BRITISH AMERICAN TOBACCO NEDERLAND BV (BAT) – SAMENVATTING VAN REACTIE OP CONCEPT WIJZIGING TABAKS- EN ROOKWARENTWET MET BETREKKING TOT UITBREIDING ROOKVERBOD NAAR ROOKLOZE EN ALTERNATIEVE TABAKSVRIJE PRODUCTEN

Hieronder vindt u een Nederlandse samenvatting van het onderstaande Engelse document met ons uitgebreide Engelse antwoord op de raadpleging over de invoering van een uitbreiding van het rookverbod naar rookloze en tabaksvrije alternatieve producten. Indien gewenst vanuit de overheid zijn wij zeer bereid om het Engelse document met onze uitgebreide reactie te vertalen naar het Nederlands.

1.1 BAT is sterk gekant tegen de uitbreiding van het rookverbod in openbare ruimten naar rookloze producten en alternatieve tabaksvrije producten. De tot dusverre door de regering gevolgde procedure met betrekking tot het voorstel is gebrekkig en ondoordacht. Wij zijn ook van mening dat het voorstel ongerechtvaardigd is omdat de regering geen rekening heeft gehouden met de bewijskracht, het wetenschappelijk oordeel en de gegevens, waaruit blijkt dat rookloze producten en alternatieve tabaksvrije producten waarschijnlijk een fractie van de risico's van sigaretten vertegenwoordigen. Deze potentieel minder schadelijke rookloze en alternatieve tabaksvrije producten ("PRRP's") worden ten onrechte gekwalificeerd met alleen negatieve gevolgen; en de regering laat na te erkennen dat middels het invoeren van dergelijke extreme regelgeving het risico wordt gelopen dat het potentieel voor deze producten om een rol te spelen bij schadebeperking in Nederland aanzienlijk wordt ondermijnd.

1.2 Hoewel wij het voorstel om het rookverbod in publieke ruimten uit te breiden met het gebruik van PRRP's niet steunen, zijn wij het erover eens dat deze producten met aandacht en respect voor anderen moeten worden gebruikt en dat voor sommige instellingen het niet toestaan van dampen binnenshuis wellicht een geschikt middel zou zijn. Daarom zou het aan individuele bedrijven en bedrijfseigenaars zelf moeten zijn om te beslissen of ze het gebruik van dampen in hun gebouwen al dan niet verbieden.

1.3 De negatieve invloed van overmatige regulering van e-sigaretten is opgemerkt door het Britse Royal College of Physicians: *"[een] risicomijdend, voorzichtige aanpak van de regulering van e-sigaretten kan worden voorgesteld als een middel om het risico op vermijdbare schade tot een minimum te beperken… **indien echter deze aanpak er toe leidt dat e-sigaretten ook minder toegankelijk, minder smakelijk of acceptabel, duurder, minder gebruiksvriendelijk of farmacologisch minder effectief maakt, of de innovatie***

en ontwikkeling van nieuwe en verbeterde producten belemmert, dan veroorzaakt deze aanpak het instandhouden van roken." [1].

1.4 Wij zijn het ook eens met de aanbeveling van Public Health England dat: "*Om rokers te helpen stoppen met roken en rookvrij te blijven, zou een meer toegankelijke benadering van dampen geschikt kunnen zijn om de keuze om te dampen ten gunste van het roken te vergemakkelijken. In het bijzonder zouden dampers niet verplicht moeten zijn om dezelfde ruimte als rokers te gebruiken, omdat dit het stoppen met roken en rookvrij te blijven kan ondermijnen."*[2] Dit geldt ook voor andere PRRP's, zoals tabaksverwarmings producten en oraal in te nemen tabaksproducten.

1.5 **De regering heeft een gebrekkig en ondoordacht proces gevolgd.** Het niet uitvoeren en/of publiceren van een evaluatie en/of Regulatory Impact Assessment (RIA) voordat de inhoudelijke besluiten zijn genomen, betekent dat de besluiten zijn genomen zonder deugdelijk bewijsmateriaal of analyse van de kosten, voordelen of andere effecten van de maatregel en zonder rekening te houden met alternatieve beleidsopties. De algemene opmerkingen bevatten niet de nodige gegevens en analyses om de beleidsontwikkeling te ondersteunen of om aan te tonen dat de uitbreiding van het rookverbod tot PRRP's noodzakelijk, passend of evenredig is als beleidsmaatregel. Als zodanig kunnen ze niet worden gebruikt om beleidsaanbevelingen te ondersteunen.

1.6 **Het standpunt van de regering dat inbreng van leden van de tabaksindustrie op basis van artikel 5.3 van de FCTC minder gewicht zullen krijgen is gebrekkig.** De Nederlandse interpretatie van artikel 5 lid 3 is onjuist gaat en gaat nadrukkelijk in tegen de vereisten van nationaal recht, waaronder beginselen van natuurlijke rechtvaardigheid en procedurele rechtvaardigheid. Bovendien, in plaats van het uitsluiten van informatie van de tabaksindustrie, vereist artikel 5 lid 3 dat het contact met de tabaksindustrie op transparante wijze plaatsvindt. Nergens vereist het WHO-Kaderverdrag uitsluiting van de tabaksindustrie van het besluitvormingsproces. In het onderhavige geval middels deze inbreng op deze consultatie worden de opmerkingen en bewijzen van BAT op een open en transparante

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1 "a *risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm… **if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking";*** Royal College of Physicians (2016), Nicotine without smoke – Tobacco Harm Reduction.

2 "*To help smokers to stop smoking and stay smokefree, a more enabling approach to vaping may be appropriate to make it an easier choice than smoking. In particular, vapers should not be required to use the same space as smokers, as this could undermine their ability to quit and stay smokefree*"; 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.

manier gepresenteerd. Bijgevolg is er geen wettelijke basis om de opmerkingen en bewijzen van BAT uit te sluiten of minder zwaar te wegen.

1.7 **De regering erkent niet de rol die PRRP's kunnen spelen bij het terugdringen van tabaksschade, een essentieel onderdeel van een rationeel en effectief tabaksbeleid.** Het reguleren van PRRP's op dezelfde manier als voor roken bestemde tabaksproducten, gaat voorbij aan het concept van het verminderen van tabaksschade (tobacco harm reduction), dat is ingebed in het Wereldhandelsorganisatie (WHO) Raamovereenkomst inzake tabaksontmoediging ("FCTC") waar Nederland partij in is, en overeenkomt met de grondrechten, beschermd door de artikelen 1 (menselijke waardigheid), artikel 7 (eerbiediging van het privé- en gezinsleven) en 35 (gezondheidszorg) van het Handvest van de grondrechten van de Europese Unie. Door voor te stellen dat het rookverbod voor openbare gelegenheden wordt uitgebreid tot PRRP's, neemt de regering de impact van het besluit op de volksgezondheid in het algemeen niet in overweging.

1.8 **Het reguleren van PRRP's op dezelfde manier als voor roken bestemde tabaksproducten kan de productcategorie uitsluiten en zal de potentiële voordelen voor de volksgezondheid die ze bieden, ondermijnen**. De misvatting dat deze producten hetzelfde zijn als voor roken bestemde tabaksproducten zal daardoor aanhouden en het zal consumenten ontmoedigen om over te schakelen naar potentieel minder schadelijke alternatieven voor traditionele tabaksproducten.

1.9 **Er is steeds meer overeenstemming onder leidende gezondheidsexperts dat het uitsluitend gebruik van PRRP's minder risico's op schade met zich meebrengt in vergelijking met het roken van traditionele tabaksproducten**. Dit wordt onderstreept door het toenemende aantal internationale organisaties en specialisten op het gebied van de volksgezondheid (inclusief die van het “UK Royal College of Physicians and Public Health England”) die pleiten voor een evenwichtige regulering van PRRP's vanwege hun potentieel om bij te dragen aan de strategie voor het verminderen van tabaksschade.

1.10 **Er zijn bewijzen dat PRRP's hebben bijgedragen tot een afname van de rook prevalentie in landen met een flexibelere regelgeving, die consumenten tevens bewust maakt van de verkrijgbaarheid en kenmerken van PRRP’s.** Gegevens uit het VK, Japan, Noorwegen en Zweden, waar substantiële wettelijke vrijheden voor PRRP's bestaan, wijzen aan dat deze landen een enorme afname van de rookprevalentie hebben ervaren in vergelijking met rechtsgebieden zoals Australië, die een vergelijkbaar restrictieve benadering hebben gehanteerd voor het reguleren van dergelijke producten.

1.11 **Bezorgdheid over gezondheidsrisico's voor omstanders, 'renormalisatie' van roken en 'de ‘gateway (opstap naar roken) door gebruik vanPRRP's worden niet onderbouwd door het huidige bewijsmateriaal**. De positie van de Nederlandse regering is in strijd met vooraanstaande volksgezondheidsorganisaties (inclusief die van “Public Health England”,

“Cancer Research UK” en de “UK Royal College of Physicians”), die hebben geconstateerd dat er geen bewijs is dat een verbod op het gebruik van PRRP's op in publieke ruimten ondersteund en dat dergelijke verboden de potentiële voordelen voor de volksgezondheid van PRRP's kunnen ondermijnen. Hetzelfde standpunt wordt ingenomen door “Action on Smoking and Health” ("ASH") (een toonaangevende liefdadigheidsorganisatie op het gebied van anti-tabak in het VK).

1.12 **Er is geen enkele basis voor het opnemen van orale, rookloze producten of niet-nicotineproducten in het voorstel.** Bij het gebruik van orale producten komen er geen emissies vrij en leiden derhalve niet tot bezorgdheid bij omstanders. Evenzo kan er geen basis zijn voor het opnemen van elektronische niet-nicotineleveringssystemen binnen het toepassingsgebied van het voorstel, aangezien deze noch tabak noch nicotine bevatten.

1.13 Indien de regering serieus streeft naar het terugdringen van de rookprevalentie zou zij in plaats van de PRRP-categorie onderdrukken en mogelijk nieuwe producten volledig elimineren, ervoor moeten zorgen dat de consument wordt geïnformeerd over de groeiende wetenschappelijke consensus - dat e-sigaretten waarschijnlijk aanzienlijk minder risico's opleveren dan conventionele tabaksproductenm, dat tabaksverwarmingsproducten dat mogelijk ook doen, en dat rokers van sigaretten het risico op schade aanzienlijk kunnen verkleinen door volledig op dergelijke producten over te stappen. Gezien de potentiële rol van PRRP's in een “harm reduction-strategie”, moet de regering efficiënte regelgeving ontwikkelen om PRRP's van hoge kwaliteit op de markt te brengen en zij zou rokers die willen overstappen moeten ondersteunen. De regering zou dit onmiddellijk moeten doen, in plaats van misvattingen over PRRP's te laten aanhouden en hun potentieel te ondermijnen door ze op dezelfde manier te reguleren als voor roken bestemde tabaksproducten.

