

SUBMISSION BY BRITISH AMERICAN TOBACCO TO THE ICELANDIC HEALTH MINISTRY IN RESPECT OF PUBLIC CONSULTATION ON THE DRAFT BILL 202 ON AN ACT ON E-CIGARETTES AND REFILL CONTAINERS FOR E-CIGARETTES – RAFRETTUR OG ÁFYLLINGAR FYRIR RAFRETTUR, AS AMENDED (the “LAW”)

1. INTRODUCTION

- a. This is British American Tobacco P.L.C (“**BAT**”) submission (the “**Submission**”), to the Icelandic Health Ministry concerning the public consultation on a draft bill to amend the act on e-cigarettes and refill containers for e-cigarettes, as previously amended (the “**Bill**”).
- b. British American Tobacco appreciates the opportunity to submit its comments on the Bill on e-cigarettes and refill containers for e-cigarettes.
- c. We support regulation of vaping products that is balanced and evidence-based and which upholds the principles of consumer choice for adults, particularly for adult smokers who wish to find an alternative to tobacco products. BAT therefore fully supports the proposed prohibition under the Bill on the sale of e-cigarettes to persons under 18. However, in the context of supporting such balanced and evidence based regulation, BAT wishes to express its concern about the Bill’s proposed extension of the:
 - i. restriction on the visibility of tobacco and tobacco trademarks at point-of-sale in Iceland to apply to e-cigarettes; and
 - ii. ban on all forms of advertising of tobacco and smoking accessories in Iceland to e-cigarettes and refill containers.

By restricting the visibility and information about harm reduced products e.g. like e-cigarettes the law itself will “freeze” the market and most likely reduce the migration of existing smokers to less harmful products. As will be further explained below, in these respects the Bill appears to be unsupported by, and running counter to, available evidence.

- d. In order to contextualise our submissions on our specific concerns regarding the Bill (as stated above), we have firstly set out below a brief overview of the current state of evidence regarding e-cigarettes (paragraph 2).

2. E-CIGARETTES: THE EVIDENCE TO SUPPORT POTENTIAL PUBLIC HEALTH BENEFITS AND HARM REDUCTION

- a. E-cigarettes do not contain tobacco, they do not rely on combustion and, as a consequence, no smoke is formed when the e-liquid is “vaped” and no tobacco tar is produced. Instead, they work by heating a liquid typically containing nicotine in a solution of either propylene glycol and/or vegetable glycerin. The heat atomises the liquid, turning the solution into a vapour. The resulting vapour is inhaled, delivering the nicotine to the user.

- b. It is widely acknowledged that it is the other constituents in cigarette smoke that cause the majority of smoking related disease, such as cancer, heart disease or pulmonary disease, not the nicotine. As reported by the Royal College of Physicians: "*[a]lthough nicotine is the addictive component of tobacco products it is the toxins and carcinogens in tobacco smoke that cause most of the harm from using tobacco.*"¹ The UK National Institute for Health and Care Excellence similarly concludes: "*Most health problems are caused by other components in tobacco smoke, not by the nicotine.*"²
- c. An independent expert review commissioned by Public Health England (2018)³, which updates the evidence from its landmark 2015 report, found, *inter alia*, that:
- i. "*[v]aping poses only a small fraction of the risks of smoking and switching completely from smoking to vaping conveys substantial health benefits over continued smoking. Based on current knowledge, stating that vaping is at least 95% less harmful than smoking remains a good way to communicate the large difference in relative risk unambiguously so that more smokers are encouraged to make the switch from smoking to vaping. It should be noted that this doesn't mean e-cigarettes are safe.*"
 - ii. "*To date, there have been no identified health risks of passive vaping to bystanders.*"
- d. A recent 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.
- e. A study by Chen et al., (2017)⁵ conducted a comparative health risk assessment of e-cigarettes and conventional cigarettes. The study found that whilst "[t]he health effects of using ECs [e-cigarettes] are still not well understood...current evidence points to ECs being less harmful than CCs [combustible cigarettes]. 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."

¹ Tobacco Advisory group of the Royal College of Physicians. 2007. *Harm reduction in nicotine addiction. Helping people who can't quit.* London RCP.

² UK National Institute for Health and Care Excellence (NICE). 2013. *Tobacco: Harm reduction approaches to smoking.*

³ 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.

⁴ Shahab et al., (2017) *Nicotine, Carcinogen, and Toxin Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users.* Ann Intern Med, 390-400.

⁵ 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.

