smoke-free products that smokers can switch to completely can help reduce the harm from smoking, and accelerate the realisation of the Government's ambition of creating a smoke-free generation. The example of e-cigarettes is instructive, and we believe that other smoke-free products, such as heat not burn, also offer the potential to reduce smoking. We are developing a range of non-combustible alternatives to smoking since we believe that no single alternative is likely to appeal to all smokers. Reflecting this, many smokers who have tried e-cigarettes have reverted to smoking, or continue to dual use combustible tobacco and e-cigarettes. For many of these smokers, heat not burn may provide a viable alternative. Although the greatest uptake of heat not burn has been in Japan, where e-cigarettes are not widely marketed, it has also proven a popular alternative to smoking in many countries where e-cigarettes were already established (such as Greece and South Korea). We believe that heat not burn could complement the success of e-cigarettes in England by reducing smoking among those who have tried and rejected vaping, or who have been unwilling to try it at all.</p> <p>Heat not burn is a relatively new product category, and we welcome further independent evidence on the relative risk of using such products compared to smoking. Given the public interest in such research, we anticipate further studies being published during the period between the close of this consultation, and the scheduled release of updated guidance in January 2020. However, based on the independent peer reviewed evidence listed below (see comment 12), we also believe that there is already sufficient evidence to recommend that switching to heat not burn products such as PMI's IQOS product is a better choice for a smoker's health than continuing to smoke. We</p>	

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			<p>recommend that the updated guidance takes into account the harm reduction potential of heat not burn.</p> <p>In addition to the independent evidence listed, we also have a wealth of data from our own research and studies. We have provided this to the Department of Health and Social Care, and Public Health England ("PHE"), and in 2017 our scientists explained our findings to the Committee for Toxicity. We remain at the disposal of NICE to provide any further information that it considers useful.</p>	
Philip Morris Limited	General	General	<p><b>Reduced exposure:</b> Kazan Federal University (study conducted by request of Russian Government) (<a href="#">here</a>) (unpublished). Results published in a comment to FDA<sup>48</sup> Gale et al., Changes in Biomarkers of Exposure on Switching from a Conventional Cigarette to Tobacco Heating Products: A Randomised, Controlled Study in Healthy Japanese Subjects, BAT, Poster 5-1888 at SRNT 2018<sup>49</sup> Tobacco Products Scientific Advisory Committee (TPSAC), 25 January 2018<sup>50</sup></p> <p><b>Reduced risk:</b></p>	<p>Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a>. Your comments have been</p>

<sup>48</sup> <https://www.regulations.gov/document?D=FDA-2017-D-3001-0103>

<sup>49</sup> [http://www.bat-science.com/groupms/sites/BAT\\_9GVJXS.nsf/vwPagesWebLive/DOAW7FNY/\\$FILE/SRNT2018%20JPBoEPK%20FINAL.PDF?openelement](http://www.bat-science.com/groupms/sites/BAT_9GVJXS.nsf/vwPagesWebLive/DOAW7FNY/$FILE/SRNT2018%20JPBoEPK%20FINAL.PDF?openelement)

<sup>50</sup> <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm583080.htm>

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			<p>UK Committee on Toxicity, Toxicological evaluation of heat-not-burn products, 12 December 2017<sup>51</sup></p> <p>PHE, Evidence review of e-cigarettes and heated tobacco products 2018, 6 February 2018<sup>52</sup></p> <p>Stephens, Comparing the cancer potencies of emissions from vapourised nicotine products including e-cigarettes with those of tobacco smoke, Tobacco Control, 4 August 2017</p> <p><b>Intended and unintended use:</b></p> <p>Tabuchi et al., Awareness and use of electronic cigarettes and heat-not-burn tobacco products in Japan, Addiction, 14 November 2015<sup>53</sup></p>	<p>reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.</p>
UK Vaping Industry Association	10	11	<p>Although the draft scope references both licensed and consumer vaping products, it is important that the majority of consideration from NICE is given to consumer vaping products. There are currently no licensed vaping products available, and given the time and process required to obtain a medical license, the UKVIA does not expect such a product to enter the market in time to inform this consultation process.</p>	<p>Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a>. Your comments have been</p>