1.14 **In het licht van bovenstaande, dringen wij er bij de regering met klem op aan het onderhavige voorstel niet in te voeren en dan ook in te trekken.** Wij zouden graag de gelegenheid hebben om met de regering samen te werken bij het opzetten van een passend kader voor de regulering van deze producten. Wij staan klaar om onze wetenschappers en het onderzoeks- en ontwikkelingsteam beschikbaar te stellen om uit te leggen hoe onze producten werken en welke wetenschap erachter zit.

BRITISH AMERICAN TOBACCO NEDERLAND B.V. SUBMISSION TO THE SECRETARY OF STATE FOR HEALTH, WELFARE AND SPORT

COMMENTS ON PROPOSAL TO AMEND THE TOBACCO AND SMOKING GOODS LAW IN CONNECTION WITH EXTENDING THE SMOKING BAN TO POTENTIALLY REDUCED RISK PRODUCTS

24 MAY 2019

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2. INTRODUCTION

2.1 This submission by British American Tobacco Nederland B.V. ("**BAT**") (the "**Response**") responds to the consultation on extending the public place smoking ban to smoke and tobacco free alternative products, including e-cigarettes/electronic nicotine delivery systems ("**ENDS**"), electronic non-nicotine delivery systems ("**ENNDS**"), tobacco heating products ("**THPs**"), and oral products (including snus) (the "**Proposal**"), issued by the Secretary of State for Health, Welfare and Sport, (the "**Consultation**").

2.2 BAT is a member of the British American Tobacco group of companies and is responsible for the importation, distribution and sale of tobacco in the Netherlands. BAT currently supplies eight brands in the Netherlands, including brands such as Pall Mall and Lucky Strike.

2.3 As explained in detail in this Response, BAT is strongly opposed to the extension of the ban as proposed. The procedure followed by the Dutch Government ("**Government**") to date in respect of the Proposal is fundamentally flawed and inadequate. We also believe that the Proposal is unjustified in that the Government has disregarded the weight of the evidence, scientific opinion, and data, which indicate that smoke and tobacco free alternative products are likely to carry a fraction of the risks of cigarettes; wrongly characterises these potentially reduced risk products ("**PRRPs**") as only having negative impacts; and fails to acknowledge that such restrictions could significantly undermine the potential for these products to play a role in harm reduction in the Netherlands.

2.4 The negative impact of excessive regulation of ENDS has been noted by the UK Royal College of Physicians ("**RCP**"): "[a] *risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm…* ***if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking***." [3] (emphasis added)

2.5 If the Government is truly serious in its aim to reduce smoking prevalence, rather than stifling the PRRP category and potentially eliminating new products altogether, it should ensure that consumers are informed about the growing scientific consensus – that ENDS likely pose substantially less risk than conventional tobacco products, and that tobacco heating products potentially do as well, and that cigarette smokers may be able to significantly reduce their risk of harm by switching completely to such products. In view of its stated objective, the Government should fully educate consumers about these facts, which can be achieved by allowing manufacturers to raise consumer awareness of these products, and by developing

[3] Royal College of Physicians (2016), Nicotine without smoke – Tobacco Harm Reduction.

efficient regulatory pathways for bringing high-quality PRRPs to market and supporting smokers who want to switch. The Government should do so immediately, rather than perpetuating misconceptions about PRRPs and undermining their potential by regulating them in the same way as combustible tobacco products.

2.6 While we do not support the proposal to extend the extreme ban on public space smoking to PRRPs, we agree that these products should be used with consideration and respect for the comfort of others around them and that it may be appropriate for some institutions to not permit the use of vaping indoors. Therefore, it should be up to individual establishments and business owners to decide whether to prohibit the use of vaping inside their premises.

2.7 The submission is structured as follows:

2.7.1 Section 2 addresses the process followed by the Government and explains why it is fundamentally flawed and inadequate to discharge its public law duty to follow a fair process and to make policy on the basis of the best facts available.

2.7.2 Section 3 explains that the Proposal is unjustified and not based on evidence. The Government fails to recognise the role that PRRPs can play in tobacco harm reduction which is embedded in the WHO Framework Convention on Tobacco Control ("**FCTC**") and in accordance with the right to health. The position is more unjustified in relation to oral products that do not produce any emissions and therefore there is no basis to include them in a public ban at all. Similarly, there can be no sound basis for including ENNDS within the scope of the Proposal when they do not contain tobacco or nicotine.

2.7.3 Section 4 highlights the potential public health benefits of PRRPs. The evidence suggests that PRRPs have contributed to reduced smoking prevalence in countries with a more flexible regulatory landscape that facilitates consumer awareness, access and use. An increasing number of international public health bodies and specialists in the areas of public health are also calling for balanced regulation of PRRPs because of their real potential to contribute to the public health strategy of tobacco harm reduction.

2.7.4 Sections 5 provide an overview of the evidence on e-cigarettes, THPs, and oral tobacco products. It shows the potentially reduced risk of these products compared to combustible tobacco products and that concerns regarding harm to bystanders, 'renormalisation' and 'gateway' for these products are not substantiated by the weight of the current evidence.

2.7.5 Section 6 concludes with our submission that the Government should reject the Proposal.

3. THE GOVERNMENT HAS FOLLOWED A FLAWED AND INADEQUATE PROCESS

3.1 The procedure followed by the Government to date in respect of extending the smoking ban to PRRPs raises serious concerns.

3.2 The failure to undertake and/or publish a regulatory impact assessment or consultation before the substantive decisions were made means that the decisions were taken without proper evidence or analysis of the costs, benefits or other impacts of the measure and without consideration of alternative policy options. The Explanatory Notes do not include the necessary evidence and analysis to support policy development. The Government has failed to demonstrate that the extension of the smoking ban to PRRPs is necessary, appropriate or proportionate as a policy measure and it cannot be relied on to support policy recommendations.

3.3 Failure to undertake a proper regulatory impact assessment

3.4 The Government has not published any proper regulatory impact in respect of the Proposal.

3.5 The Explanatory Notes do not include the necessary evidence and analysis to support policy development and is an adequate basis to conclude that the expansion of the “smoking ban” is necessary, appropriate and proportionate, including:

3.5.1 The Explanatory Notes assert that the extension of the “smoking ban” to PRRPs is justified because, *inter alia,* such products are "harmful" to human health. We accept that PRRPs are not risk-free and we agree that more research is needed into the long-term effects of novel products, including ENDS and THPs. Our view is also that PRRPs are not suitable for, *inter alia,* people under the age of 18, and pregnant or breast-feeding women. However, the weight of the international evidence to date indicates that PRRPs are likely to be substantially less hazardous than conventional tobacco products, and that incentivising smokers to switch from using combustibles products to PRRPs can confer a substantial public health benefit. The evidence also suggests that PRRPs are mainly used by current or ex-smokers, and that as such, concerns of a 'gateway' effect are not substantiated.

3.5.2 The Explanatory Notes fail to consider the weight of the international evidence suggesting that PRRPs are not harmful to bystanders.

3.5.3 The Explanatory Notes do not provide any direct evidence, or quantification, on the impact of extending the smoking ban to PRRPs. This does not satisfy the onus on the state to show that the measure is appropriate for securing the attainment of the objective and does not go beyond what was necessary to attain it.

3.5.4 The inadequacy in the attempt at identifying the costs of the Proposal renders the policy unjustified.

3.5.5 The Explanatory Notes do not consider any unintended consequences of regulating PRRPs in the same way as combustibles, including potential negative impacts on public health.

3.6 A regulatory impact assessment ("**RIA**") that conducted a thorough analysis of the Proposal, including whether it is necessary and whether there are less burdensome means of achieving the regulatory objective, should have been undertaken to enable the Government to properly scrutinise the Proposal.

3.1 RIAs form an essential part of a transparent, accountable and empirically-based regulatory system. They provide a formal method for ensuring that government action is justified and based on a clear understanding of cause and effect, alternative policy options and the impacts of regulatory decisions on different stakeholder groups.

3.2 An RIA is also the cornerstone of internationally accepted principles of Better Regulation, such as those defined by the Organization for Economic Co-operation and Development of which the Netherlands is a member. The importance of conducting an RIA was underscored by a 2019 OECD publication on Better Regulation Practices across the European Union, which states that "[w]*here EU countries include additional regulatory measures in excess of those provided in EU laws, it is important that these measure*[s] *be subject to appropriate consultation and impact assessment as part of their design, to ensure that the anticipated gains from EU laws are realised*."[4]

3.3 The EU Better Regulation initiative also explains the dangers of regulation not being correctly supported by a proper impact assessment: "*poorly conceived and ill-considered regulation can prove to be excessive and go beyond what is strictly necessary … regulation can be overly prescriptive, unjustifiably expensive or counterproductive. Layers of overlapping regulation can develop overtime, affecting businesses, the voluntary sector, public authorities and the general public*."[5]

3.4 The Government's failure to undertake an evidence-based RIA means that the Proposal cannot be shown to be justified as proportionate, necessary or adequate.

3.5 **Lack of meaningful consultation**

3.6 The Government did not seek any views from stakeholders or allow them the opportunity to comment on the analysis and evidence used to justify extending the smoking ban to PRRPs

4 OECD (2019), Better Regulation Practices across the European Union. Available here: https://read.oecd-ilibrary.org/governance/better-regulation-practices-across-the-european-union_9789264311732-en#page1.

5 *Better Regulation: Simply Explained*, European Commission, 2006 http://ec.europa.eu/smart-regulation/better_regulation/documents/brochure/brochure_en.pdf.

before the regulations were published. Furthermore, the consultation now being run after a decision has already been taken calls into question the genuineness of the Consultation. The timing, content and unreasonable duration of the Consultation fails to provide any meaningful level of transparency or participation on the process.

3.7 It is a fundamental principle of consultation that it takes place at a time when proposals are still at a formative stage, and that the product of the consultation is given conscientious consideration. The is highlighted by the European Commission Impact Assessment Guidelines, which also note that the consultation process should engage all affected stakeholders; ensure that stakeholders can comment on a clear problem definition, description of the possible options and their impacts; maintain contact with stakeholders throughout the process and provide feedback; and analyse stakeholders' contributions for the decision-making process and report fully in the impact assessment report on how the input was used.[6] The process being conducted by the Government does not meet any of these standards.

3.8 We also raise with some concern the Government's position that submissions made by members of the tobacco industry will be afforded less weight on the basis of Article 5.3 of the FCTC.

