1. Executive Summary

1.1. BAT is pleased to offer evidence to the Commons Select Committee on Science and Technology “the committee” and respectfully requests the opportunity to provide oral evidence.

1.2. E-cigarettes and other alternative nicotine products represent a huge technological revolution that has led to new potential opportunities for tobacco harm reduction.

1.3. There is a growing body of evidence that indicates that e-cigarettes are a less harmful alternative to tobacco. This growing body of evidence is being added to every day, by governments, NGOs and private sector companies.

1.4. E-cigarettes have provided an exit out of smoking for millions of smokers. Concerns about the possible effect on re-normalisation of and “gateway” into smoking are proving unfounded.

1.5. Nevertheless, consumers are choosing these products because of their growing confidence. This is due to an increasing focus on product standards coupled with innovation.

1.6. However, a number of issues are potentially inhibiting the growth of the category, namely the introduction of disproportionate regulation and a need to ensure that all players in the market adhere to the highest level of product standards.

1.7. E-cigarettes are just one part of this story, with new and innovative products such as tobacco heated products and other non-tobacco products (such as tobacco free nicotine pouches), offering consumers new potential alternatives to smoking. Consumers are actively looking for new products and new avenues, but 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. Therefore, we believe that it is important that the committee consider not just e-cigarettes, but what can be done to support the innovation and evolution of the whole non-combustible tobacco and nicotine product category. 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 no single solution for all consumers and consumer choice must be at the heart of both category innovation and policy.

1.8. At BAT, we know that the growth of the e-cigarette category is about understanding and responding to consumers and offering them choice. We were the first tobacco company to launch an e-cigarette in the UK and today we are market leaders. We sell e-cigarettes through a range of channels, online, in large and small retail stores and through pharmacies such as Lloyds and Boots.

1.9. We believe that it is vital that the market is supported to allow innovation and the growth of the e-cigarette and other alternative tobacco nicotine product categories. To this end, we invest heavily in our own research and development (R&D) activities and have published 109 scientific papers in the last three years. We have 1,500 people employed across science, technology and innovation and 55% of senior R&D talent are now external hires. There are more people employed in our R&D Centre in Southampton today, dedicated to science, innovation and technology, than were employed when the site was a tobacco factory.
2. Key issues relating to Health

2.1. Understanding impact on human health of e-cigarettes

2.1.1. An increasing number of health experts have concluded that e-cigarettes manufactured to robust quality and safety standards are less harmful than 'conventional' tobacco products. E-cigarettes do not contain tobacco, they do not rely on combustion and, therefore, no smoke or tobacco tar is formed when the e-liquid is "vaped".

2.1.2. Whilst e-cigarettes contain nicotine, which is addictive, the harm of smoking is primarily caused by other constituents of tobacco smoke. This has generally been acknowledged by public health organisations\(^1\), such as Public Health England and the Royal College of Physicians\(^2,3\).

2.1.3. A number of recent scientific studies have reinforced that e-cigarettes are likely to be significantly less hazardous than 'conventional' tobacco products. For example:

- A study funded by Cancer Research UK (2017)\(^4\) 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.
- A study by Chen et al., (2017)\(^5\) conducted a comparative health risk assessment of e-cigarettes and conventional cigarettes and suggested the use of e-cigarettes could save lives.
- A study by Levy et al., (2017)\(^6\) 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 86.7 million fewer LYL [life years lost] due to cigarette use occur in the Optimistic Scenario."

2.1.4. We are aware that some studies have pointed to the potential adverse health effects of e-cigarettes. For example, the USSGR Report (2016)\(^7\) and WHO Report (2016)\(^8\) raise a number

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1 See, for example, statements by the International Agency for Research on Cancer ("IARC"), the UK National Institute for Health and Care Excellence ("NICE"), and the Truth Initiative.
2 "[t]he harm of smoking is therefore caused not by nicotine, but by other constituents of tobacco smoke. Non-tobacco nicotine products that reproduce the nicotine delivery and behavioural characteristics of smoking, without the many other toxins in tobacco smoke, therefore have the potential to allow smokers to continue to use nicotine and avoid the significant harm to themselves and others that smoking causes."
3 Royal College of Physicians (2016), Nicotine without smoke: Tobacco harm reduction at p. 184.
7 US Surgeon General ("USSGR") (2017), E-Cigarette Use Among Youth and Young Adults
8 WHO FCTC (2016), Report on Electronic Nicotine Delivery Systems ("ENDS") and Electronic Non-Nicotine Delivery Systems ("ENNDS") to the
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) and the UK Centre for Tobacco and Alcohol Studies). Our view is also that e-cigarettes are not suitable for pregnant or breast-feeding women, people under the age of 18, people who are allergic/sensitive to nicotine, people who should avoid tobacco or nicotine products for medical reasons, or people with an unstable heart condition, severe hypertension or diabetes.

