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

COMMENTS ON PROPOSAL TO AMEND THE TOBACCO AND SMOKING PRODUCTS DECREE IN CONNECTION WITH THE INTRODUCTION OF STANDARD PACKAGING FOR ELECTRONIC VAPOR GOODS

18 SEPTEMBER 2020

CONTENTS

1. INLEIDING

1.1 Deze inbreng van B.A.T. Nederland (BAT) is een reactie op de internetconsultatie uitgevaardigd door het ministerie van Volksgezondheid, Welzijn en Sport (ministerie) om per AMvB een een grondslag te creëeren om bij ministeriële regeling eisen te stellen aan het uiterlijk van de verpakkingen van sigaren en elektronische dampwaar (het '**Voorstel**').

1.2 B.A.T. Nederland, een onderdeel van de British American Tobacco Group ('**BAT**'), ontwikkelt en vermarkt nicotineproducten met potentieel gereduceerd risico en rookvrije tabaksproducten.

1.3 BAT is een voortrekker in de ontwikkeling en verkoop van een uitgebreid assortiment producten met een potentieel minder schadelijk risicoprofiel (PRRP's) die een alternatieve vorm van roken bieden waarbij geen tabak wordt verbrand (bv. e-sigaretten). In dit kader heeft BAT uitvoerig geïnvesteerd in zijn activiteiten op het vlak van onderzoek en ontwikkeling ('**R&D**'). Sinds 2012 heeft BAT samen met Reynolds American Inc. ongeveer $4 miljard geïnvesteerd in de ontwikkeling van zijn PRRP-segment. Voor BAT zijn meer dan 1100 mensen werkzaam in de bedrijfstakken wetenschap, technologie en innovatie, en op dit moment zijn 55% van de senior R&D-medewerkers externe werkkrachten. BAT's groeiende portfolio PRRP-producten omvat elektronische vapeartikelen (e-sigaretten), tabakverwarmingsproducten ('**THP**') en tabaksvrije zakjes nicotine voor oraal gebruik.

1.4 Zoals aangegeven in deze inbreng zijn wij sterk gekant tegen het Voorstel. Standaardverpakkingen voorschrijven voor e-sigaretten, die vooraanstaande gezondheidsinstanties en deskundigen over de hele wereld onderschrijven als een potentieel veel minder schadelijk alternatief voor de traditionele tabaksproducten, kan niet gerechtvaardigd worden op basis van het bewijs, zal de mogelijke voordelen die e-sigaretten voor de volksgezondheid hebben ondermijnen, en riskeert de productcategorie in zijn geheel te belemmeren.

1.5 Wij zijn van mening dat het Voorstel ingaat tegen de belangen van consumenten die traditionele tabaksproducten roken en de overheidsdoelstelling om de volksgezondheid te bevorderen. Standaardverpakkingen voor e-sigaretten zou de misleidende boodschap geven dat e-sigaretten dezelfde risico's hebben als gewone sigaretten. Dit ontzegt consumenten waarheidsgetrouwe informatie en kan rokers ervan weerhouden over te schakelen op deze producten met een potentieel minder schadelijk risicoprofiel.

1.6 Het Voorstel dient tevens beschouwd te worden in het kader van het huidige verbod op reclame voor e-sigaretten, het feit dat e-sigaretten nog vrij nieuw zijn op de markt (in tegenstelling tot de traditionele tabaksproducten, die reeds ingeburgerd zijn) en dat vele rokers zich nog niet ten volle bewust zijn van het bestaan of de eigenschappen van e-sigaretten. Daarom is het essentieel dat fabrikanten de mogelijkheid krijgen om consumenten middels productverpakking op de hoogte te stellen van de kenmerken en beschikbaarheid van hun producten en om aan rokers deze producten als een waardig alternatief voor de traditionele tabaksproducten te laten zien, en zo om deze producten een rol te laten spelen in de beperking van gezondheidsschade in Nederland.