3.9 Article 5.3 is expressly limited by the requirements of national law, which include principles of natural justice and procedural fairness. As the Hague District Court ruled Article 5.3 is about ""*protecting tobacco control policies from the interests of the tobacco industry*" …" (*Dutch Stichting Rookpreventie Jeugd versus the State of the Netherlands*). Accordingly, Article 5.3 cannot be used as a basis to deny the tobacco manufactures right to fully participate in the consultation process.

3.10 Nor do the Guidelines on Article 5.3 provide any basis for the Government's position. The Guidelines only contain non-binding policy "recommendations" to address "*tobacco industry interference in public health policy*". These cannot in any way be characterised as being binding as a matter of international law and nor can they be used to provide an incorrect construction of Article 5.3 to say that somehow this provision now requires Governments to exclude tobacco industry evidence or afford it less weight as a matter of principle.

3.11 Rather than requiring the exclusion of tobacco industry evidence, Article 5.3 requires that dealings with the tobacco industry be conducted on a transparent basis. In the present case, BAT's submissions and evidence are being presented in an open and transparent manner.

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6 European Commission Impact Assessment Guidelines at page 19, http://ec.europa.eu/smart-regulation/impact/commission_guidelines/docs/iag_2009_en.pdf.

4. EXTENDING THE PUBLIC PLACE SMOKING BAN TO PRRPs IS UNJUSTIFIED

4.1 The Government's National Prevention Agreement rightly has as its central objective, the protection of public health and prevention of youth smoking initiation. However, in proposing to extend the public place smoking ban to PRRPs the Government wrongly characterises PRRPs as only having negative impacts and fails to acknowledge the weight of evidence, scientific opinion and data that indicate that PRRPs likely carry a fraction of the risks of cigarettes and that if smokers who would not otherwise quit were to switch to using PRRPs exclusively this could have huge public health benefits.

4.2 The Government's position is contrary to public health organisations, which have found that a there is no evidence to support a ban on use of PRRPs in public places, and that such bans may undermine the potential public health benefits of PRRPs. These statements include:

- "*To date, there have been no identified health risks of passive vaping to bystanders.*"[7] **Public Health England ("PHE")**
- "*Based on the evidence currently available, we do not believe there is justification for an indoor ban on e-cigarettes, either on the basis of potential harm to bystanders from second-hand vapour or that they renormalize smoking tobacco".*[8] **Cancer Research UK**
- "*Given the lack of evidence on the harmfulness of e-cigarette vapour to others… it would be inappropriate for national legislation to prohibit their use in public places and workplaces.*"[9] **RCP**
- "*The rationale behind the legislation to prohibit smoking in enclosed public places was based on the harm caused to workers by exposure to secondhand smoke. Such evidence does not exist for secondhand vapour from electronic cigarettes*"[10] **Action on Smoking and Health UK ("ASH").**

4.3 PHE has also recommended that: "*To help smokers to stop smoking and stay smokefree, a more enabling approach to vaping may be appropriate to make it an easier choice than smoking. In particular, vapers should not be required to use the same space as smokers, as*

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7 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*.

8 Cancer Research UK Briefing: Electronic Cigarettes. Available at: https://www.cancerresearchuk.org/sites/default/files/e-cigarette_briefing_nov_2016_final.pdf.

9 RCP (2016), *Nicotine without smoke: Tobacco harm reduction*. Available at: https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0.

10 ASH (2015), *Will you permit or prohibit e-cigarette use on your premises*. Available at: http://ash.org.uk/information-and-resources/briefings/will-you-permit-or-prohibit-e-cigarette-use-on-your-premises/.

this could undermine their ability to quit and stay smokefree."[11] This equally applies to other PRRPs, such as tobacco heating products and oral tobacco products.

4.4 In extending the public place smoking ban to PRRPs, the Government threatens the commercial viability of PRRPs, and fails to recognise that such restrictions risk undermining the potential for these products to play a role in harm reduction in the Netherlands. Regulating PRRPs in the same way as combustibles will perpetuate the misconception that these products are the same as combustibles, and will discourage consumers from switching to potentially reduced risk alternatives to traditional tobacco products. The position is even more unjustified in relation to oral tobacco products that do not produce any emissions and therefore there is no rational basis to include them in a public ban at all. Similarly, there can be no justifiable basis for including ENNDS within the scope of the Proposal when they do not contain tobacco or nicotine.

Tobacco Harm Reduction is an Essential Component of a Rational and Effective Tobacco Control Policy

4.5 Tobacco harm reduction is a recognised public health strategy to lower the health risks to individuals and wider society associated with using tobacco products. It is an example of the concept of harm reduction that has been successfully applied as a strategy for reducing risks and resulting harm inherent in substance use and risky behaviours. Tobacco harm reduction starts from the insight that the vast majority of harm done by tobacco use is done by *smoke* – the products of combustion arising from burning tobacco – and not by nicotine. This has been known since at least the 1970s. So the opportunity exists for a potentially significant win for public health by eliminating the inhalation of cigarette smoke for people who continue to use nicotine.

4.6 The FCTC was adopted in 2003. Those drafting the FCTC did not and could not have predicted the emergence of ENDS and THPs as genuine alternatives that could drive down consumption of cigarettes and other combustible tobacco products.

4.7 Nevertheless, the concept of tobacco harm reduction is firmly embedded in the WHO FCTC. Specifically, in defining tobacco control, Article 1(d) of the FCTC recognises that "*tobacco control*" concerns not just "*a range of* [tobacco] *supply, demand*" measures, but also the adoption of "***harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke***" (emphasis added). The WHO has also recognised the role of tobacco harm reduction, stating: "[i]*f the great majority of tobacco smokers who are unable or unwilling to quit would switch without delay to using an alternative source of nicotine with lower health*

11 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.

risks, and eventually stop using it, this would represent a significant contemporary public health achievement."[12]

4.8 Harm reduction is also in accordance with the internationally recognized 'right to health' as recognised under Article 1 (human dignity), Article 7 (respect for private and family life) and Article 35 (health care) of the Charter of Fundamental Rights of the European Union ("**the Charter**"). This encapsulates the right to control one's health and body and includes the right to receive accurate health information in order to make informed decisions that are in line with one's own motives, reasons and values.

4.9 The preamble to the European Social Charter also states that: "*Everyone has the right to benefit from any measures enabling him to enjoy the highest possible standard of health attainable*" and Article 11 requires states to take measures to prevent disease and to encourage individual responsibility in matters of health. Moreover, facilitating a high level of health protection is required under Title XIV, Article 168(1) of the Treaty on the Function of the European Union ("**TFEU**"), which states that "*A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities"*.

4.10 The findings of the 2007 report of the RCP (one of the oldest and most prestigious medical societies in the world) was unequivocal: "[i]*n this report we make the case for harm reduction strategies to protect smokers. We demonstrate that smokers smoke predominantly for nicotine, that nicotine itself is not especially hazardous, and that* ***if nicotine could be provided in a form that is acceptable and effective as a cigarette substitute, millions of lives could be saved***."[13]

4.11 More recently, a number of public health experts noted in a September 2018 letter calling on the WHO to reject prohibition and embrace 'tobacco harm reduction' and risk-proportionate regulation of tobacco and nicotine products: "[m]*illions of smokers have moved from cigarettes to less harmful alternatives where the laws allow it. Where* [Alternative Nicotine Delivery Systems] *have been popular, we have seen rapid declines in adult smoking, for example in the United Kingdom, Sweden, the United States, and in Japan where cigarette consumption fell by 27 percent in the two years between first quarter 2016 and the same period in 2018 following the introduction of heated tobacco products.*"[14]

4.12 A subsequent letter in October 2018, from a group of 72 independent specialists in nicotine science, policy and practice, calling on the WHO to embrace technology innovation in the fight against diseases caused by smoking, also stated: "[i]*n the field of tobacco control and*

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12 WHO FCTC (2016), *Report on Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS) to the seventh session of the Conference of the Parties*, available at http://www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf at paragraph 5.

13 Royal College of Physicians. *Harm reduction in nicotine addiction: helping people who can't quit*. A report by the Tobacco Advisory Group of the Royal College of Physicians. London, United Kingdom; 2007 (emphasis added).

14 https://clivebates.com/documents/WHOCOP8LetterSeptember2018.pdf.

public health, the world has changed significantly since the Framework Convention on Tobacco Control was signed in 2003. It is impossible to ignore or dismiss the rise of Alternative Nicotine Delivery Systems (ANDS). These are established and new technologies that deliver nicotine to the user without combustion of tobacco leaf and inhalation of tobacco smoke. These technologies offer the prospect of significant and rapid public health gains through 'tobacco harm reduction'. Users who cannot or choose not to quit using nicotine have the option to switch from the highest risk products (primarily cigarettes) to products that are, beyond reasonable doubt, much lower risk than smoking products (e.g. pure nicotine products, low-toxicity smokeless tobacco products, vaping or heated tobacco products). We believe this strategy could make a substantial contribution to the Sustainable Development Goal to reduce premature deaths through non-communicable diseases (SDG Target 3.4)."[15]

4.13 The most recent report from Public Health England issued in February 2019 also reiterates the value of vaping products as harm reduction tools, and emphasizes that health care professionals should do more to support their use by smokers seeking to quit: "*[c]ombining* [ENDS] *(the most popular source of support used by smokers in the general population), with stop smoking service support (which is the most effective type of support), should be a recommended option available to all smokers. This was the proposal from the previous report, which is still valid. Stop smoking practitioners and health professionals should provide behavioural support to smokers who want to use an* [ENDS] *to help them quit smoking. Stop smoking practitioners and health professionals supporting smokers to quit should receive education and training on using* [ENDS] *in quit attempts*."[16]

4.14 Regulating PRRPs in the same way as combustible products ignores the concept of tobacco harm reduction which is embedded in the WHO FCTC.

5. THE POTENTIAL PUBLIC HEALTH BENEFIT OF PRRPS

5.1 The potential public health benefit of PRRPs is underscored by the evidence from countries with a more flexible regulatory landscape that facilitates consumer awareness, access and use, which indicates that PRRPs have contributed to reduced smoking prevalence.

5.2 For example, in the UK where there is reasonable means of product distribution and public place vaping is largely unrestricted, there was a significant 23% decline in smoking prevalence, dropping from 20.4% (2012) to 15.8% in 2016, following the introduction of e-cigarettes. A November 2017 study by the Institute for Economic Affairs found that the adult smoking rate in the UK had "*barely moved after the smoking ban introduced in 2007, but once e-cigarettes became mainstream consumer products it went onto sharp decline.*"[17]

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15 https://clivebates.com/documents/WHOCOP8LetterOctober2018.pdf at p1.