2.1.5. We acknowledge that e-cigarettes are not risk free and agree that more research is needed into the long-term effects of the use of e-cigarettes. 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. Given this, a growing number of public health authorities and experts have expressed the view that if we wait for long term evidence to emerge and prohibit or hinder the use of e-cigarettes, we could miss a tremendous opportunity to save lives on a large scale.

2.1.6. To this end, we invest heavily in our own research and development (R&D) activities. We have 1,500 people employed across science, technology and innovation and 55% of senior R&D talent are now external hires. There are more people employed in our R&D Centre in Southampton today, dedicated to science, innovation and technology, than were employed when the site was a tobacco factory. We have published 109 scientific papers in the last three years. In common with best regulatory practice in assessing reduced risk, we have developed a suite of different studies for our products that look at not only the composition of the vapour but also issues such as how these products are used in real life and the impact of the vapour on human cells cultured in the laboratory.

2.1.7. We are also in the process of commencing two long-term clinical studies for both our e-cigarette product (Vype) and our tobacco heating product (glo) to understand better the likely effects of long term usage.

2.2. The benefits and risks of e-cigarettes as a ‘stop smoking’ tool alongside any gaps in evidence

2.2.1. BAT does not market its products as 'stop smoking' devices. Claims relating to smoking cessation can only be made on products that have been licensed by the Medicines and Healthcare products Regulatory Agency (MHRA). However, we are aware that there is a growing body of scientific evidence\(^9,10,11\) that supports the use of e-cigarettes in assisting

\(^9\) Shu-Hong et al., (2017) *E-cigarette use and associated changes in population smoking cessation: evidence from US current population surveys.* BMJ 2017


smoking cessation, such as a recent study by Levy 12 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.13

2.2.2. We also refer the Committee to the Submission by Associate Professor Colin Mendelsohn (2017), ‘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.

2.2.3. We further note that a growing number of governments and public health bodies, including UK NHS, the National Centre for Smoking Cessation and Training, Cancer Research UK, and New Zealand Ministry of Health, actively support e-cigarettes as part of their tobacco harm reduction activities.14

2.2.4. We also note that the Government’s own Tobacco Control Plan15 commits Public Heath England to:

“provide evidence based guidance for health professionals to support them in advising smokers who want to use e-cigarettes or other nicotine delivery systems to quit”

2.2.5. We are aware of the growing proliferation of e-cigarettes as part of local authority stop smoking strategies. While we do not, and cannot, make any claims regarding smoking cessation, it is clear many stop smoking services are doing so. As NHS trusts continue their drive to reduce the level of smoking, we believe that the e-cigarette industry has a role in this.

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

"Gateway Effect"

2.3.1. As the evidence above shows, e-cigarettes have provided a gateway out of smoking for

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13 ASH: Use of E-cigarettes among adults in Great Britain. May 2017

14 We note, that some studies and public health experts have also pointed to the potential role of e-cigarettes in assisting people with serious mental illness to cease smoking. See, for example, the study by Ratschen (2014), Electronic cigarettes in mental health settings – solving a conundrum? Psychiatric Bulletin, 38(5):226-9.

millions of smokers. 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.

2.3.2. Furthermore, no meaningful data support the proposition that e-cigarettes have a ‘gateway effect’ on youth smoking. 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."

For example:

- A recent systematic review of the evidence conducted by the University of Victoria, Canada (2017) 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".

- A UK study by Bauld et al., (2017) which assessed recent trends in ever and regular use of e-cigarettes and tobacco among 11-16 year olds, similarly found that their "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."

- A US study published by Kozlowski et al., (2017) also concluded that "risks for youth posed by e-cigarettes likely fall far short of those feared by the products' opponents" and that, currently "youth use of e-cigarettes is unlikely to increase the ranks of future cigarette smokers."