<sup>51</sup> <https://cot.food.gov.uk/cotstatements/cotstatementsyrs/cot-statements-2017/statement-on-heat-not-burn-tobacco-products>

<sup>52</sup> <https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review>

<sup>53</sup> <https://onlinelibrary.wiley.com/doi/abs/10.1111/add.13231>

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				reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.
UK Vaping Industry Association	11	16 and 19	We recommend that the draft scope should include updating the guidelines on workplace smoking cessation and supporting employers to help employees to stop smoking. As stated at point 3 above, most employers do not have policies that consider vaping and trade union guidance in this area does not public health opinion. There is a clear need for central guidance on this point to assist workers switching from smoking to a less harmful alternative, and NICE guidelines should lead the way by being updated to specifically reference vaping.	Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a> . Your comments have been reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.

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UK Vaping Industry Association	4	16 - 18	<p>The draft scope references 2015 figures concerning the number of vapers who are dual users of vaping and cigarettes. However, we recommend consideration is given to more up to date figures; 2017 statistics from ASH reported that more ex-smokers (1.5million) use vaping products than are dual users of vaping products and cigarettes (1.3million).<sup>54</sup> Similarly the 2018 update to ASH evidence in this area highlighted that there has been an increase in the proportion of ex-smokers (9.5% to 10.3%) who report using vaping products.<sup>55</sup></p> <p>Although there are only slight differences between the different figures, the ASH statistics are evidence that vaping is an effective smoking cessation tool. Every update to statistics in this area demonstrates that more smokers are using vaping to quit and this should be reflected in advice to clinicians.</p> <p>ASH factsheet: Use of electronic cigarettes (vapourisers) among adults in Great Britain, May 2017  <sup>2</sup> ASH supplementary evidence for the Science and Technology Select Committee, 27 March 2018</p>	<p>Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a>. Your comments have been reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.</p>

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UK Vaping Industry Association	4	19 - 22	<p>There are additional statistics concerning the uptake of vaping products by young people than referenced in the draft scope. We suggest a fuller picture of statistics in this area is given to ensure clinicians and those inputting into the draft guidance are accurately informed.</p> <p>ASH statistics from 2018 confirm that regular use of vaping products among young people remains rare, particularly among young people who do not also smoke; just 0.4% of young people who do not smoke currently vape.<sup>56</sup></p> <p>Consideration should also be given to evidence confirming that vaping is not acting as a 'gateway' into smoking for young people:</p> <ul style="list-style-type: none"> <li>A recent analysis of the use of vaping products taken from various separate UK studies revealed that, although there is some experimentation amongst young people who have never- smoked, there is no evidence of this group of young people regularly using vaping products.<sup>57</sup></li> <li>The UK's largest ever analysis of data from research studies recently showed there is no evidence that vaping products are leading young people into smoking. The study was a collaboration between the UK Centre for</li> </ul>	<p>Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a>. Your comments have been reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.</p>

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			<p>Tobacco and Alcohol Studies, Public Health England, Action on Smoking and Health, and the DECIPHer Centre at the University of Cardiff, and found that regular use of e-cigarettes among young people who have never smoked was negligible – between 0.1% and 0.5%.<sup>58</sup></p> <ul style="list-style-type: none"> <li>• There have also been significant declines in youth smoking rates. Recent statistics indicate that only 7% of 15 year olds in England smoke regularly (at least once a week), compared to 8% in 2014, and 20% in 2006.<sup>59</sup></li> <li>• In 2017, the British Medical Association noted in their key messages for policymakers that: <i>“Though awareness of and experimentation with e-cigarettes is increasing in the UK, few children are becoming regular users of e-cigarettes. Nearly all of those that are currently or have previously smoked”</i> and continued: <i>“Current data on e-cigarette use and smoking does not support concerns that e-cigarettes will promote tobacco use among children and young people. Youth cigarette smoking has declined over the period of time that e-cigarettes have become increasingly available”</i>.<sup>60</sup></li> </ul> <p><sup>3</sup> ASH supplementary evidence for the Science and Technology Select Committee, 27 March 2018</p>	