16 Public Health England, Vaping in England: an evidence update February 2019. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/781748/Vaping_in_England_an_evidence_update_February_2019.pdf.

17 Institute for Economic Affairs. (2017) *Vaping Solutions: An easy Brexit win*.

West et al., (2014)[18] estimated the number of additional long-term quitters in England generated by ENDS in 2014, were between 16,000 and 22,000. Similarly, Beard et al., (2016)[19] estimated that ENDS may have contributed about 18,000 additional long-term ex-smokers in the England in 2015. Referring to these studies, the 2018 Public Health England Report concluded that: "[w]*hile caution is needed with these figures, the evidence suggests that e-cigarettes have contributed tens of thousands of additional quitters in England.*"[20]

5.3 More recent data also show that most vapers in England (51%) have stopped smoking and of the 45% who still smoke, half say that they are vaping in order to stop smoking.[21] What is more, figures show that over 900,000 people have quit both smoking and vaping in Great Britain.[22] In contrast, in Australia where there is a *de-facto* ban on tobacco-free vapour products there was no statistically significant decline in the three years from 2013-2016 (despite plain packaging having been introduced for cigarettes in 2012, together with significant and repeated excise increases).[23]

5.4 The UK Parliamentary report on ENDS by the House of Commons Science and Technology Committee (2018)[24] found that "[t]*here remain some gaps in the evidence about how effective e-cigarettes are as a stop smoking tool in comparison to other nicotine replacement therapies. Nevertheless, an estimated 2.9 million people in the UK are using e-cigarettes, and tens of thousands are using them to successfully quit smoking each year.* ***Concerns about the risk of e-cigarettes potentially providing a 'gateway' into conventional smoking have not materialised to any significant degree***" (emphasis added).

5.5 A study by Notley et al., (2018)[25] explored patterns of use and reported experiences of vapers quitting smoking using an ENDS in relation to long-term smoking status in the UK. The study concluded that: "[o]*ur data demonstrates that e-cigarettes may be a unique harm reduction innovation for smoking relapse prevention. E-cigarettes meet the needs of some ex-smokers by substituting physical, psychological, social, cultural and identity-related*

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18 West R, Shahab L, Brown J. *Estimating the population impact of e-cigarettes on smoking cessation in England*. Addiction. 2016;111(6):1118-9.

19 Beard E, West R, Michie S, Brown J. *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 Brit Med J. 2016;354:i4645-i.

20 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.

21 Public Health England (2018), *Public Health Matters (Blog) - Turning the tide on tobacco: Smoking in England hits a new low*. Available at: https://publichealthmatters.blog.gov.uk/2018/07/03/turning-the-tide-on-tobacco-smoking-in-england-hits-a-new-low/.

22 https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandlifeexpectancies/bulletins/adultsmokinghabitsingreatbritain/2017.

23 https://www.aihw.gov.au/getmedia/15db8c15-7062-4cde-bfa4-3c2079f30af3/21028.pdf.aspx?inline=true.

24 House of Commons Science and Technology Committee, E-cigarettes, Seventh Report of Session 2017-19 (Report, together with formal minutes relating to the report), published on 17 August 2018.

25 Notley C, Ward E, Dawkins L, Holland R. The unique contribution of e-cigarettes for tobacco harm reduction in supporting smoking relapse prevention. Harm Red. J. 2018 15:31 https://doi.org/10.1186/s12954-018-0237-7 at p1.

aspects of tobacco addiction. Some vapers reported that they found vaping pleasurable and enjoyable – being more than a substitute but actually preferred, over time, to tobacco smoking. This clearly suggests that vaping is a viable long-term substitute for smoking, with substantial implications for tobacco harm reduction."

5.6 Experience from markets where other smoke free alternatives have been available for some time also supports the concept that smokers can transition to alternative nicotine delivery systems, with potential decreases in smoking prevalence. For example, snus is a product that has been available in Sweden for many years. In the March 2017 Eurobarometer survey,[26] Sweden reported daily smoking prevalence of 5%, by far the lowest national level in Europe in comparison with EU wide daily smoking prevalence of 24%. As one study reports: "[s]*nus has both contributed to decreasing initiation of smoking and, when used subsequent to smoking, appears to facilitate smoking cessation. All these effects suggest that the availability and use of snus has been a major factor behind Sweden's record-low prevalence of smoking and the lowest level of tobacco-related mortality among men in Europe*."[27] This is also supported by a study by Ramström L., (2016)[28], which found that "[t]*hose who began daily tobacco use using snus were much less likely to subsequently take up smoking than those who had not, both among males (17.6% vs. 45.9%), and females (8.2% vs. 40.2%). Further, among those who started using snus after starting as smokers, 76.3% of men and 71.6% of women had stopped smoking completely, including 31.5% of the men and 28.6% of the women who had quit all forms of tobacco.*" Snus has gained popularity in Sweden while cigarette smoking prevalence has declined since 1970. In addition, evidence indicates that Sweden had the lowest level of lung cancer and Chronic Obstructive Pulmonary Disease mortality (two major smoking-related diseases) in 2016 out of 10 comparable countries.[29] The Swedish experience with snus supports the concept that smokers can transition to alternative nicotine products, with potential decreases in smoking prevalence and the number of deaths associated with smoking.

5.7 Norway has experienced similar results with its more recent growth in snus consumption helping drive down smoking prevalence. Lund et al (2014)[30] studied how the availability of snus influenced overall tobacco consumption, smoking initiation and smoking cessation in Norway. They found that the increased use of snus has not led to an increase in overall tobacco consumption, as sales of cigarettes have decreased in Norway. The study concludes that snus has contributed to a decrease in cigarette consumption through three

26 Eurobarometer, report 458, issued May 2017: March 2017 survey data.
27 Ramström L., (2016) *Patterns of Smoking and Snus Use in Sweden: Implications for Public Health* Int. J. Environ. Res. Public Health 2016, 13(11), 1110.
28 Ramström L., (2016) Patterns of Smoking and Snus Use in Sweden: Implications for Public Health Int. J. Environ. Res. Public Health 2016, 13(11), 1110.
29 http://www.healthdata.org/sweden.
30 Lund et al (2014*), How Has the Availability of Snus Influenced Cigarette Smoking in Norway?* Int. J. Environ. Res. Public Health 2014, 11, 11705-11717.

mechanisms: (1) as a method of smoking cessation; (2) as an alternative product for new generations of tobacco-prone consumers who otherwise would take up smoking; and (3) as an alternative to cigarettes for smokers who are unwilling to quit tobacco altogether or find it difficult to do so through traditional cessation techniques. For example, the market share for snus increased from 4% in 1985 to 28% in 2012, but overall tobacco consumption decreased by 20.3% over this same period. Among young male adults, the prevalence of smoking (daily and occasional) was reduced from 50% in 1985 to 21% in 2013. Snus was the most common method for smoking cessation. Notably, Statistics Norway reports that in 2018, prevalence of daily snus use exceeded that of daily cigarette smoking, which has fallen to only 11%.[31] Thus, availability of snus continues to help drive down cigarette smoking rates in Norway.

5.8 In Japan, THPs have emerged as a potentially strong tool for reducing smoking prevalence. A Berenberg analysts' report estimated that, during 2017, the total tobacco "*stick*" market (including cigarettes and tobacco sticks for THPs) declined by just over 2%, but within that the cigarette market declined by 12.5%, with the balance being the growth of the THP segment.[32] This suggests that a number of smokers have switched to THPs and this trend indicates that THPs may potentially be another route to delivering on a tobacco harm reduction strategy.

5.9 An increasing number of international public health bodies and specialists in the areas of public health are also calling for balanced regulation of PRRPs because of their real potential to contribute to the public health strategy of tobacco harm reduction. For example:

5.9.1 The RCP recommended in its 2016 report "Nicotine without smoke: Tobacco harm reduction," that: "*in the interests of public health it is important to promote the use of e-cigarettes,* [nicotine-replacement therapy] *and other non-tobacco nicotine products as widely as possible as a substitute for smoking in the UK*."

5.9.2 In February 2018, Public Health England opined that "[r]*egulations need to balance the risks of e-cigarettes with their potential benefits – and achieve key aims of reducing smoking and continuing to avoid uptake of e-cigarettes by non-smokers. This requires keeping them under regular review and evaluating their impact*" and "[p]*olicies on tobacco and e-cigarettes should have at their core the recognition that nicotine use per se presents minimal risk of serious harm to physical health and that its addictiveness depends on how it is administered*."[33]

5.9.3 In August 2018, a major UK parliamentary inquiry into e-cigarettes concluded: "*E-cigarettes present an opportunity to significantly accelerate already declining*

31 https://www.ssb.no/en/helse/artikler-og-publikasjoner/snus-more-used-than-cigarettes.
32 Berenberg analysts' report on Tobacco sector, issued 10 January 2018.
33 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.*

smoking rates, and thereby tackle one of the largest causes of death in the UK today. […] *There should be a shift to a more risk-proportionate regulatory environment; where regulations, advertising rules and tax duties reflect the evidence of the relative harms of the various e-cigarette and tobacco products available.*"[34]

5.10 In 2016, the value of ENDS in a tobacco harm reduction strategy was also recognised in a guidance document on the use of ENDS in public places and workplaces published by PHE. Its authors concluded that: "*e-cigarettes have significant potential to help reduce tobacco use and the serious harm it causes to smokers.*"[35] The PHE report proposes five key principles intended to *"guide the development of evidence-based policies that maximise the potential for e-cigarettes to improve public health while managing the risks in any particular setting."* These principles are:

"Make clear the distinction between vaping and smoking

E-cigarette use does not meet the legal or clinical definitions of smoking. Furthermore, international peer-reviewed evidence suggests that e-cigarettes carry a fraction of the risk of cigarettes and have the potential to help drive down smoking rates and improve public health. So policies need to be clear on the differences between vaping and smoking.

Ensure policies are informed by the evidence on health risks for bystanders

International peer-reviewed evidence indicates that the risk to the health of bystanders from second-hand e-cigarette vapour is extremely low and insufficient to justify prohibiting e-cigarettes. This evidence should inform risk assessments.

Identify and manage risks of uptake by children and young people

E-cigarette use is not recommended for young people and this is reflected in the UK's age of sale and advertising restrictions. However, because adult smokers use e-cigarettes to quit smoking and stay smokefree, the products can help reduce children's and young people's exposure to second-hand smoke and smoking role models. In developing policies for child and youth settings, guarding against potential youth uptake should be balanced with fostering an environment where it is easier for adults not to smoke.