- f. A study by Levy et al., (2017)⁶ modelled the population impact in the future if more smokers in the US switched to e-cigarettes. They estimated that taking into account several parameters such as cessation, initiation and relative harm, switching cigarette smokers to e-cigarette use over a 10-year period would lead to 1.6 to 6.6 million fewer premature deaths in the US under a pessimistic and optimistic scenario respectively. The authors concluded that "*a strategy of replacing cigarette by e-cigarette use can yield substantial gains, even with conservative assumptions about related risks. Most important, an e-cigarette substitution strategy provides the justification to redouble efforts to target cigarette use, as it is called for by the WHO Framework Convention for Tobacco Control.*"
- g. A recent systematic review noted that "*Comparing the emissions of vaping to smoking, the studies are very encouraging for the potential of vapour devices for tobacco harm reduction. Vapour devices do not deliver tar, and emissions do not contain 61 of 79 cigarette toxins. Vaping produced exponentially lower level of cancer causing agents, tobacco-specific nitrosamines, and volatile organic compounds.*"⁷ The report does acknowledge however, that further research is needed.
- h. Finally, a panel of experts in nicotine science, medicine, toxicology and public health policy applied a multi-criteria decision analysis approach, developed by the Independent Scientific Committee on Drugs in 2010, to tobacco and nicotine products based on harms to users and harms to the wider society. The study attributed a relative harm score of 100% for conventional cigarettes, while giving a score of 4% for vaping products⁸.
- i.
- j. In view of this evidence, there is a growing international consensus that vaping products have the potential to be significantly less risky than conventional cigarettes and that they have a significant potential for harm reduction. In May 2014, 53 leading experts on Nicotine Science and Public Health Policy addressed a letter to Margaret Chan, Director General of the World Health Organization, expressing their concern about the marginalization of and insufficient emphasis on harm reduction as part of a critical strategy of tobacco policy. These experts concluded: "*The potential for tobacco harm reduction products to reduce the burden of smoking related disease is very large, and these products could be among the most significant health innovations of the 21st Century – perhaps saving hundreds of millions of lives. The urge to control and suppress them as tobacco products should be resisted and instead regulation that is fit for purpose and designed to realize the potential should be championed by WHO.*"⁹
- k. In July 2016, the potential use of e-cigarettes in a public health strategy was also recognized in a guidance document on the use of e-cigarettes in public places and workplaces published by

⁶Levy et al., (2017) *Potential deaths averted in USA by replacing cigarettes with e-cigarettes*. Tobacco Control. Aug 30.

⁷ See 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.)

⁸ Nutt et al, *Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach* . Eur Addict Res 2014;20:218–225, at 224, Fig 3 at 223. See also Fagerström Report, ¶ 20 and fn. 18.

⁹ Letter to Margaret Chan, Director General WHO. Signed by 53 leading public health leaders from around the world. Available at <<http://nicotinepolicy.net/documents/letters/MargaretChan.pdf>>

Public Health England. Its authors concluded that *"We believe e-cigarettes have the potential to make a significant contribution to its achievement. Realizing this potential depends on fostering an environment in which e-cigarettes can provide a route out of smoking for England's eight million smokers, without providing a route into smoking for children or non-smokers."*¹⁰

- l.** Bearing in mind the significant potential for public health benefits and harm reduction, BAT argues in favor of an evidence-based regulatory framework that provides adult consumers with access to vaping products that are manufactured to robust quality and safety standards without imposing unwarranted or disproportionate restrictions.
- m. Gateway Effect:** Regarding the "gateway effect", there are no rigorous studies that demonstrate that the use of e-cigarettes by young people – let alone the visibility of e-cigarette use in indoor public places – causes increased smoking. The ASH UK study (and several others, for example the Pearson et al. (2012) and Gmel et al. (2013) studies¹¹) shows that the incidence of e-cigarette use among never smokers is very low, and that e-cigarette trial and usage is far more prevalent among existing and former smokers.
- n.** Similarly, the 2018 review of the evidence by Public Health England, found that *"If EC use was causing smoking at the population level, these reductions in youth cigarette smoking [in the UK] would have significantly slowed or indeed reversed in the UK. This is not happening, and suggests that EC are not currently undermining what decades of efforts to prevent youth smoking uptake have achieved"*. Another review of the available research concluded that *"although there have been claims that [e-cigarettes are]... acting as a 'gateway' to smoking in young people, the evidence does not support this assertion. Regular use of [e-cigarettes] by nonsmokers is rare and no migration from [e-cigarettes] to smoking has been documented (let alone whether this occurred in individuals not predisposed to smoking in the first place). The advent of [e-cigarettes] has been accompanied by a decrease rather than increase in smoking uptake by children."*¹²
- o.** Further, a 2016 report by the UK's Royal College of Physicians concluded that: *"[r]enormalisation concerns, based on the premise that e-cigarette use encourages tobacco smoking among others, also have no basis in experience to date"*.¹³ A recent systematic review also noted that *"tobacco use in the US, Canada, and other countries is declining significantly among 12 – 19 year olds as vapour device use is increasing. Two independent regression*