1.7 Wij erkennen de bezorgdheid over nicotine- en tabaksgebruik door jongeren zoals beschreven in het Nationaal Preventieakkoord, [1] en zijn het ermee eens dat enkel volwassenen nicotine- en tabaksproducten mogen gebruiken. Er zijn echter verschillende wettelijke alternatieven die beter geschikt zijn om de toegang en het gebruik door jongeren aan banden te leggen en tegelijk te verzekeren dat volwassen rokers geïnformeerd worden over, en voldoende toegang hebben tot, een keur aan alternatieven voor traditionele tabaksproducten die potentieel minder schadelijk zijn, en die deze rokers in staat stellen om op zulke producten over te stappen.

1.8 Voor alle duidelijkheid: wij zijn niet tegen regulering. Integendeel zelf. Regulering is essentieel om een verantwoorde groei en consumententoegang te verzekeren, en om rokers die wensen over te stappen te ondersteunen. Wel vragen wij om proportionele - geen willekeurige of ondoordachte - maatregelen die oog hebben voor de relatieve risico's en deze

[1] Het Nationaal Preventieakkoord: Een gezonder Nederland

producten niet over één kam te scheren met traditionele tabaksproducten. Zoals een groep onafhankelijke experts inzake volksgezondheid onlangs aangaf: ***"een beleid dat geen onderscheid maakt, komt de volksgezondheid niet ten goede"***.[2]

2. SAMENVATTING

2.1 BAT Nederland is om verschillende redenen gekant tegen het Voorstel dat voor e-sigaretten standaardverpakkingen voorschrijft, o.a.:

2.1.1 HET VOORSTEL HEEFT NADELIG EFFECT OP VOLKSGEZONDHEID

2.1.2 Het is aannemelijk dat het Voorstel een nadelig effect zal hebben op de volksgezondheid doordat het gebruik van traditionele tabaksproducten met groter risico in stand wordt gehouden.

2.1.3 Door standaardverpakkingen voor e-sigaretten voor te stellen, schat het ministerie de algemene impact van zijn beslissing op de volksgezondheid verkeerd in, en schat het de rechten van rokers niet naar waarde.

2.1.4 In concreto gaat het ministerie voorbij aan de voordelen die e-sigaretten voor de volksgezondheid hebben, aangezien zij rokers een alternatief met potentieel gereduceerd risico verschaffen ten opzichte van de traditionele tabaksproducten waar de tabak wordt verbrand. Het merendeel van het hedendaagse wetenschappelijke onderzoek wijst erop dat het gunstig is rokers te informeren over e-sigaretten en hen in staat te stellen om over te stappen naar e-sigaretten; dit is een belangrijk onderdeel van een overheidsbeleid dat de beperking van tabaksschade tot doel heeft.

2.1.5 Er zijn sterke aanwijzingen dat e-sigaretten, in landen met soepelere voorschriften, ertoe hebben bijgedragen dat er minder gerookt wordt doordat consumenten zich bewust zijn van het bestaan en de eigenschappen van e-sigaretten. Het is belangrijk en zelfs noodzakelijk om onderzoek te doen m.b.t. de zorgen dat e-sigaretten nicotinegebruik bij niet-rokers (ook jongeren) veroorzaken en een 'opstap naar roken zou zijn, maar deze bewering is niet gebaseerd op enig geloofwaardig bewijs.

2.1.6 Het ministerie gaat voorbij aan het feit dat de buitensporige beperkingen op e-sigaretten, zoals standaardverpakkingen, de markt voor zulke producten aan banden dreigen te leggen en hun potentieel in de beperking van gezondheidsschade en de ongelijkheid op gezondheidsgebied in Nederland ondermijnen of zelfs geheel tenietdoen.

2.1.7 Standaardverpakkingen voor e-sigaretten opleggen, m.a.w. deze producten op dezelfde wijze reguleren als de traditionele tabaksproducten, zal de potentiële voordelen van e-sigaretten voor de volksgezondheid ondermijnen en dreigt de productcategorie te belemmeren door o.a.:

(1) De misleidende boodschap over te brengen dat e-sigaretten qua gezondheidsrisico's vergelijkbaar zijn met gewone sigaretten, en zo de huidige misvattingen over de relatieve risico's van deze producten bestendigen en rokers ontmoedigen om over te stappen;

(2) Obstakels te vormen voor het bewustzijn en het gebruik van het product door de productcommunicatie buitensporig aan banden te leggen; en

(3) Bijkomende kosten en obstakels op te werpen tegen een eventuele overstap, en zo innovatie tegen te werken en de

[2] Fairchild et al (2019) Evidence, alarm, and the debate over e-cigarettes, Science13 dec 2019: 1318-1320.

beschikbare productopties te reduceren voor rokers die wensen over te stappen.