Support smokers to stop smoking and stay smokefree

E-cigarettes are used almost exclusively by smokers and ex-smokers and are now the most popular stop smoking aid in England. To help smokers to stop smoking and stay smokefree, a more enabling approach to vaping may be appropriate to make it an easier choice than

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34 House of Commons Science and Technology Committee, E-cigarettes, Seventh Report of Session 2017-19 (Report, together with formal minutes relating to the report), published on 17 August 2018.

35 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.

smoking. In particular, vapers should not be required to use the same space as smokers, as this could undermine their ability to quit and stay smokefree.

Support compliance with smokefree law and policies

Maintain and support compliance with smokefree requirements by emphasising a clear distinction between smoking and vaping. Indicate accurately where vaping is permitted or prohibited, and communicate the policy clearly to everyone it affects."[36]

5.11 We strongly urge the Government to adopt these principles, which equally apply to other smoke- and tobacco-free alternative products, including THPs and oral products which similarly offer a significant potential to help contribute to tobacco harm reduction.

5.12 In sum, the international evidence indicates that PRRPs have contributed to reducing smoking prevalence in countries with a more flexible regulatory landscape. Regulating PRRPs in the same way as combustibles will undermine this potential, contrary to the Government's public health objectives.

6. THE WEIGHT OF EVIDENCE DOES NOT SUPPORT THE PROPOSAL

6.1 The Government's presentation of the evidence, as set out in the Explanatory Notes, is incomplete. The Explanatory Notes provide no critical analysis, and simply relies on limited selected literature to support its conclusions. The Government fails to adequately consider the evidence of the comparative risk of PRRPs and the weight of evidence that does not support its position. As such, the Explanatory Notes are an improper basis to justify the Proposal. Rather than being evidence based, these regulations are being driven by a political ideology of an 'abstinence-only' approach to tobacco and nicotine, which is likely to be counterproductive to its stated objectives.

6.2 Below we provide an overview of the evidence relating to ENDS, THPs and oral products which shows the potentially reduced risk of these products compared to combustible tobacco products, and that concerns regarding harm to bystanders, 'renormalisation' and 'gateway' for these products are not substantiated by the weight of the current evidence.

6.3 Electronic Nicotine Delivery Systems

Health Effects

6.4 There is increasing agreement amongst health experts that exclusive use of ENDS that are manufactured to robust quality and safety standards confers reduced risks of harm as compared to smoking conventional cigarettes. ENDS do not contain tobacco (whilst ENNDS

[36] Public Health England (2016), *E-cigarettes in public places and workplaces: a 5-point guide to policy making*, available at https://www.gov.uk/government/publications/use-of-e-cigarettes-in-public-places-and-workplaces/e-cigarettes-in-public-places-and-workplaces-a-5-point-guide-to-policy-making.

contain neither tobacco nor nicotine), they do not rely on combustion and, as a consequence, no smoke is formed when the e-liquid is "vaped".

6.5 In its 2016 report, “Nicotine without smoke: Tobacco harm reduction” the RCP states: "[a]*lthough it is not possible to quantify the long-term health risks associated with e-cigarettes precisely, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure*."[37]

6.6 A study funded by Cancer Research UK (2017),[38] 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 ENDS 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 smoke conventional cigarettes.

6.7 An independent expert review commissioned by PHE (2018),[39] which updates the evidence from its landmark 2015 report, found, *inter alia*, that:

6.7.1 "[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*."

6.7.2 "*To date, there have been no identified health risks of passive vaping to bystanders*."

6.8 The recent systematic review of the scientific literature undertaken by NASEM for the US Food and Drug Administration,[40] concluded, *inter alia*, that:

6.8.1 "*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*".

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37 Royal College of Physicians of London. Nicotine without smoke tobacco harm reduction. Royal College of Physicians of London; 2016 at p84.

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

39 Public Health England was established on 1 April 2013 and brings together public health specialists from more than 70 organisations. It works with national and local government, industry and the UK National Health Service. http://www.nhs.uk/NHSEngland/thenhs/healthregulators/Pages/public-health-england.aspx; 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.

40 NASEM (2018), Public Health Consequences of E-Cigarettes.

6.8.2 "*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*".

6.8.3 "*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*".

6.9 Whilst the NASEM Report concluded that there was 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 Gonievicz, a member of the NAS committee which conducted the study, stated: "[t]*he relationship is just correlation. We did not make any conclusion that electronic cigarettes cause smoking*…"[41] Levy et al., (2018), has criticised the NASEM Report's conclusion, noting that "[i]*n examining population-level trends in youth smoking, the NASEM Report was limited by its reliance on a single data source, its failure to incorporate past trends in smoking before vaping became popular, and failure to examine trends in established smoking among young adults where the progression to more established smoking is likely to be more apparent*."[42]

6.10 A report by the UK House of Commons Science and Technology Committee on ENDS (2018)[43], found, *inter alia*, that "[t]*here is clear evidence that e-cigarettes are substantially less harmful than conventional cigarettes. Public Health England estimate e-cigarettes as 95% less harmful, although the evidence available does not currently allow a precise figure to be determined. E-cigarettes lack the tar and carbon monoxide of conventional cigarettes – the most dangerous components of conventional cigarettes – which are produced by combustion. Some potentially harmful compounds are present in both products, such as heavy metals, but at substantially lower levels in e-cigarettes.* ***Researchers have found it almost impossible to measure the risks from 'second-hand' e-cigarette vapour because any potentially harmful compounds released into the surrounding area are so negligible***" (emphasis added).

6.11 Polosa et al., (2018),[44] conducted a long-term prospective study of respiratory parameters in a cohort of smokers with chronic obstructive pulmonary disease who ceased or substantially reduced conventional cigarette use with ENDS. The authors concluded that "[t]*he present study suggests that regular EC* [e-cigarette] *use ameliorates several health effect indicators*

41 https://globalnews.ca/news/3984754/are-e-cigarettes-harmful-or-helpful/.

42 Levy et al., (2018) Examining the relationship of vaping to smoking initiation among US youth and young adults: a reality check.

43 House of Commons Science and Technology Committee, E-cigarettes, Seventh Report of Session 2017-19 (Report, together with formal minutes relating to the report), published on 17 August 2018.

44 Polosa et al., (2018) *Health effects in COPD smokers who switch to electronic cigarettes: a retrospective-prospective 3-year follow-up.*

in COPD and demonstrates that these beneficial effects may continue in the longer term. By markedly reducing the number of conventional cigarettes smoked per day and hence exposure to their numerous hazardous toxicants, EC use may not only enhance COPD outcomes, but may also bestow an overall health advantage. Therefore, EC use may be exploited as a less harmful strategy to potentially halt or reverse COPD-related outcomes, and in general, to reduce the risk of smoking-related diseases or the harm from smoking-associated comorbidities."

6.12 As noted above, an increasing number of international public health bodies and specialists in the areas of public health are also calling for balanced regulation of ENDS because of their real potential to contribute to the public health strategy of tobacco harm reduction.

6.13 A growing number of Governments and other public health bodies have also actively supported ENDS as part of their tobacco harm reduction activities, encouraging people who do not want to stop smoking to switch to ENDS.[45] For example:

6.13.1 The **American Cancer Society** ("**ACS**") 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 products.*"[46]

6.13.2 The **UK National Health Service** ("**NHS**") supports the use of ENDS in quit-attempts, referring to ENDS on its "*Stop smoking treatments*" website, and stating that "[r]*esearch has found that e-cigarettes can help you give up smoking, so you may want to try them rather than the medications listed above…*"[47] In 2017, the UK NHS-backed "Stoptober" campaign also featured ENDS in its televised adverts, and stated on its website that "[e]-*cigarettes are a great way to help combat nicotine cravings and carry a fraction of the risk of cigarettes*."[48]

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45 We note also, 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, study by Ratschen (2014), *Electronic cigarettes in mental health settings – solving a conundrum?* Psychiatric Bulletin, 38(5):226-9.

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

47 NHS choices *Stop smoking treatments*. Available at: http://www.nhs.uk/conditions/smoking-(quitting)/Pages/Treatment.aspx.

48 *Stoptober*. Available at: https://www.nhs.uk/oneyou/stoptober/home#1YM7RIcJl1z0RLbD.97.

6.13.3 A briefing note by **Cancer Research UK** (2016), "*E-Cigarettes in Stop Smoking Services"* recommends that "[s]*top Smoking Services are currently seeing a reduction in the number of clients and one contributing factor is likely to be the increase in e-cigarette use. These services should be accepting of e-cigarette use and support those who wish to use them alongside behavioural support as an aid to stop smoking. Services should provide patients with basic information and advice about e-cigarettes. This will maximise the reach of the service and improve e-cigarette users' chances of stopping smoking.*"[49]

6.13.4 A **New Zealand Ministry of Health** position statement on ENDS, published in October 2017, states: "[r]*ecent decisions taken by Government have increased the focus on harm reduction with an aim to support smokers to switch to significantly less harmful products like e-cigarettes*" and "[t]*he Ministry of Health encourages smokers who want to use e-cigarettes to quit smoking to seek the support of local stop smoking services. Local stop smoking services provide smokers with the best chance of quitting successfully and should support smokers who want to quit with the help of e-cigarettes.*"**[50]**

6.13.5 **Health Canada**'s current tobacco control strategy states "[t]*raditional cessation approaches are not the only tools available to help Canadians transition away from smoking cigarettes, the most deadly nicotine delivery system. A* ***harm reduction approach*** *aims to reduce the negative consequences of cigarette smoking by recognizing the potential benefits of using less harmful alternatives*". It adds "***Vaping is less harmful than smoking.*** *Completely replacing cigarettes with a vaping product will significantly reduce a smoker's exposure to toxic and cancer-causing chemicals. Adults can access vaping products containing nicotine as a less harmful alternative to smoking*."[51]

6.13.6 **Former FDA Commissioner** Scott Gottlieb, M.D., also stated that the FDA "*see*[s] *the possibility for ENDS products like e-cigarettes and other novel forms of nicotine-delivery to provide a potentially less harmful alternative for currently addicted individual adult smokers who still want to get access to satisfying levels of nicotine without many of the harmful effects that come with the combustion of tobacco.*"[52]

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49 Cancer Research UK (2016), *E-Cigarettes in Stop Smoking Services*. Available at: https://www.cancerresearchuk.org/sites/default/files/e-cig_in_sss_0.pdf.

50 http://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/e-cigarettes.

51 Health Canada, Tobacco Strategy Overview, see: https://www.canada.ca/en/health-canada/services/publications/healthy-living/canada-tobacco-strategy/overview-canada-tobacco-strategy.html, emphasis in original.