- 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, a study by Conner et al., (2017) which, concluded that e-cigarette use among adolescents is associated with smoking initiation. However, this study has been criticised by experts, such as Professor Linda Bauld noting the study does not provide evidence that using e-cigarettes causes young people to become smokers. Similarly, a study by Soneji et al.,
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."  

"Re-normalisation"

2.3.3. It is clear that E-cigarettes support tobacco control efforts and no reliable data supports the proposition that e-cigarettes "re-normalise" smoking. A review of the available evidence by PHE (2015) 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."

2.3.4. Many studies also contradict renormalisation concerns and indicate that e-cigarettes may contribute to lower smoking prevalence rates. For example, a study by ASH (2017) found that for the first time there were more ex-smokers than current smokers using e-cigarettes. These findings are also supported by data from the US Center for Disease Control and Prevention ("CDC") National Health Interview Survey (2016), which 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.

27 ASH Fact Sheet (May 2017), Use of e-cigarettes (vapourisers) among adults in Great Britain
28 "[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."
3. Key Issues relating to regulation

3.1. New regulations have changed the Market

3.1.1. The introduction of the Tobacco Products Directive 2014 (“Directive”)\(^ {30}\) brought a sweeping set of changes to the e-cigarette market. Prior to the introduction of the Directive (transposed into UK law via the Tobacco and Related Products Regulations 2016 (“Regulations”)\(^ {31}\)), e-cigarettes were regulated as consumer products and subject to general consumer regulation. The Directive introduced a new and comprehensive regulatory regime covering almost all aspects of the development, marketing and sale of e-cigarettes.

3.1.2. We believe that key elements of the Directive are important in building consumer confidence such as the provisions that ensure consumers are aware of the ingredients contained within e-liquids as well as requirements ensuring e-cigarettes benefit from increased scrutiny and oversight to ensure that consumers are protected and fully informed of any potential risks as well as the requirements regarding childproofing of products.

3.1.3. BAT has been one of the key proponents of strengthening quality controls and enhancing standards across the category. In 2015, BAT was part of a group of seven stakeholders who worked with the British Standards Institute\(^ {32}\) to develop the first set of standards for e-cigarettes covering purity of e-liquids, emissions analysis and battery safety.

3.2. However certain elements of the Directive and the Regulations have gone too far

3.2.1. Since 2014, when the Directive was agreed, there has been a growing body of evidence demonstrating the potential benefits of e-cigarettes. Therefore, it is argued that the Directive, and therefore the Regulations, are not up to date and that some elements of the Directive/Regulations were designed without a full understanding of the implications.

3.2.2. We believe that certain aspects of the Directive and the Regulations have little impact in protecting consumers - for example requirements on minimum tank/cap/bottle sizes. These rules were introduced without evidence as to their impact and rather such measures restrict choice and make vaping less appealing to smokers who might otherwise switch. This is important because there are still many smokers in the UK who have either never tried e-cigarettes or have reverted back to cigarettes. We believe that these restrictions should be reconsidered at the earliest possible opportunity to allow the category to continue to grow.

3.2.3. Similarly, the heavy restrictions on advertising have undermined consumer knowledge of the category and contributed to a growing confusion amongst adult consumers regarding the potential benefits of these products. A recent ASH survey noted:\(^ {33}\) “A growing proportion of the public and smokers fail to recognise that e-cigarettes are less harmful than smoking. In 2017 only 13% of adults correctly identified that e-cigarettes are a lot less harmful than smoking compared to 21% in 2013”.

\(^{30}\) Tobacco Products Directive 2014 implemented in the UK as the Tobacco and Related Products Regulations 2016
\(^{33}\) ASH: Use of E-cigarettes among adults in Great Britain. May 2017
3.2.4. The advertising restrictions required under the Directive have limited the ability of responsible manufacturers and retailers to provide accurate and complete information about these products to adult consumers, including those considering switching away from cigarettes. The restrictions introduced by the Directive and transposed via the Regulations are unnecessarily restrictive, and undermine adult consumer knowledge of this category.