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			<p><sup>4</sup> Bauld, L et al: "E-Cigarette Uptake Amongst UK Youth: Experimentation, but Little or No Regular Use in Nonsmokers", <i>Nicotine &amp; Tobacco Research</i>, 2016</p> <p><sup>5</sup> Bauld, L., et al., Young People's Use of E-Cigarettes across the United Kingdom: Findings from Five Surveys 2015-2017. <i>Int J Environ Res Public Health</i>, 2017. 14(9) and <a href="http://ash.org.uk/media-and-news/press-releases-media-and-news/uks-largest-ever-analysis-of-data-shows-no-evidence-that-e-cigarettes-are-leading-young-people-into-smoking/">http://ash.org.uk/media-and-news/press-releases-media-and-news/uks-largest-ever-analysis-of-data-shows-no-evidence-that-e-cigarettes-are-leading-young-people-into-smoking/</a>.</p> <p><sup>6</sup> NHS Digital (2017) Smoking, Drinking and Drug Use Among Young People in England 2016. Available at: <a href="http://digital.nhs.uk/catalogue/PUB30132">digital.nhs.uk/catalogue/PUB30132</a></p> <p><sup>7</sup> British Medical Association, Position Paper on E-Cigarettes, 29 November 2017: <a href="https://www.bma.org.uk/collective-voice/policy-and-research/public-and-population-health/tobacco/e-cigarettes">https://www.bma.org.uk/collective-voice/policy-and-research/public-and-population-health/tobacco/e-cigarettes</a></p>	
UK Vaping Industry Association	5	28	<p>It is very important that employee and trade union representatives are made aware of the work by NICE to update guidelines in this area. The UKVIA attended a meeting of the All Party Parliamentary Group for E-Cigarettes to discuss workplace vaping policy alongside a representative of the TUC and UNISON. It was clear that workplace policies for smoking and vaping are conflated in most cases, and the TUC remains extremely reluctant to embrace vaping as a smoking cessation tool.<sup>61</sup> This is clearly not consistent with the public health consensus around vaping.</p>	<p>Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco</a></p>

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			<sup>8</sup> The minutes for the APPG for E-Cigarettes can be provided on request. Please also see the advice from the TUC's health and safety representative: <a href="https://www.tuc.org.uk/blogs/vape-or-not-vape-work">https://www.tuc.org.uk/blogs/vape-or-not-vape-work</a>	<a href="#">organisations</a> . Your comments have been reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.
UK Vaping Industry Association	7	24 - 25	The scope rightly suggests that the updated cessation and harm reduction guidelines will cover those using licensed NRT products as a means of reducing harm from smoking. However, we feel that smokers currently using vaping as a means to reduce smoking should also be a focus of the guidelines. As discussed at point 1 above, there remains a significant minority of vapers who are dual vapers and smokers, and the guidelines should focus on convincing these people to switch completely to the less harmful alternative of vaping.	Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a> . Your comments have been reviewed for factual inaccuracy claims. None have been identified. The

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				comments have not otherwise been considered.
UK Vaping Industry Association	9	12 - 19	<p>We welcome the focus on mass media campaigns for prevention and promotion of harm reduction alternatives to smoking. Although direct person to person stop smoking advice is important for smoking cessation, there is evidence to suggest that public awareness campaigns around the benefits of vaping as a less harmful alternative to smoking are effective.</p> <p>The Government's Stoptober campaign in 2017 reference vaping for the first time and this led to:</p> <ul style="list-style-type: none"> <li>- UKVIA members reporting a considerable rise in starter-kit sales during the Stoptober campaign. For example, Vape Club, the UK's largest online vape e-liquid shop and JAC Vapour, a leading retailer, wholesaler and producer of vaping products, have experienced increases in starter kit sales by <b>37%</b> and <b>65%</b> year on year respectively. Vaporized, the UK's largest vape retail chain, experienced a <b>40% year on year rise</b> in sales in October.<sup>62</sup></li> </ul>	<p>Thank you for your comment. Your organisation is treated as a respondent rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a>. Your comments have been reviewed for factual inaccuracy claims. None have been identified. The</p>