2.1.8 In zijn rapport van 2016 onderkende het Royal College of Physicians in het Verenigd Koninkrijk het gevaar van overmatige reglulering, waaronder standaardverpakkingen:

"'A risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm, eg exposure to toxins in e-cigarette vapour, renormalisation, gateway progression to smoking, or other real or potential risks. ***However, 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]

2.1.9 Wij vragen het ministerie nadrukkelijk om in plaats van e-sigaretten op dezelfde wijze te benaderen als traditionele tabaksproducten, zich te richten op de ontwikkeling van een evenwichtig regelgevingsstelsel ter ondersteuning van de markt voor e-sigaretten, zodat volwassen rokers toegang hebben tot en zich bewust zijn van een keur aan alternatieven voor traditionele tabak met een potentieel gereduceerd risico, en tegelijk jongeren behoeden voor het gebruik van tabaks- en nicotineproducten.

2.1.10 **HET VOORSTEL IS VEREIST NOCH GERECHTVAARDIGD DOOR HET WHO-KADERVERDRAG INZAKE TABAKSONTMOEDIGING**

2.1.11 Het Kaderverdrag inzake tabaksontmoediging ('**FCTC**') van de Wereldgezondheidsorganisatie ('**WHO**') heeft het niet over de regulering van e-sigaretten noch heeft zij de bedoeling dit te doen.

2.1.12 E-sigaretten zijn geen 'tabaksproducten' aangezien zij niet gemaakt zijn van tabak en niet worden gerookt. Bijgevolg is het FCTC geen legitieme basis voor de regulering van deze producten.

2.1.13 Zelfs als het FCTC van toepassing was op e-sigaretten, ziet het FCTC de beperking van tabaksschade als onderdeel van de strategie ter verbetering van de volksgezondheid: tabaksverbruik en de blootstelling aan tabaksrook worden er immers door verminderd. Een juiste toepassing van het FCTC zou dan ook evenwichtige, proportionele regulering inhouden die oog heeft voor de relatieve risico's van verschillende producten, en tot doel heeft het potentieel van e-sigaretten te maximaliseren zodat ze de gezondheidsbelasting gerelateerd aan roken vermindert en het gebruik door niet-rokers (zoals jongeren) tot een minimum wordt beperkt.

2.1.14 Het standpunt van het WHO ten aanzien van e-sigaretten als onderdeel van beleid tot beperking van tabaksschade is zwaar bekritiseerd door onafhankelijke experts. Zij vinden dat ze niet op feiten gebaseerd is[4] en gestoeld op een foutieve en verouderde politieke ideologie die enkel maar onthouding van tabak en nicotine voorschrijft.

2.1.15 **HET VOORSTEL IS ONWETTIG**

2.1.16 Het Voorstel is strijdig met een aantal wettelijke rechten, wat de wettigheid ervan in het geding brengt. Enkele hiervan zijn:

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

4 Zie bv. https://www.sciencemediacentre.org/expert-reaction-to-world-health-organisation-qa-on-electronic-cigarettes/.

1. Het voorstel om standaardverpakkingen in te voeren voor e-sigaretten heeft geen juridische gronden krachtens de tabaksproductenrichtlijn van de EU (2014/40/EU) ('**TPD**').

2. Het Voorstel beperkt onterecht het vrije verkeer van goederen tussen Nederland en andere EU-lidstaten.

3. Het Voorstel zou een inbreuk zijn op de persoonlijke keuzevrijheid van rokers

4. Het Voorstel zou een schending zijn van het recht van fabrikanten en winkeliers om een bedrijf te voeren, en hun recht op vrije meningsuiting en hun eigendomsrecht, met inbegrip van handelsmerkrechten, zoals beschermd door de Nederlandse Grondwet en het Europees Verdrag tot bescherming van de Rechten van de Mens ('**ECHR**'), en het Handvest van de grondrechten van de Europese Unie.

5. Het Voorstel schendt het verbod op willekeur, omdat er onvoldoende rekening wordt gehouden met de belangen van degenen die onevenredig worden geraakt.