52 FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on new enforcement actions and a Youth Tobacco Prevention Plan to stop youth use of, and access to, JUUL and other e-cigarettes, available at

Health Risks to Bystanders

6.14 Concerns that ENDS vapour poses health risks to bystanders are not substantiated by the current evidence.

6.15 As stated above, ENDS do not rely on combustion and, as a consequence, no smoke is formed when the e-liquid is "vaped". Vapour is comprised largely of "*nicotine and some other particles, primarily consisting of flavours, aroma transporters, glycerol and PG* [propylene glycol]."[53] . Furthermore, e-cigarettes do not emit vapour when not being actively vaped, unlike conventional cigarettes that continuously burn and emit smoke between puffs. To quote PHE, "*there is no side-stream vapour emitted from the end of an e-cigarette, just the exhaled vapour entering the atmosphere*".[54]

6.16 Whilst ENDS vapour can contain some of the toxicants present in tobacco smoke, these are at much lower levels compared to the smoke from conventional cigarettes.[55] This was explained by Professor Ricardo Polosa[56], Director of the Institute for International Medicine and Clinical Immunology of the University of Catania, Italy, who stated in oral testimony to the UK House of Commons Science and Technology Committee inquiry on e-cigarettes, that "[i]*t is very well known historically that combustible cigarette smoke is a big cause of diseases, mainly because of side-stream smoke and the smoke that is generated between puffs. An electronic cigarette does not operate on the same principle. It does not have the deadly side-stream smoke and does not generate any smoke or aerosol between operating cycles. Aerosols are emitted by these products only when you exhale. That sets the principle that, on common sense, you will immediately identify that there is less risk just because of that. If you then consider that, as Public Health England and the Royal College of Physicians have already emphasised in their comprehensive reviews,* ***these aerosols are 95% less harmful than common tobacco, you will immediately realise that, from a percentage point of view, the risks will be miniscule***." (emphasis added)

6.17 A study by Burstyn et al., (2014)[57], which conducted a comprehensive review of the chemicals present in e-cigarette vapour, concluded that "*there is no evidence that vaping produces inhalable exposures to contaminants of the aerosol that would warrant health concerns by the standards that are used to ensure safety of workplaces*."

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https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm605432.htm (dated April 24, 2018).

53 Hajek et al., (2014) *Electronic cigarettes: Review of use, content, safety, effects on smokers, and potential for harm and benefit. Addiction, 109(11):1801-10.*

54 McNeill, A. et al. *Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England*. PHE, 2018, p.162.

55 *Hajek et al., (2014) Electronic cigarettes: Review of use, content, safety, effects on smokers, and potential for harm and benefit. Addiction, 109(11):1801-10.*

56 Professor Ricardo Polosa (2018), Oral evidence taken on 9 January 2018, HC (2017–19) 505, Q7 [Professor Polosa].

57 Burstyn et al., (2014) *Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health* risks. BMC Public Health, 14:18.

6.18 A systematic review of the evidence conducted by Glasser et al (2017)[58] found that: "[s]*econdhand vapor studies to date show that non-users may be exposed to nicotine in ENDS vapor but the level of exposure is low, and exposure to other compounds also appears very low, or at trace or non-detectable levels when compared with secondhand smoke. It is unclear if any levels are sufficient to be of biological concern to humans. More-definitive studies are needed before conclusions about harm can be made*."

6.19 An evaluation of employee's exposure to vaping-related chemicals in the air of a vape shop undertaken by the US Department of Health and Human Services for Diseases Control and Prevention in 2016, found that concentrations of vaping-related chemicals in air samples were below occupational exposure limits.[59]

6.20 As noted above, many public health authorities have also taken the view that based on the evidence, there is no basis for banning the use of ENDS in public places as a measure to protect bystanders' health, and that such bans may undermine the potential public health benefits of e-cigarettes.

6.21 Avino et al., (2018)[60] undertook an experiment to evaluate the exposure to second-hand aerosol from conventional and electronic cigarettes and to estimate the consequent dose received by passive smokers/vapers and the related lung cancer risk. The authors estimated that the small increase in lung cancer risk for passive smoking was five orders of magnitude higher than for passive vaping.

6.22 Accordingly, the evidence to date does not justify bans on public place vaping due to claims that there are health risks of passive vaping to bystanders. We also concur with the PHE statement that a more "enabling approach" should be taken to vaping. However, as noted above, we also agree that vapers should use products with consideration and respect for the comfort of others around them and that it may be appropriate for some institutions to not permit the use of ENDS indoors. Therefore, it should be up to individual establishments and business owners to decide whether to prohibit the use of ENDS inside their premises.

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58 Glasser AM, Collins L, Pearson JL, Abudayyeh H, Niaura RS, Abrams DB, et al. Overview of electronic nicotine delivery systems: A systematic review. Am J Prev Med. 2017;52(2):e33-e66.

59 Zwack L, Stefaniak A, LeBouf R. Evaluation of chemical exposures at a vape shop: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health; 2017. Available from: https://www.cdc.gov/niosh/hhe/reports/pdfs/2015-0107-3279.pdf.

60 Avino, P., Scungio, M., Stabile, L., Cortellessa, G., Buonanno, G., Manigrasso, M. (2018). Second-hand aerosol from tobacco and electronic cigarettes: evaluation of the smoker emission rates and doses and lung cancer risk of passive smokers and vapers. The Science of the Total Environment, 9; 642: 137-147, doi: 10.1016/j.scitotenv.2018.06.059.

"Re-normalisation"

6.23 The overall weight of evidence does not support the proposition that increasing the availability of ENDS would undermine tobacco control measures by "renormalising" smoking.

6.24 Professor Britton and Dr Ilze Bogdanovica, in a report commissioned by Public Health England commented that the "*use of electronic cigarettes in smoke free places is more likely to lead to normalisation of nicotine devices than to smoking, and hence potential benefit as a support to existing well smoke-free policies*."[61]

6.25 A report commissioned by PHE (2014), [62] also concludes that the use of ENDS in smoke free places is unlikely to give rise to renormalisation concerns:

> *"*[A]*lthough similar in appearance, even cigalike products are easily distinguishable, both in appearance and smell, from tobacco cigarettes. Therefore, use of electronic cigarettes in smoke free places is more likely to lead to a normalisation of nicotine devices than to smoking, and hence potential benefit as a support to existing well smoke-free policies*."

6.26 In fact, many studies contradict renormalisation concerns and instead indicate that ENDS may contribute to lower smoking prevalence rates. For example, a study by ASH (2018)[63] found that "[a]*n estimated 3.2 million adults in Great Britain currently use e-cigarettes (vape), up from 700,000 in 2012…There are now more ex-smokers (1.7) who use –e-cigarettes than current smokers (1.4 million). This means that over half (52%) of e-cigarette users are ex-smokers with 44% being current tobacco smokers. The main reason given by current vapers for use of e-cigarettes is to help them stop smoking.*"

6.27 Similarly, the RCP in its 2016 report[64] stated: "*There are concerns that e-cigarettes will increase tobacco smoking by renormalising the act of smoking, acting as a gateway to smoking in young people, and being used for temporary, not permanent, abstinence from smoking. To date, there is* ***no evidence that any of these processes is occurring to any significant degree in the UK****. Rather, the available evidence to date indicates that e-cigarettes are being used almost exclusively as safer alternatives to smoked tobacco, by confirmed smokers who are trying to reduce harm to themselves or others from smoking, or to quit smoking completely."* (emphasis added)

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61 Electronic Cigarettes: a report commissioned by Public Health England (2014) https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311887/Ecigarettes_report.pdf.

62 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.

63 ASH (2018), Use of e-cigarettes among young people in Great Britain.

64 Royal College of Physicians. Nicotine without smoke: Tobacco harm reduction (2016). p. 190. Available at: file:///C:/Users/as18058/Downloads/Nicotine%20without%20smoke_0.pdf.

6.28 A study by Farsalinos et al., (2017)[65] also found that "*daily EC* [ENDS] *use is predominantly observed in current and former smokers but is very rare among never smokers.*" The study found that only 0.08% of never-smokers used an e-cigarette on a daily basis, and that only 0.04% of never smokers used a nicotine-containing e-cigarette daily.

6.29 The use of re-normalisation arguments as a basis for stringent regulation of ENDS has also been criticised. Voigt (2018)[66] argues that renormalization concerns do not justify such measures. It is not clear that the denormalization of smoking that has occurred over the past few decades has been an unequivocally positive development. In particular, critics have been concerned that the shifting norms about smoking have also led to the stigmatization of smokers. This stigmatization not only conflicts with concerns of equality, but also may not have the desired effect of reducing smoking prevalence.

"Gateway Effect"

6.30 The overall weight of the evidence does not support the proposition that ENDS have a '*gateway effect'* whereby never-smokers who use ENDS are thereby caused to transition to smoking cigarettes.

6.31 A number of comprehensive reviews by independent organisations have criticised 'gateway' arguments that have been made in relation to ENDS and concluded that there is no reliable evidence of a gateway effect.

6.32 For example, the 2016 RCP Report[67] found that vaping products are not a gateway to smoking; that use is confined almost exclusively to those who are using or have used tobacco; that vaping does not "normalize" smoking; and that there is no evidence that non-smokers and teens are drawn to vaping products and will end up smoking as a result.

6.33 A 2018 factsheet by ASH on the use of ENDS among young people in Great Britain found that "[u]*se of e-cigarettes remains very low among young people (11-18 year olds) in Great Britain; just 2% use e-cigarettes at least weekly, another 2% use them once a month or less and 12% of youths have tried them just once or twice. A majority haven't tried e-cigarettes (76%) while 7% are unaware of e-cigarettes altogether*." ASH also found that "[e]-*cigarette use is confined almost entirely to those who currently or have previously smoked tobacco cigarettes. Of those who have never tried or used tobacco cigarettes, 87% haven't tried e-cigarettes, 7% are unaware of e-cigarettes, 5% have tried them just once or twice and less*

65 Farsalinos KE, Poulas K, Voudris V, Le Houezec J. (2017) *Prevalence and correlates of current daily use of electronic cigarettes in the European Union: analysis of the 2014 Eurobarometer survey*. Internal and emergency medicine.

66 Voigt K. (2015). Smoking Norms and the Regulation of E-Cigarettes. *American journal of public health*, *105*(10), 1967-72.