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			<p>Please insert each new comment in a new row</p> <ul style="list-style-type: none"> <li>- The UKVIA's on VApril vaping awareness month had significant success targeting smokers looking to stop smoking.<sup>63</sup></li> <li>- 2018 figures from ASH suggest that, although vaping still has a perception problem, campaigns such as Stoptober have had some impact on the public perception of vaping; a greater proportion of the public correctly identify that e-cigarettes are less harmful than smoking (50% in 2018 compared to 43% in 2017).<sup>64</sup></li> </ul> <p><sup>9</sup> <a href="http://www.ukvia.co.uk/parliamentarians-call-on-government-to-keep-promoting-the-health-benefits-of-vaping-in-the-wake-of-public-health-englands-successful-advertising-campaign/">http://www.ukvia.co.uk/parliamentarians-call-on-government-to-keep-promoting-the-health-benefits-of-vaping-in-the-wake-of-public-health-englands-successful-advertising-campaign/</a></p> <p><sup>10</sup> Figures and statistics from VApril available on request.</p> <p><sup>11</sup> ASH supplementary evidence for the Science and Technology Select Committee, 27 March 2018</p>	comments have not otherwise been considered.
UK Vaping Industry Association	The use of incentives	General	The UKVIA recommends that consideration is given to extend the scope to review the potential for offering incentives to smokers to switch to vaping as a less harmful alternative to smoking:	Thank you for your comment. Your organisation is treated as a respondent

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			<ul style="list-style-type: none"> <li>- This incentive could take the form of a voucher system for smokers on low incomes or from high risk groups to exchange for a free vaping starter kit. The incentive could be administered in partnership with local authority stop smoking services.</li> <li>- As is referenced at point 6 above, there are currently no medically licensed products available for prescription by medical professionals and a voucher system would ensure that it is possible to access consumer vaping products across the income spectrum.</li> <li>- Some concern was expressed by Liz Kendall MP as part of the Science and Technology Committee's inquiry into E-Cigarettes that the 'starter' costs of vaping could make switching difficult for low income smokers.<sup>65</sup></li> <li>- The industry would be willing to engage in partnerships with clinicians and stop smoking services to operate such an incentive scheme.</li> </ul>	rather than a stakeholder by NICE in accordance with its <a href="#">position statement on engaging with tobacco organisations</a> . Your comments have been reviewed for factual inaccuracy claims. None have been identified. The comments have not otherwise been considered.
		12	<a href="http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/science-and-technology-committee/ecigarettes/oral/82792.html">http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/science-and-technology-committee/ecigarettes/oral/82792.html</a>	

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Document processed	Organisation name – Stakeholder or respondent	Disclosure on tobacco funding / links	Number of comments extracted	Comments
Draft Scope	Nicoventures Holdings Limited ('Nicoventures')	Nicoventures is part of the British American Tobacco Group, focused on Next Generation Products (including e-cigarettes).	7	
Draft Scope	UK Vaping Industry Association	The UKVIA is a partnership of the leading producers, distributors and vendors of vaping products. The Association includes a cross-section of the entire industry including independent vape companies, pharmaceutical owned companies and tobacco companies. All members have equal voting rights and pay equal membership fees. Four of our Associations twenty-four members are tobacco owned brands.	8	