2.1.17 **HET VOORSTEL IS ONGEPAST EN DISPROPORTIONEEL**

2.1.18 Standaardverpakkingen toepassen voor e-sigaretten, een productcategorie met veel minder giftige stoffen en een kleiner geschat risicoprofiel dan sigaretten, en waarvan de beschikbaarheid aantoonbaar verband houdt met dalingen in rookcijfers, is niet enkel ongepast en discriminerend, maar kan ook ongunstig zijn voor de volksgezondheid, aangezien het gebruik van de gevaarlijkere traditionele tabaksproducten waarbij verbranding vrij komt behouden blijft.

2.1.19 In plaats van dat het de volksgezondheid ten goede komt, heeft dit Voorstel ingrijpende nadelige effecten tot gevolg. Het Voorstel wordt niet gesteund door, en gaat juist in tegen de meeste wetenschappelijke bewijzen, die ervoor pleiten volwassen rokers toegang te geven tot de informatie die nodig is om een onderscheid te maken tussen de verschillende producten. En daarmee consumenten een weloverwogen keuze te laten maken, als belangrijk onderdeel van een overheidsstrategie gericht op de reductie van tabaksschade.

2.1.20 Het potentieel van e-sigaretten om bij te dragen aan het verminderen van schade door tabaksgebruik zal belemmerend en waarschijnlijk zelfs geheel tenietgedaan worden als rokers geen informatie kunnen krijgen over deze producten en/of als deze producten veel minder aanvaardbaar worden als alternatief voor de traditionele tabaksproducten.

2.1.21 Standaardverpakkingen voor e-sigaretten opleggen zou bovendien de illegale handel bevorderen doordat de stimulans om voor legale producten te betalen weggenomen wordt, aangezien deze laatste er niet meer uitzien als premium producten en moeilijker te onderscheiden zullen zijn van (niet-gereguleerde) illegale producten.

2.1.22 Er zijn bovendien verschillende alternatieve regulerende opties die beter geschikt zijn om te zorgen dat jongeren minder toegang hebben tot e-sigaretten en minder kans maken om te beginnen. Deze maatregelen hebben het bijkomende voordeel dat ze de volksgezondheid aanzienlijk ten goede komen doordat ze een vermindering van tabaksschade in de hand werken. Denk bv. aan:

(A) Strenge handhavingsmaatregelen invoeren om ervoor te zorgen dat winkeliers en derden de wet naleven en jongeren geen e-sigaretten of tabaksproducten verschaffen;

(B) Sancties invoeren voor personen die betrapt worden op het verschaffen van e-sigaretten of tabaksproducten aan jongeren;

(C) Verplichte trainingen geven aan ieder die e-sigaretten en tabaksproducten verkoopt;

(D) Voorlichtingsprogramma's en bewustmakingsinitiatieven invoeren om ervoor te zorgen dat volwassenen geen e-sigaretten kopen voor jongeren;

(E) Webverkopers verplichten een degelijke externe leeftijdsverificatieprocedure te gebruiken alvorens online bestellingen van e-sigaretten of tabaksproducten te aanvaarden;

(F) Gerichte voorlichtingsprogramma's voor jongeren invoeren teneinde ervoor te zorgen dat zij geen tabaks- en nicotineproducten gaan gebruiken.

2.1.23 **HET VOORSTEL ZOU DE INTERNATIONALE VERPLICHTINGEN VAN NEDERLAND SCHENDEN**

2.1.24 Het Voorstel zou internationale verplichtingen op grond van de verdragen van de Wereldhandelsorganisatie ('**WTO**') schenden, bv. de Overeenkomst inzake de handelsaspecten van de intellectuele eigendom ('**TRIPs-verdrag**'), het Verdrag aangaande technische belemmeringen voor de handel ('**TBT-verdrag**') en de Algemene Overeenkomst betreffende tarieven en handel uit 1994 ('**GATT**').

2.1.25 **HET VOORSTEL WERD NIET ONDERWORPEN AAN EEN GEDEGEN PROCES**

2.1.26 Het Voorstel is onwettig. En zelfs als het wettig zou zijn, zou een effectbeoordeling die de voorgestelde maatregel grondig analyseert (o.a. of deze noodzakelijk en effectief is, en of er minder zware middelen zijn om de doelstellingen te bereiken) ondernomen moeten zijn, naast een zinvol consultatieproces dat het Ministerie in staat stelt het Voorstel correct onder de loep te nemen.