67 Royal College of Physicians. *Nicotine without smoke: Tobacco harm reduction*. London: RCP, 2016; *E-cigarettes: an evidence update*: a report commissioned by Public Health England.

than 1% use them with any regularity. These low levels have been found consistently across all waves of the youth survey."[68]

6.34 A study by Levy et al., (2018)[69] examined the temporal relationship between vaping and youth smoking using multiple data sets to explore the question of whether vaping promotes smoking initiation in the US. The authors found that "[a] *long-term decline in smoking prevalence among US youth accelerated after 2013 when vaping became more widespread. These findings were also observed for US young adults, especially those ages 18-21. We also found that the decline in more established smoking, as measured by daily smoking, smoking half pack a day or having smoked at least 100 cigarettes and currently smoking some days or every day, markedly accelerated when vaping increased. Like previous analyses, the proportion of daily to past 30-day smoking decreased slowly through 2012, but the extent of the decline in this measure of smoking intensity increased once vaping became popular. The results were consistent across different surveys, suggesting that the results are robust across different methods of data collection.*"

6.35 The PHE report (2018) [70] found that "[d]*espite some experimentation with these devices among never smokers, EC* [ENDS] *are attracting very few young people who have never smoked into regular use*" and that "*EC use among never smokers in GB remains very rare at less than 1%, similar to the level of use of NRT. Among never smokers who have ever used EC, a minority have used nicotine-containing liquids and the vast majority have not progressed to regular use.*" These findings were supported by the 2019 PHE evidence update, which found that "[i]*n England and in Great Britain as a whole, experimentation with EC has steadily increased in recent years. However, regular use remains low, with 1.7% of 11 to 18 year olds in Great Britain reporting at least weekly use in 2018 (it was 0.4% among 11 year olds and 2.6% among 18 year olds). Vaping continues to be associated with smoking. The proportion of young people who have never smoked who use EC at least weekly remains very low (0.2% of 11 – 18 year olds in 2018)…* "[71]

6.36 The most recent data from New Zealand also provide no indication of a youth gateway effect into smoking from vaping.[72] Youth smoking rates continue to decline, daily use of ENDS is rare and is largely confined to those who have smoked. Although a third of Year 10 students reported having tried an e-cigarette, only 0.4% of Year 10 students who never smoked

68 ASH (2018), Use of e-cigarettes among young people in Great Britain.

69 Levy et al., (2018) Examining the relationship of vaping to smoking initiation among US youth and young adults: a reality check.

70 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.

71 Public Health England, Vaping in England: an evidence update February 2019. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/781748/Vaping_in_England_an_evidence_update_February_2019.pdf.

72 ASH New Zealand 2019. Fact sheet - 2018 ASH Year 10 Snapshot, E-cigarettes and vaping. Available via: https://www.ash.org.nz/ash_year_10.

reported using ENDS daily. ASH also found that whilst the proportion of users trying ENDS has increased since 2014 in New Zealand, this has not been accompanied by a comparable increase in daily use.

6.37 Shapiro (2018) [73] concluded that: "[t]*o date, there is no evidence of a gateway effect to regular smoking, although some young people will experiment with e-cigarettes because of the novelty factor and may also try cigarettes too. Specific studies show that use of e-cigarettes among young people is largely experimental with the majority using flavours that do not even contain nicotine.*"

6.38 A systematic review of the evidence conducted by the University of Victoria, Canada (2017),[74] found that: "[f]*our population survey studies found that tobacco use rates among youth were declining as vapour device prevalence increased. The two regression analysis studies provided the strongest evidence that vapour device use does not lead to tobacco use among youth, as US adolescents with access to vapour devices had lower rates of tobacco uptake than those who were banned from the legal purchase of vapour devices*."

6.39 The same report 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*" and the authors stated that "**[p]*olicy should not be driven by ungrounded fears of a "gateway effect" but, rather, be geared towards helping tobacco smokers quit and ensuring that only the safest devices are legally available, thereby reducing harm for both direct and second hand exposure***"[75] (emphasis added).

6.40 Studies that purport to show that youth who initiate smoking with ENDS are more likely to be smoking conventional cigarettes do not establish that it is the use of ENDS that leads to smoking, or if instead individual characteristics predict both ENDS use and future smoking.

6.41 Indeed, commenting on studies that purport to find a gateway effect, Gartner (2017)[76] states: "[s]*everal things should be considered in the interpretation of these studies:*

> *1. A proportion of the young people who try vaping and then smoking would have also tried smoking without trying vaping due to a common liability to experiment with substance use.*
>
> *2. It is plausible that vaping may increase the likelihood of experimenting with smoking through increased familiarity with a behaviour that resembles smoking*

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73 *Shapiro (2018) No Fire, No Smoke: The Global State of Tobacco Harm Reduction 2018 (2018). London: Knowledge-Action-Change.*

74 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.

75 Ibid.

76 Gartner CE. E-cigarettes and youth smoking: be alert but not alarmed. *Tob Control*; 2017 Sep 8;tobaccocontrol-2017-054002.

and/or curiosity about how the two experiences compare. But it is unknown how many of those who might try smoking who would not have done so without trying vaping first will then go on to become regular smokers.

3. The baseline waves of these longitudinal studies were conducted in locations and at times when there were no age restrictions on sales of vaping products. In such a regulatory context, it is not surprising that young people may have tried the product with less restrictions first. This pattern may change as 18+ age restrictions are adopted in more jurisdictions.

4. The absolute number of young people regularly vaping or smoking remains low and appears to be decreasing."

6.42 PHE 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*." This includes measurements of vaping and smoking and other factors not measured in the studies (such as sensation seeking, curiosity, expectancies, genetic vulnerabilities) that may explain why some young people had tried smoking by follow-up.[77]

6.43 A study by Warner (2018)[78] which sought to provide a broad overview of issues and evidence on tobacco harm reduction, concluded that "[a]*s with previous examples of public health harm reduction, we cannot know in advance, with absolute certainty that e-cigarettes, or THR* [tobacco harm reduction] *more generally, are unequivocally desirable. So, we have to go with the best available evidence. Lives are at stake. What does that best evidence indicate?*

Adolescents are giving up tobacco, at an unprecedented rate;

E-cigarettes appear to be increasing smoking cessation;

And even if vaping causes some never-smoking adolescents to try smoking, a moderate rate of increased smoking cessation by adults makes e-cigarettes a net public health good."

6.44 Accordingly, while it remains important to monitor the use of ENDS by young people, claims that ENDS are causing an increase in cigarette smoking are not substantiated by the current evidence.

77 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.*

78 Kenneth E Warner (2018). How to Think—Not Feel—about Tobacco Harm Reduction, Nicotine & Tobacco Research. Available at: https://doi.org/10.1093/ntr/nty084.

6.45 **Tobacco Heating Products**

Health Effects

6.46 A THP is a category of device with a tobacco consumable that is designed to deliver greatly reduced toxicant emissions in comparison with conventional cigarettes. THPs achieve this by controlled heating of a tobacco consumable to temperatures much lower than are achieved in a conventional burning cigarette. Consumption of THPs involves no combustion or smoke. They produce a nicotine-containing aerosol composed mainly of water, humectant (e.g. glycerol), nicotine, and flavourings. Because the tobacco is neither burned nor excessively heated, the aerosol produced by tobacco heating products contain far fewer and lower levels of odorous, irritant, or toxic chemicals than does conventional cigarette smoke.

6.47 Whilst acknowledging the need for more research, the emerging scientific evidence suggests that THPs are likely to be substantially less hazardous than traditional combustible cigarettes. For example, in its 2018 report, PHE concluded that "[t]*he available evidence suggests that heated tobacco products may be considerably less harmful than tobacco cigarettes.*" [79]

6.48 British American Tobacco peer-reviewed scientific research on the aerosol from its THP (glo™) published in 2017, found a 90-95% reduction as compared to smoke from a conventional reference cigarette, in the emission of nine harmful toxicants that the WHO recommends to reduce in cigarette smoke.[80,81]

6.49 The UK Committee on Technology (2017)[82], which reviewed data for heat-not-burn products (British American Tobacco's glo™ iFuse product and Philip Morris International's IQOS product), found a reduction of 50-90% in the harmful and potentially harmful compounds in the aerosol generated by the devices as compared to the smoke from conventional cigarettes. The UK Committee on Technology found that "*the exposure to compounds of concern in using heat-not-burn tobacco products is reduced compared to that from conventional cigarette smoke. It is likely that there is a reduction in overall risk to health for conventional smokers who switch to heat-not-burn tobacco products.*"

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79 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.

80 Comparison between smoking tobacco smoke of a 3R4F standard cigarette (about 9 mg of tar) and aerosol from heating tobacco by glo.

81 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).

82 UK Committee on Toxicology, *Toxicological evaluation of novel heat-not-burn tobacco products* – non-technical summary, 2017.

6.50 A study by Caponnetto et al., (2018)[83] which investigated the carbon monoxide in the exhaled breath ("eCo") of participants after use of two THPs found "*no eCO elevations during inhalation testing with HTPs* [Heated Tobacco Products] *under investigation in any of the study participants. Our findings concur with findings from e-cigarette studies as well as from manufacturer and independent data on HTPs.*"

6.51 A clinical study by Gale et al., (2018)[84], which investigated whether biomarkers of toxicant exposure were reduced when smokers switched from smoking combustible cigarettes to using THPs, found that, "*when smokers switched from smoking combustible cigarettes to using tobacco heating products their exposure to smoke toxicants was significantly decreased. In many cases, this was to the same extent as that seen when they quit smoking completely*. *This may indicate that these products have the potential to be reduced exposure and/or reduced risk tobacco products when used by smokers whose cigarette consumption is displaced completely.*"

6.52 Haziza C. et al. (2017) 85 assessed the reduction in levels of exposure to harmful and potentially harmful constituents in consumers using a THP system compared to conventional cigarettes. The authors found that "[t]*he levels of exposure to HPHCs* [harmful and potentially harmful constituents] *were significantly reduced in participants switching to THS 2.2* [THP]*, compared to CC* [conventional cigarette] *use. More importantly, the magnitude of exposure reduction observed was close to that which was seen in participants who abstained from smoking for 5 days, while nicotine uptake was maintained….*"

6.53 Mallock N. et al (2018)[86] found that "*levels of major carcinogens are markedly reduced in the emissions of the analysed HNB* [heat not burn] *product in relation to the conventional tobacco cigarettes and that monitoring these emissions using standardized machine smoking procedures generates reliable and reproducible data which provide a useful basis to assess exposure and human health risks.*"

6.54 Farsalinos et al. (2018)[87] compared the levels of carbonyl emissions from Philip Morris International's IQOS THP, an e-cigarette, and Marlboro Red cigarettes using three puffing regimes. The authors found that *"*[t]*he IQOS heated tobacco product emits substantially*

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83 Caponnetto et al., (2018) *Carbon monoxide levels afte rinhalation from new generation heated tobacco products.*

84 Gale, N. et al. (2018) Changes in Biomarkers of Exposure on Switching From a Conventional Cigarette to Tobacco Heating Products: A Randomized, Controlled Study in Healthy Japanese Subjects Nathan Gale.