3.2.5. Nevertheless, we welcome the work of the Advertising Standards Authority (“ASA”), the Committee on Advertising Practices and the Department of Health, who have made a pragmatic attempt to provide as much clarity and flexibility as they can within the current regulatory structure. In this respect, we welcomed the recent proposal by the ASA to remove the prohibition on health claims from unlicensed nicotine containing e-cigarettes. The removal of this prohibition should allow manufacturers to make more legitimate and substantiated claims about their products thus enabling adult consumers to make fully informed choices. However, the extreme restrictions on where advertisements can be placed will remain unless Government action is taken to open up the channels to allow consumers to be properly informed.

3.2.6. On that basis, we would recommend that the Government takes the opportunity to reconsider the impact of these Regulations and in particular:

- As acknowledged in the Tobacco Control Plan, urgently conduct a regulatory impact assessment of the Regulations to determine if there are areas for review and repeal – particularly in light of BREXIT.
- Identify opportunities (which it is acknowledged may only be able to take effect post-BREXIT), to relax the restrictions on marketing and advertising to allow responsible marketing in line with other industries.

3.3. The importance of enforcement

3.3.1. As noted by the recent All Party Parliamentary Group on e-cigarettes to be effective, regulations must be enforced or they risk being devalued entirely. According to the APPG report, the vaping industry has invested over six million pounds in meeting and adopting the Directive/Regulations. This is not a question of scale of business, with business of all sizes spending considerable sums to ensure compliance. It is incumbent on regulators and enforcement agencies to ensure that the Regulations that are in place are fully enforced.

3.3.2. While it is difficult to fully ascertain the scale of the issue, we have seen instances of sales of products that do not conform to various elements of the TPD including labelling requirements, tank size and other elements.

3.3.3. It is vital that enforcement agencies such as Trading standards take a robust approach to those who do not comply with the Regulations and we would recommend greater resources are provided to support them achieving this.

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3.4. The importance of a supportive taxation policy

3.4.1. The Government’s Tobacco Control Plan 2018[1] stated that the evidence is increasingly clear that e-cigarettes are a less harmful alternative to smoking tobacco. The Government is endorsing their use as such. A supportive taxation policy is required to support such a plan.

3.4.2. If an excise duty were levied on e-cigarettes, this would increase their price and reduce consumers’ incentive to continue to switch from conventional cigarettes to e-cigarettes. This would be contrary to the Government’s support for the use of e-cigarettes as part of their tobacco harm reduction activities.

3.4.3. On that basis, we believe that the Government should confirm that it will not introduce excise for e-cigarette and e-liquid products

4. Key Issues relating to finance

4.1. Creating a “Centre of Excellence”

4.1.1. The UK e-cigarette market is the world’s second largest behind the US. In addition, the UK is a progressive country in terms of its approach to harm reduction. The UK has already established itself as a global leader in many aspects of e-cigarette policy. We believe the opportunity exists for the UK to be the “Silicon Valley” of e-cigarettes and a “centre of excellence.”

4.1.2. As the global market for e-cigarettes develops, the UK is uniquely placed to gain a competitive advantage in e-cigarette innovation and development. The global market for e-cigarettes is growing every year. EY estimates that by 2020, sales are projected to rise to just under £12bn, increasing at a Compound Average Growth Rate (CAGR) of 17% per year.

4.1.3. As noted by the Government’s own industrial strategy, the ability to innovate is critical to Britain’s future economic success. At present, there are only a small number of businesses, BAT being one, which have the capacity to carry out a high standard of e-cigarette related research and innovation regarding the e-cigarette category here in the UK.

4.1.4. At our global R&D facility in Southampton, we have invested heavily in our laboratories and have brought together over 250 scientists from a range of disciplines (including 50 PHDs) to develop and innovate new and more advanced e-cigarettes and vapour products. BAT shares the Government’s ethos of embracing innovation to create good jobs and secure existing jobs.

4.1.5. There are some who question the role of tobacco companies in the e-cigarette debate. We believe that we have much to offer in terms of consumer knowledge, R&D knowledge and expertise. We believe that the Government should create an industry/government roundtable to help develop a long-term approach to supporting the continued growth of the industry and making the UK the global leader in e-cigarette innovation creating thousands of new jobs.

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5. Novel Tobacco Products and other alternatives to tobacco

5.1. Whilst the Committee has invited comments on the health, regulatory and financial implications of e-cigarettes, we understand that there exist gaps in the knowledge regarding other potential alternatives to smoking such as tobacco heating products ("THP") and tobacco free nicotine pouches. The following section has been included to provide some basic background knowledge to such products, which we would be happy to supplement.