2.1.27 De noodzaak van een dergelijke effect beoodeling staat beschreven in aanwijzing 2.2. van de Aanwijzinge voor de regelgeving

"*Regelgeving is noodzakelijk indien aannemelijk is dat het concrete voorstel een effectieve, efficiënte en evenredige reactie vormt op het maatschappelijke probleem dat aanleiding geeft voor die regelgeving. Daarvoor is dus vereist dat voldoende zekerheid bestaat dat de voorgestelde regeling werkelijk zal leiden tot het oplossen of verminderen van dat probleem, dat er geen minder bezwarende alternatieven zijn, en dat de kosten en lasten daarvan gerechtvaardigd worden door de ernst van het probleem. Indien niet aan elke van deze voorwaarden is voldaan, bestaat onvoldoende grond om tot regelgeving (in de voorgenomen vorm) over te gaan. Eventueel kan in zo'n geval een alternatief, minder bezwarend sturingsinstrument worden ingezet, of dient simpelweg van overheidsingrijpen te worden afgezien.*"

2.1.28 De bekrachtiging van doeltreffende en op feiten berustende regelgeving die de doelstellingen op het vlak van de volksgezondheid behalen, en het wettelijk kader van Nederland die internationale verplichtingen respecteert, staat centraal in het uitstippelen van op feiten gebaseerde, transparante en werkzame regelgeving.

2.1.29 Het ministerie heeft echter geen effectbeoordeling of studies naar aanleiding van het Voorstel openbaar gemaakt. Het heeft geen substantiële redenen of aanwijzingen gegeven waarom het Voorstel noodzakelijk of geschikt is voor e-sigaretten, noch heeft het een evenredigheidsanalyse verschaft.

2.1.30 Bovendien heeft het ministerie vóór de publicatie van dit Voorstel geen mening van belanghebbenden uit de e-sigaret sector ingewonnen of hen de gelegenheid gegeven commentaar te leveren op de analyse en het bewijs dat is gebruikt om het opleggen van standaardverpakkingen te rechtvaardigen.

2.1.31 Bij gebrek aan een op feiten gebaseerde effectbeoordeling kan niet worden aangetoond dat het Voorstel noodzakelijk, gepast en proportioneel is. Het ministerie kan dan ook niet aantonen dat het Voorstel voldoet aan de verplichtingen ingevolge het Verdrag betreffende de werking van de Europese Unie ('**TFEU**') en de verdragen van de Wereldhandelsorganisatie.

3. OVERVIEW OF E-CIGARETTES

3.1 E-cigarette products are handheld battery-powered electronic devices that heat a liquid formulation to create an inhalable vapour. They contain no tobacco and no combustion takes place.

3.2 Most e-cigarette products are based on 'coil and wick' technology. The coil – also known as an atomiser – heats a cotton wick that conveys the liquid, producing a vapour that is inhaled.

3.3 Generally, e-cigarette products are either closed or open systems. Closed systems feature a closed cartridge containing e-liquid. Vapers insert replacement cartridges to continue using the device. Open systems enable the vaper to refill the e-liquid and mix flavours to their taste.

3.4 The diagrams below identify the main features of two of BAT's e-cigarette variants, the Vype ePod and the ePen3, which are closed system e-cigarettes:

3.5 As shown in the above diagrams, the device consists of a number of components which can be assembled and disassembled by the user. There are two primary components: a rechargeable battery and a replaceable e-liquid containing cartridge.

3.6 The above devices also have removable mouthpieces (inside which the cartridge fits) and a screw connection by which the cartridge is connected to the battery section. The ePen3 can only be used in combination with disposable cartridges pre-filled with Vype proprietary e-liquids.

3.7 To operate the device, a user presses a power button situated on the outer casing. This causes current to flow from the battery to the heating coil which heats the e-liquid soaked wick. This causes the e-liquid to vaporise and generate an aerosol which is inhaled by the user via the mouthpiece.