¹⁰ Public Health England (2016), Use of e-cigarettes in public places and workplaces – Advice to inform evidence-based policy making, available at <https://www.gov.uk/government/publications/use-of-e-cigarettes-in-public-places-and-workplaces>

¹¹ Gmel G et al. *Use of electronic cigarettes among young Swiss men.* J Epidemiol Community Health (2013). See also Pearson JL et al. *e-Cigarette awareness, use, and harm perceptions in US adults.* (Am J Public Health 2012)

¹² See Hajek et al. *Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit,* Addictio (2014) citing US Center for Disease Control and Prevention. National Youth Tobacco Survey (NYTS). Smoking and Tobacco Use. 2012.

¹³ Nicotine without smoke: Tobacco harm reduction: a report by the Tobacco Advisory Group of the Royal College of Physicians. Available at < <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoketobacco-harm-reduction-0>>

analyses provide solid evidence against a gateway effect. Comparing rates of youth tobacco use in US states with and without bans on sales to minors, where adolescents had access to vapour devices, the prevalence of tobacco use was lower.”¹⁴

3. RETAIL DISPLAY BAN

- a. It is noted that the Bill proposes to apply the restrictions on the visibility of tobacco products at point-of-sale to e-cigarettes (Article 10 of the Bill).
- b. BAT is of the clear opinion that visible display of e-cigarettes in stores should be allowed.
- c. As discussed above, the scientific evidence demonstrates that e-cigarettes have the potential to be significantly less hazardous than conventional cigarettes. Given their reduced-risk potential, they should have fewer retail display restrictions than cigarettes.
- d. A display ban will make it harder for suppliers of e-cigarettes to become established in the Icelandic market and communicate information regarding the products to allow consumers a proper opportunity to make an informed choice. E-cigarettes are relatively unknown to consumers compared to conventional cigarettes, and their potential to contribute to tobacco harm reduction will be impeded if consumers are unaware of their availability and attributes.
- e. We believe that because of the potential of e-cigarettes to play a significant role in tobacco harm reduction, retail display should be permitted to ensure that they are a visible, available and accessible alternative for smokers. Limiting their retail display and regulating them in the same way as conventional cigarettes makes it harder for smokers to know of their availability, discourages switching, and may give rise to misperceptions regarding their potential public health benefits relative to cigarettes.

4. ADVERTISING BAN

- a. It is noted that the Bill proposes to apply the ban on all forms of advertising of tobacco products to e-cigarettes and refill containers (Article 10 of the Bill).
- b. We believe that proportionate marketing freedoms are essential to enable the e-cigarette category to fulfil its likely potential in terms of public health benefits.
- c. 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 access objective and factual information about the products. This has been recognized by public health organisations, including Public Health England, which in 2018

¹⁴ See 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.).

found 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."¹⁵ NGOs including ASH have also 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".¹⁶

- d. In August 2016 the UK's Royal College of Physicians (RCP) released a comprehensive analysis of nicotine and e-cigarettes in its report "Nicotine without smoke: Tobacco harm reduction".¹⁷ In this report the RCP recommended that *"in the interests of public health it is important to promote the use of e-cigarettes, NRT and other non-tobacco nicotine products as widely as possible as a substitute for smoking in the UK."*

- e. We would urge you to have regard to the treatment of e-cigarettes in the United States (the "US"), as an example of a less restrictive advertising regime, which presents an approach that is cognizant of the potential public health benefits of e-cigarettes. In the US, the Food and Drug Administration ("FDA") Deeming Regulations (the "**Deeming Regulations**"), which regulate e-cigarettes at the federal level,¹⁸ prescribe a flexible advertising regime for e-cigarettes.