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- 
- <sup>i</sup> Shu-Hong et al., (2017) E-cigarette use and associated changes in population smoking cessation: evidence from US current population surveys. BMJ 2017
  - <sup>ii</sup> Beard et al., (2016) 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
  - <sup>iii</sup> Farsalinos et al., (2016) Electronic cigarette use in the European Union: analysis of a representative sample of 27 460 Europeans from 28 countries. Addiction [Journal] 111:11
  - <sup>iv</sup> Levy et al., (2017) The Relationship of E-Cigarette Use to Cigarette Quit Attempts and Cessation: Insights from a Large, Nationally Representative U.S. Survey
  - <sup>v</sup> ASH: Use of E-cigarettes among adults in Great Britain. May 2017
  - <sup>vi</sup> <https://www.clivebates.com/documents/Australia2017/Mendelsohn.pdf>
  - <sup>vii</sup> Shahab et al., (2017) Nicotine, Carcinogen, and Toxin Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users. Ann Intern Med, 390-400.
  - <sup>viii</sup> Chen et al., (2017) A Comparative Health Risk Assessment of Electronic Cigarettes and Conventional Cigarettes. International journal of environmental research and public health, 14(4), 382.
  - <sup>ix</sup> Levy et al., (2017) Potential deaths averted in USA by replacing cigarettes with e-cigarettes. Tobacco Control. Aug 30.
  - <sup>x</sup> NASEM (2018), Public Health Consequences of E-Cigarettes, available at <https://www.nap.edu/catalog/24952/public-health-consequences-of-e-cigarettes>.
  - <sup>xi</sup> US Surgeon General ("USSGR") (2017), E-Cigarette Use Among Youth and Young Adults
  - <sup>xii</sup> WHO FCTC (2016), Report on Electronic Nicotine Delivery Systems ("ENDS") and Electronic Non-Nicotine Delivery Systems ("ENNDS") to the seventh session of the Conference of the Parties
  - <sup>xiii</sup> <https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-017-0187-5>
  - <sup>xiv</sup> [http://ukctas.net/news/commentary-on-WHO-report-on-ENDS&ENNDS.html?\\_sm\\_aui=iVV1Q7Mj1jW4WMrV](http://ukctas.net/news/commentary-on-WHO-report-on-ENDS&ENNDS.html?_sm_aui=iVV1Q7Mj1jW4WMrV)
  - <sup>xv</sup> <https://www.ncbi.nlm.nih.gov/pubmed/29623987>
  - <sup>xvi</sup> We note that a number of comprehensive reviews by independent organisations, including the RCP, have criticised 'gateway' arguments, concluding that there is no reliable evidence of any such effect. See Royal College of Physicians. Nicotine without smoke: Tobacco harm reduction; E-cigarettes: an evidence update: a report commissioned by Public Health England; O'Leary et al. (2017), Clearing the Air: A systematic review on the harms and benefits of e-cigarettes and vapour devices: Victoria, BC: Centre for Addictions Research of BC.
  - <sup>xvii</sup> ASH UK Fact Sheet May 2017, Use of e-cigarettes among adults in Great Britain 2017, <http://ash.org.uk/information-and-resources/fact-sheets/use-of-e-cigarettes-among-adults-in-great-britain-2017/>
  - <sup>xviii</sup> O'Leary et al. (2017), Clearing the Air: A systematic review on the harms and benefits of e-cigarettes and vapour devices: Victoria, BC: Centre for Addictions Research of BC.

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## NICE guideline on tobacco suite: prevention, cessation and harm reduction (update)

### Consultation on draft scope Respondent comments table

14/05/2018 to 11/06/2018

*Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.*

<sup>xxix</sup> Ibid.

<sup>xx</sup> Bauld et al., (2017) Young People's Use of e-cigarettes across the United Kingdom: Findings from Five Surveys 2015-2017. International Journal of Environmental Research and Public Health, 14(9):973.