3.8 Vype e-liquids contain vegetable glycerol, propylene glycol, water, flavouring and nicotine (although some e-liquids are also available in nicotine-free form).

3.9 The vegetable glycerol and propylene glycol are 'humectants', which are substances that retain moisture. They give the aerosol its body as well as carrying the flavours and the nicotine. The vegetable glycerol, propylene glycol and nicotine used in the e-liquid are all pharmaceutical-grade. The flavourings are all food-grade. The e-liquid does not contain any ingredients that are classified as carcinogens, mutagens, reprotoxins or respiratory sensitisers.

3.10 As e-cigarettes do not contain tobacco and there is no combustion, the vapour from e-cigarettes contains substantially lower levels of the toxicants found in the smoke produced when tobacco is burned.

3.11 **A copy of a BAT Scientific Information for Vype Electronic Nicotine Delivery Systems is provided as Appendix 2 to this Response. This** presents peer reviewed published scientific evidence suggesting the potential of the Vype e-cigarettes as an instrument to support tobacco harm reduction. This scientific evidence includes:

3.11.1 An overall reduction in emission toxicant levels for Vype products is in the order of 98%-99% relative to the scientific reference cigarette, focusing on the list of nine priority toxicants proposed for reduction via product regulation by the WHO Study Group on Tobacco Product Regulation (“WHO TobReg”).

3.11.2 Reduced toxicity responses across a series of laboratory toxicological tests, which findings are in accordance with Public Health England’s and the UK Royal College of Physicians’ predictions of the significantly reduced relative risk of e-

cigarette use compared to smoking. In particular, the scientific information document states:

"We have used traditional toxicological tests such as the Bacterial Reverse Mutation Test [Thorne 2016 and Thorne 2017b], as defined by the OECD, and the Neutral Red Uptake [Azzopardi 2016] test for cytotoxicity, both of which gave none or little response to the Vype e-cigarettes aerosol, whereas the reference cigarette induced dose dependent mutagenic and cytotoxic responses. Additional toxicological tests for oxidative stress [Taylor 2016a], genotoxicity [Thorne 2017a], tumour promotion [Breheny 2016], wound healing (a cell migration test likely relevant to cardiovascular disease) [Taylor 2016b] and blood vessel cytotoxicity [Bozhilova 2020] all showed much reduced response or no response with the Vype e-cigarettes aerosol compared to the cigarette smoke. A series of dosimetric studies were undertaken to ensure that equivalent amounts of aerosol were delivered to the cellular systems during both cigarette and Vype e-cigarettes exposure [Adamson 2016]. These results are consistent with the chemical analysis of the Vype e-cigarettes emissions [Margham 2016] and provide pre-clinical support for the emissions of Vype e-cigarettes to be associated with reduced toxicity in laboratory tests compared to cigarette smoke.

Furthermore, studies that define the disease pathways and underlying mechanisms were investigated using a global and holistic systems science approach. In these studies [Banerjee 2016 and Haswell 2017], a reconstituted 3D human respiratory tissue, Muclilair™, was exposed to 3R4F reference cigarette smoke or Vype e-cigarettes aerosol followed by transcriptomic analysis. When this biologically relevant 3D cell system was exposed to cigarette smoke, a number of genes associated with disease relevant end-points (e.g. tissue damage, inflammation, respiratory damage) were up regulated. When the cellular system was exposed to Vype e-cigarettes aerosol, the same endpoints showed substantially reduced responses. An advantage of this approach was that mechanistic insights could be gained into the drivers of disease responses, for example inflammation damage. In this case, the cytokines which underpin the inflammatory response were measured for both smoke and e-cigarette aerosol exposure. It was found that a significant number of cytokines were expressed in the 3D tissue when exposed to cigarette smoke but with Vype e-cigarettes exposure there was little to no cytokine expression [Banerjee 2016]. Such findings are in accordance with the [Public Health England, Royal College of Physicians, National Academies of Sciences and the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment's] *predictions of the significantly reduced relative risk of e-cigarette use compared to smoking."*

3.11.3 Reduced impact on indoor air quality of using the Vype e-cigarettes (compared to smoking), with the levels of particulate matter in the air during Vype e-cigarettes use not exceeding the WHO's air quality standards.