- f. The Deeming Regulations currently permit advertisements on, for example: *"promotional materials (point-of-sale or non-point-of-sale), billboards, posters, placards, published journals, newspapers, magazines, other periodicals, catalogues, leaflets, brochures, direct mail, shelf-talkers, display racks, Internet Web pages, television, electronic mail correspondence, and also include those communicated via mobile telephone, smartphone, microblog, social media Web site, or other communication tool; Web sites, applications, or other programs that allow for the sharing of audio, video, or photography files; video and audio promotions ..."*¹⁹ The FDA has noted that it *"will consider the health effects of all products before determining whether to issue additional regulations"*.²⁰

5. THE PROPOSALS ARE DISPROPORTIONATE

- a. The Bill's proposed extension to include a retail display ban of products, and a blanket prohibition on the advertising of e-cigarettes is disproportionate. The proposals are not supported by and run counter to, the growing scientific evidence and as such the proposal could undermine the potential public health benefit of e-cigarettes. In addition, there are effective,

¹⁵ 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

¹⁶ ASH fact sheet April 2014, Use of Electronic Cigarettes by adults in Great Britain. http://www.ash.org.uk/files/documents/ASH_891.pdf (accessed on 4th June 2014)

¹⁷ Nicotine without smoke: Tobacco harm reduction: a report by the Tobacco Advisory Group of the Royal College of Physicians. Available at < <https://www.rcplondon.ac.uk/projects/outputs/nicotine-withoutsmoke-tobacco-harm-reduction-0>>

¹⁸ The Deeming Regulations have been in effect since 8 August 2016. Note that e-cigarettes are also regulated at a State level.

¹⁹ Deeming Regulation, 81 FR at 29062, see also 29064. Note that any such advertisements are permitted subject to various requirements under the Deeming Regulations.

²⁰ Deeming Regulation, 81 FR at 29042.

balanced, alternatives to meet public health objectives.

- b.** The proposals are not necessary or adequate for the purpose of reducing risks to public health because:
- i.** Policies need to be clear on the differences between vaping and smoking. As noted by Public Health England: "*If e-cigarettes are to do their job of making smoking less of a social norm, they must be clearly positioned as products that help adult smokers to quit. In this way, vaping becomes synonymous with the rejection of smoking.*"²¹
 - ii.** There is no credible evidence suggesting that the retail display of products increases youth initiation. As outlined above, studies show that the incidence of e-cigarette use among never smokers is very low, and that e-cigarette trial and usage is far more prevalent among existing and former smokers. Banning the retail display of products undermines their potential as a visible, available and accessible alternative for adult smokers.
 - iii.** A complete advertising ban would undermine the potential of e-cigarettes as an alternative to smoking. It is important that consumers who may use e-cigarettes have ready access to accurate product information and also understand that e-cigarettes represent a potential harm reduced alternative to combustible tobacco products. As such, responsible marketing is critical both to convey information and to denote clearly the difference between e-cigarettes and combustible tobacco products.
- c.** There are more effective and less onerous alternatives to ensure that e-cigarettes are as safe and effective as possible while managing the risks. These include:
- i.** Allowing the responsible display of e-cigarettes products at point of sale so that e-cigarettes are visible, available and accessible alternatives for adult smokers, while ensuring the enforcement of minimum age purchase laws.
 - ii.** Allowing the responsible marketing of e-cigarettes that is only directed at adults, both in terms of the content of such communications and by virtue of media placement. This would protect against advertising directed at youth while also ensuring that consumers can make fully informed choices and allowing e-cigarettes to be a visible, available and accessible alternative for adult smokers.

6. CONCLUSIONS

²¹ Public Health England (2016), Use of e-cigarettes in public places and workplaces – Advice to inform evidence-based policy making, available at <https://www.gov.uk/government/publications/use-of-ecigarettes-in-public-places-and-workplaces>.

- a. Cigarettes and e-cigarettes are fundamentally different products. E-cigarettes do not contain tobacco, there is no combustion and they do not produce smoke. Given the differences in product characteristics, e-cigarette use should not be subject to the same restrictions as conventional cigarettes.
- b. There is growing consensus among scientists and public health professionals that e-cigarettes are likely to be much less hazardous than conventional cigarettes and that they should be incorporated into a harm reduction strategy.
- c. Visible display of e-cigarettes in stores should be allowed, to allow consumers to make informed choices and allow for products with a potential reduced risk profile to be visible, available and accessible as an alternative for smokers.
- d. Proportionate marketing freedoms are essential to enable the e-cigarette category to reach its likely potential in terms of public health benefits.
- e. We support regulation of e-cigarettes that is balanced and evidence-based and which upholds the principles of consumer choice for adults, particularly for adult smokers who wish to find an alternative to tobacco products. There is currently insufficient evidence to restrict retail display or impose a blanket prohibition on advertising.