<sup>xxi</sup> Kozlowski et al. (2017), Adolescents and e-cigarettes: Objects of concern may appear larger than they are. Drug & Alcohol Dependence, 174:20914

<sup>xxii</sup> Conner et al., (2017) Do electronic cigarettes increase cigarette smoking in UK adolescents. Tobacco Control

<sup>xxiii</sup> Soneji et al., (2017) Association between initial use of e-cigarettes and subsequent cigarette smoking among Adolescents and Young Adults: A systematic review and meta-analysis. JAMA Pediatr. 1;171(8):788-797.

<sup>xxiv</sup> Expert reaction to study of adolescents, e-cigarettes and smoking, June 26, 2017 (Prof Ann McNeill). <http://www.sciencemediacentre.org/expertreaction-to-review-of-e-cigarettes-and-smoking-in-young-adults/>

<sup>xxv</sup> <https://globalnews.ca/news/3984754/are-e-cigarettes-harmful-or-helpful/>

<sup>xxvi</sup> Snowden (2017) Vaping solutions: an easy Brexit win, Institute of Economic Affairs (IEA), available at [http://kingsfund.blogs.com/health\\_management/2017/11/vaping-solutions-an-easy-brexit-win.html](http://kingsfund.blogs.com/health_management/2017/11/vaping-solutions-an-easy-brexit-win.html).

<sup>xxvii</sup> E-cigarettes: an evidence update: a report commissioned by Public Health England. See also Electronic cigarettes: a report commissioned by Public Health England. Available at [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/311887/E-cigarettes\\_report.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311887/E-cigarettes_report.pdf)

<sup>xxviii</sup> ASH Fact Sheet (May 2017), Use of e-cigarettes (vapourisers) among adults in Great Britain

<sup>xxix</sup> "[f]or the first time there are more ex-smokers (1.5 million) who use e-cigarettes than current smokers (1.3 million). Over half (52%) of e-cigarette users are now ex-smokers and 45% are smokers."

<sup>xxx</sup> Submission by Associate Professor Colin Mendelsohn (2017), Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia.

Available at: <https://www.clivebates.com/documents/Australia2017/Mendelsohn.pdf> See also: <https://www.cdc.gov/nchs/data/nhis/earlyrelease/earlyrelease201605.pdf>

<sup>xxxi</sup> Niaura (2016), Re-thinking nicotine and its effects, at p. 3. See also, the UK National Institute for Health and Care Excellence ("NICE") (2013), Smoking: Harm reduction, which found that "most health problems are caused by other components in tobacco smoke, not by the nicotine" at p. 97.

<sup>xxxii</sup> McNeill A, Brose LS, Calder R, Bauld L & Robson D., Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England, 2018

<sup>xxxiii</sup> McNeill A, Brose LS, Calder R, Bauld L & Robson D., Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England, 2018

<sup>xxxiv</sup> Forster, et al., Assessment of novel tobacco heating product THP1.0. Part 3: Comprehensive chemical characterisation of harmful and potentially harmful aerosol emissions, Regulatory Toxicology and Pharmacology (2017).

<sup>xxxv</sup> BAT Science Press Release, Clinical study reveals smokers who switch to glo had significantly reduced exposure to toxicants, 24th February 2018

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<sup>xxxvi</sup> Forster et al., Assessment of tobacco heating product THP1.0. Part 4: Characterisation of indoor air quality and odour., Regulatory Toxicology and Pharmacology (2018), 0273-2300 2017

<sup>xxxvii</sup> American Cancer Society Position Statement on Electronic Cigarettes, available at <https://www.cancer.org/healthy/stay-away-from-tobacco/e-cigarette-position-statement.html>

<sup>xxxviii</sup> ASH fact sheet April 2014, Use of Electronic Cigarettes by adults in Great Britain. [http://www.ash.org.uk/files/documents/ASH\\_891.pdf](http://www.ash.org.uk/files/documents/ASH_891.pdf) (accessed on 4th June 2014)

<sup>xxxix</sup> McNeill A, Brose LS, Calder R, Bauld L & Robson D., Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England, 2018

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