3.11.4 Empirical modelling suggesting an overall beneficial effect from launching e-cigarettes.

3.12 The scientific information document concludes:

"*We have conducted a series of chemical, in vitro biological and a range of human studies on Vype e-cigarettes in comparison to scientific reference cigarettes or commercial cigarettes. The results from these studies when considered in their totality are in line with the findings of* [Public Health England, Royal College of Physicians, National Academies of Sciences and the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment] *and they demonstrate that Vype e-cigarettes have the potential to be a reduced risk product in comparison to cigarettes. Longer term clinical studies will help to further substantiate Vype e-cigarette potential to contribute to harm reduction on a population level*."

3.13 Published peer-reviewed research by BAT, which is referred to in the scientific information document, includes an examination of 150 chemical emissions from the Vype e-cigarette, a

reference tobacco cigarette (Ky3R4F) and laboratory air/method blanks.[5] All measurements were conducted by an independent, contract research laboratory, using ISO 17025 accredited methods, which found that:

3.13.1 Of the 150 measures examined in the e-cigarette aerosol, 104 were not detected and 21 were present due to laboratory background;

3.13.2 Of the 25 detected aerosol constituents, 9 were present at levels too low to be quantified and 16 were generated in whole or in part by the e-cigarette;

3.13.3 Depending on the regulatory list considered and the puffing regime used, the emissions of toxicants identified for regulation were from 82 to >99% lower on a per-puff basis from the e-cigarette, compared with those from the reference cigarette; and

3.13.4 Thus, the aerosol from the e-cigarette is compositionally less complex than cigarette smoke and contains significantly lower levels of toxicants.

3.14 Cunningham 2020 details the comparisons between cigarette smoke and Vype ePen aerosol, organized by four public health priority toxicant lists:

3.14.1 the nine WHO TobReg constituents proposed for mandated lowering in cigarette smoke;[6]

3.14.2 the 18 constituents on the US Food and Drug Administration ("**FDA**") abbreviated harmful and potentially harmful constituents reporting list;[7]

3.14.3 the Health Canada list of 44 tobacco smoke toxicants;[8] and

3.14.4 the full FDA list of 96 HPHCs (other than the three species for which no analytical method was available).

3.15 As described in the scientific information document, levels of the nine WHO TobReg priority cigarette smoke toxicants were more than 99% lower in the aerosols from each of five e-cigarettes as compared with the commercial and reference cigarettes[9].

4. REQUIRING PLAIN PACKAGING FOR E-CIGARETTES IS CONTRARY TO PUBLIC HEALTH

4.1 In proposing plain packaging for e-cigarettes, the Ministry has failed to assess the impact of its decision on public health overall or to value appropriately the rights of smokers.

4.2 Specifically, the Ministry has failed to consider the public health benefit of e-cigarettes as a potentially reduced risk alternative to combustible tobacco for smokers.

4.3 The Ministry fails to recognise that plain packaging for e-cigarettes risks foreclosing the market in such products and undermining, if not eliminating altogether, the potential for these products to play a role in tobacco harm reduction and in reducing health inequalities in the Netherlands.

4.4 If e-cigarettes are to fulfil their potential for tobacco harm reduction in the Netherlands, it is essential that the Ministry enacts a regulatory framework that promotes (rather than stifles) innovation and growth. This framework must provide efficient regulatory pathways for both

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5 J Margham, K McAdam, M Forster, C Liu, C Wright, D Mariner, C Proctor. Chemical composition of an e-cigarette aerosol – a quantitative comparison with cigarette smoke, Chem. Res. Toxicol. 29 (2016) 1662–1678.

6 Burns DM, Dybing E, Gray N*, et al.,* (2008) Mandated lowering of toxicants in cigarette smoke: a description of the World Health Organization TobReg proposal Tobacco Control 2008;17:132-141. Available here

7 Food and Drug Administration (2012) Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke; Established List, April 2012, available here

8 Liu, C., McAdam, K. G., and Perfetti, T. A. (2011) Some recent topics in cigarette smoke science. Mini-Rev. Mini-Rev. Org. Chem. 8, 349−359.

9 Cunningham A., McAdam K., Thissen J., Digard H. The evolving e-cigarette: comparative chemical analyses of e-cigarette vapour chemistry and cigarette smoke. 2020 Submitted to Frontiers in Toxicology.

bringing the highest quality e-cigarettes to market and supporting smokers who want to switch to such products, including by allowing manufacturers to raise consumer awareness of these products and their features.