85 Haziza, C, et al. (2016) Assessment of the reduction in levels of exposure to harmful and potentially harmful constituents in Japanese subjects using a novel tobacco heating system compared with conventional cigarettes and smoking abstinence: A randomized controlled study in confinement. Regulatory Toxicology and Pharmacology 2017; 81: 489–499.

86 Mallock N. et al (2018) Levels of selected analytes in the emissions of "heat not burn" tobacco products that are relevant to assess human health risks. Archives of Toxicology. 2018 May 5. doi: 10.1007/s00204-018-2215-y.[Epub ahead of print] PubMed PMID: 29730817.

87 Farsalinos et al. (2018). Carbonyl emissions from a novel heated tobacco product (IQOS): comparison with an e-cigarette and a tobacco cigarette, Addiction. Available at https://doi.org/10.1111/add.14365.

lower levels of carbonyls than a commercial tobacco cigarette (Marlboro Red) but higher levels than a Nautilus Mini e-cigarette." However, the authors highlight *"that the absolute difference in carbonyl emissions between the heated tobacco products and the e-cigarette is low when compared to the difference between these products and tobacco cigarette smoke."* The authors conclude that "*although not harmless, the findings suggest that IQOS products can have a role as harm reduction products if smokers switch to them and stop using combustible cigarettes – although far more testing is required.*"

6.55 A recent systematic review of the peer-reviewed literature on THPs by Simonavicius et al., (2018)[88] found that "[f]*ive RCTs* [randomised controlled trials] *demonstrated that switching from smoking cigarettes to using HnB significantly reduces but does not eliminate exposure to HPHC* [harmful and potentially harmful compounds]."

Health Risks to Bystanders

6.56 While noting the need for more research, PHE in its 2018 review of the evidence on ENDS and THPs, concluded that "[c]*ompared 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). The extent of the reduction found varies between studies*."

6.57 Professor David Harrison from the UK Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment stated in his oral testimony to the House of Commons Science and Technology that "[w]*ith e-cigarettes or with heat-not-burn, there is a similar issue. Everything is reduced compared with cigarette smoke, but bystander effect effects are something to be aware of. One would expect, however, that the dose would be commensurately less than for cigarettes.*"

6.58 In its response to the House of Commons Science and Technology Committee Report on ENDS, the UK Government noted that "[t]*here is a reduction in risk to bystanders where conventional smokers switch to heat not burn products.*"

Gateway Effect

6.59 We are not aware of any reliable data that supports the proposition that THPs have a 'gateway effect' that leads to increased uptake of cigarette smoking.

88 Simonavicius et al., (2018) *Heat-not-burn tobacco products: a systematic literature review.*

6.60 **Oral Tobacco Products**

Health Effects

6.61 The category of oral tobacco products covers a wide range of products that differ in their toxicant content and risk profiles. However, there is a growing recognition that the exclusive use of oral tobacco products can present less risk to users than continued smoking.[89]

6.62 Within the oral tobacco category, snus is at the low end of the risk continuum model. Though not risk free, there is a scientific consensus that Swedish snus is dramatically less dangerous than conventional cigarettes. Although more recent tobacco-free, nicotine-containing oral products are too new for the same extensive database of evidence to exist, the absence of tobacco leads to greatly reduced toxicants and suggests potentially reduced health risks when these products are used as a complete substitute for continued smoking.

6.63 Shapiro (2018) explains that: "[t]*he relatively lower risks from smokeless tobacco products in general and Swedish-style snus in particular are well evidenced in the literature backed by decades of research. In summary, snus is a safer nicotine delivery product because:*

> *It is pasteurised to remove toxins*;
>
> *There is no inhalation, so no risk of respiratory disease which accounts for nearly half of all smoking-related deaths*;
>
> *There is no significant association with premature deaths, diabetes, pancreatic and oral cancers, heart disease or stroke*."[90]

6.64 In a 2007 report, the RCP concludes that "[o]*n toxicological and epidemiological grounds, some of the Swedish smokeless products appear to be associated with the lowest potential for harm to health*."**[91]** Similarly, the WHO Scientific Advisory Committee on Tobacco Product Regulation has concluded that "[a]*mong the smokeless tobacco products on the market, products with low levels of nitrosamines, such as Swedish snus, are considerably less hazardous than cigarettes*."**[92]**

6.65 In Levy et al (2004) a panel of experts estimated the relative risk of low-nitrosamine smokeless tobacco (LN-SLT), including snus. In comparison with smoking, the experts

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89 Royal College of Physicians. Harm reduction in nicotine addiction: helping people who can't quit. A report by the Tobacco Advisory Group of the Royal College of Physicians. London, United Kingdom, 2007; SCENIHR (Scientific Committee on Emerging and Newly-Identified Health Risks), Scientific opinion on the Health Effects of Smokeless Tobacco Products, 6 February 2008; WHO (2008), The scientific basis of tobacco product regulation: second report of a WHO study group (WHO technical report series; no. 951).

90 Shapiro (2018) *No Fire, No Smoke: The Global State of Tobacco Harm Reduction 2018* (2018). London: Knowledge-Action-Change, at p68.

91 Royal College of Physicians. Harm reduction in nicotine addiction: helping people who can't quit. A report by the Tobacco Advisory Group of the Royal College of Physicians. London: RCP, 2007.

92 The scientific basis of tobacco product regulation: second report of a WHO study group (WHO technical report series; no. 951), p273.

estimated at least a 90% reduction in the relative risk of LN-SLT use.[93] More recently, in 2014, a panel of experts attributed a relative harm score of 100% for conventional cigarettes, while giving a score of 5% for snus.[94]

6.66 The Global Burden of Diseases, Injuries, and Risk Factors Study 2016 (GBD 2016) (the only peer-reviewed, comprehensive, and annual assessment of risk factor burden by age, sex, cause, and location for a long time series that complies with the Guidelines for Accurate and Transparent Health Estimates Reporting (GATHER)), did not find sufficient evidence of a relative risk of greater than one for any health outcome for snus. The authors stated: "*existing evidence does not support attributing burden* [of disease] *to snus or similar smokeless tobacco products*." [95]

Health Risk to Bystanders

6.67 Oral tobacco products are smokeless. As such they do not produce any emissions and present no health risks to bystanders, or cause any smoke or smell that may be considered unpleasant or inconvenient to bystanders. Accordingly, there is no rational basis to include these products in a public place smoking ban.

Gateway Effect

6.68 There is no reliable data that supports the proposition that snus has a 'gateway effect' that leads to increased uptake of cigarette smoking.

6.69 The European Union Scientific Committee on Emerging and Newly Identified Health Risks concluded, in its opinion on 6 February 2008 that "[t]*he Swedish data, with its prospective and long-term follow-up do not lend much support to the theory that smokeless tobacco (i.e. Swedish snus) is a gateway to future smoking*."[96]

6.70 Lund et al., (2013) states with regard to Norway, that: "[a]*t the aggregate level, the correlation between snus use and smoking is negative in the sense that the proportion of young snus users have increased, while the proportion of young smokers have declined. If a strong gateway effect really existed, we should rather expect to find that the increase in snus use*

93 Levy D et al. The Relative Risks of a Low-Nitrosamine Smokeless Tobacco Product Compared with Smoking Cigarettes: Estimates of a Panel of Experts. Cancer Epidemiol Biomarkers Prev 2004;13(12):2035–42.

94 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.

95 Global, regional and national comparative risk assessment of 84 behavioural, environmental and occupational, and metabolic risks or clusters of risks: a systematic analysis for the Global Burden of Disease Study 2016. *Lancet*; 2017, 390, 1345–1422.

96 Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) (2008). Health effects of smokeless tobacco products, Scientific Committee on Emerging and Newly Identified Health Risks, European Commission, Brussels.

was associated with a subsequent increase in the percentage of smokers – and not a reduction." [97]

6.71 Lee (2015) considers how the gateway hypothesis should be properly investigated and reviews those studies that appear to provide data relevant to the relationship between snus and conventional cigarette smoking. He concludes: "[t]*here is currently no good information relating to the question of whether prior snus use might encourage initiation of smoking. All the studies have weaknesses in design or analysis that render their conclusions unreliable, particularly as data on other factors relevant to smoking initiation are not taken into account*."[98]

6.72 A study by Ramström et al., (2016)[99] which analysed the relationships between snus use and smoking in Sweden, concluded that "[i]*t appears that snus has contributed to decreasing initiation of smoking rather than serving as a gateway to smoking. Smokers who have taken up snus use have quit smoking to a significantly greater extent than smokers without snus use, and a substantial proportion has eventually quit snus use as well and become tobacco free. These effects have been consistent across five decades…*"

7. CONCLUSION

7.1 In conclusion, the proposal to ban public place use of smoke and tobacco free alternatives, including ENDS, THPs and oral products, in the same way as combustible tobacco products is not supported by the evidence and represents a missed opportunity for the Government to advance its goal of reducing the projected burden of tobacco related disease:

7.1.1 There is international recognition that tobacco harm reduction is an essential component of a rational and effective tobacco control policy. In proposing that the public place smoking ban also be applied to PRRPs, the Government is failing to assess the impact of the decision on public health overall.

7.1.2 Regulating PRRPs in the same way as tobacco products risks foreclosing the product category and will undermine the potential public health benefits they offer.

7.1.3 There is increasing agreement among health experts that exclusive use of PRRPs confers reduced risks of harm as compared to smoking conventional cigarettes.

7.1.4 The evidence suggests that PRRPs have contributed to reducing smoking prevalence in countries with a more flexible regulatory landscape that facilitates consumer awareness, access and use.

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97 Karl Erik Lund, (2013) "Tobacco harm reduction in the real world: has the availability of snus in Norway increased smoking cessation?", Drugs and Alcohol Today, Vol. 13 Issue: 2, pp.92-101, https://doi.org/10.1108/DAT-02-2013-0006.

98 Peter N Lee Appropriate and inappropriate methods for investigating the “gateway” hypothesis, with a review of the evidence linking prior snus use to later cigarette smoking., Harm Reduction Journal (2015) 12:8.

99 Ramström et al., (2016), *Patterns of Smoking and Snus Use in Sweden: Implications for Public Health.*

7.1.5 The overall weight of the evidence does not support the Government's Proposal, but suggests that PRRPs have provided a gateway out of smoking for thousands of smokers.

7.1.6 There is no basis for including oral smokeless products in the Proposal. These products do no produce any emissions and therefore create no concerns for bystanders. Similarly, there can be no justified basis for including ENNDS within the scope of the Proposal when they do not contain tobacco or nicotine.

7.2 In light of the above, we strongly urge the Government to reject the Proposal to extend the public place smoking ban to smoke and tobacco free alternative products, including ENDS/ENNDS, THPs, and oral products.