5.2. Tobacco heated products

5.2.1. A THP is a category of device and tobacco consumable that is designed to reduce the emissions from tobacco when consumed.

5.2.2. THPs contain tobacco, however, their properties and mode of operation mean that they are very different to conventional combustible tobacco products, including cigarettes. THPs achieve this by controlled heating of a tobacco consumable to temperatures much lower than are achieved in a burning cigarette.

5.2.3. The consumer inserts a tobacco consumable into the device and turns it on by means of a button which initiates the heating of the tobacco. Once the initial heating phase is complete, the tobacco heating product is ready to be used. The tobacco heating product generates heated tobacco vapour composed mainly of water, glycerine, nicotine and flavour. The product thereby enables the adult user to inhale and exhale the heated tobacco vapour.

5.2.4. Once this cycle is complete, the tobacco consumable is removed from the device and a new one must be inserted for the next use.

5.2.5. THPs are fundamentally different to all forms of combustible tobacco, including cigarettes, roll-your-own tobacco, pipe tobacco, cigars and cigarillos. This is because:

- The tobacco in THPs is heated (typically at temperatures between 250-350°C), but is not burnt. When cigarettes are smoked, conversely, the tobacco in them is heated at much higher temperatures (in excess of 900°C), and burns.
- No cigarette smoke is created from THPs which, instead, produce a nicotine-containing aerosol (known colloquially as ‘tobacco vapour’), composed mainly of water, humectant (e.g. glycerol), nicotine and flavourings.

5.2.6. The emerging scientific evidence is pointing towards the potential for substantially reduced risk from using THPs as compared to cigarettes. Scientists at BAT have used a series of tests...
specifically developed to help assess the potential risk profile of its THPs relative to cigarettes. The tests included analysing how people use the products, the content of the vapour and what that vapour does to cells in certain laboratory tests. The results were then combined to create an overall picture that shows the vapour to be relatively simple compared to cigarette smoke and to have much less, or no (depending on the particular test used), impact on cells in the lab compared to cigarette smoke. We are currently conducting further clinical studies to further assess the risk profile of THPs relative to cigarettes which will be subject to peer review.

5.2.7. Although there exists third party evidence from several UK and international public health bodies and researchers on the likely risk reduction from using e-cigarettes compared to smoking cigarettes, no scientific research on the harm from THPs has yet been conducted by independent third parties.

5.2.8. However, as more scientific insight is generated it will be important that THPs and combustible cigarettes be treated separately from a regulatory perspective given their potentially different risk profiles, including the excise treatment of THPs.

5.3. Snus and tobacco free nicotine pouches

5.3.1. Snus is a smokeless tobacco product, which is consumed by placing a small pouch of tobacco under the lip and against the gum, to allow the nicotine to be absorbed quickly into the body. It is banned in the UK but is legal in Sweden.

5.3.2. As part of our commitment to offering consumers alternatives to tobacco, we have a tobacco free nicotine pouch product which, is used in a similar way to Snus pouches. It is an innovative and new product that uses environmentally friendly methods in its production.

5.3.3. However, while this product is similar to Snus, it differs in a number of crucial areas. Most importantly it contains no tobacco and releases no vapour but still provides the nicotine that consumers look for. What many people do not realise is that it is the toxicants in cigarette smoke released from the burning of tobacco that cause the majority of smoking related diseases, not the nicotine. As the UK National Institute for Health & Care Excellence (NICE) said in their 2013 report: “Most health problems are caused by other components in tobacco smoke, not by the nicotine.”

5.3.4. However, because nicotine is an addictive substance the use of which can lead to dependence, we believe nicotine products should only be consumed by informed, adult consumers. Further, certain groups of people, such as those suffering from unstable heart disease, severe hypertension or diabetes, and pregnant women, should not use nicotine.

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39 However, it is important when interpreting results from scientific tests to distinguish between the level of toxicants heated tobacco products produce relative to combustible tobacco from the relative likelihood that this will translate into a reduction in smoking-related diseases. It is not yet possible for us to translate the relative level of toxicants from heated tobacco products into what it is likely to mean in terms of the consumer’s exposure to those toxicants and, in turn, the likely risk of contracting disease compared to cigarettes.

40 Tobacco: Harm reduction approaches to smoking, a report by the UK National Institute for Health and Care Excellence (NICE), 2013