4.5 However, far from fostering an environment in which the potential of these products can be realised the implementation of plain packaging will serve only to reduce awareness of e-cigarettes and discourage smokers from switching to such products, thereby perpetuating public tobacco harm rather than improving it.

4.6 **Tobacco harm reduction**

4.7 Tobacco harm reduction is a recognised public health strategy to lower the projected health impacts for individuals and the wider society associated with using tobacco products. The United States Institute of Medicine has defined tobacco harm reduction as "*decreasing total morbidity and mortality, without the complete elimination of tobacco and nicotine use*."[10] 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 other risky behaviours.

4.8 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. Therefore, the opportunity exists for a potential significant gain for public health by eliminating the inhalation of cigarette smoke for people who continue to use nicotine.

4.9 The concept of tobacco harm reduction is in accordance with the internationally recognised 'right to health' which encapsulates the right to control one's health and body. This includes awareness of and access to acceptable potentially reduced risk nicotine products, including e-cigarettes, and accurate health information in order to make informed decisions in line with one's own motives, reasons and values. For example:

4.9.1 The preamble to the WHO Constitution 1946[11] states that: "*The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition*."

4.9.2 Article 12 of the International Covenant on Economic, Social and Cultural Rights 1966[12] recognises: "*the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*."

4.9.3 The European Social Charter (revised) of 1996[13] states that: "*Everyone has the right to benefit from any measures enabling them to enjoy the highest possible standard of health attainable*". Article 11 requires Member States to take measures to remove the causes of ill-health; and "*to provide advisory and educational facilities for the promotion of health and the encouragement of individual responsibility in matters of health*."

4.9.4 The 1986 WHO Ottawa Charter for Health Promotion[14] states: "*Health promotion is the process of enabling people to increase control over, and to improve, their health. People cannot achieve their fullest health potential unless they are able to take control of those things which determine their health*." The Charter also stresses that: "*Any obstacles to health promotion should be removed with the aim of making healthy choices the easiest choices*".

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10 K. Stratton, P. Shetty, R. Wallace, S. Bondurant (Eds.). Clearing the smoke: assessing the science base for tobacco harm reduction. Washington, DC: The National Academies Press, 2001.

11 Constitution of The World Health Organization. Available at https://www.who.int/governance/eb/who_constitution_en.pdf.

12 International Covenant on Economic, Social and Cultural Rights. Available at https://www.ohchr.org/en/professionalinterest/pages/cescr.aspx.

13 European Social Charter (Revised). Available at https://www.coe.int/en/web/conventions/full-list/-/conventions/rms/090000168007cf93.

14 World Health Organisation, *Ottawa Charter for Health Promotion.* WHO, 1986. Available at *https://www.who.int/healthpromotion/conferences/previous/ottawa/en/*.

4.10 Notwithstanding the fact that the WHO FCTC is not a legitimate basis for regulating e-cigarettes (as further explained below), the concept of tobacco harm reduction is nevertheless firmly embedded in it. The preamble to the FCTC recalls the right to health under international human rights agreements and states that Parties are "[d]*etermined to promote measures of tobacco control based on current and relevant, scientific, technical and economic considerations*." 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.*"

4.11 We refer also to paragraphs [1.1 – 1.6] of **Appendix 1** to this Response which provide additional supporting materials from independent sources.

4.12 In proposing plain packaging for e-cigarettes the Ministry has disregarded the potential public health benefits of e-cigarettes for smokers (as endorsed by many public health experts) and their correlative rights to be accurately informed of the attributes of particular tobacco products.

4.13 **There is increasing agreement amongst health experts that exclusive use of e-cigarettes exposes consumers to significantly reduced toxicants and is estimated to pose substantially reduced risks of harm as compared to continued smoking of cigarettes.**

4.14 Globally, it is accepted that most of the harm associated with tobacco is caused by inhaling the smoke produced by the combustion of tobacco and not nicotine itself, with public health agencies such as the UK Royal College of Physicians stating that: "[t]*he harm of smoking is therefore caused not by nicotine, but by other constituents of tobacco smoke. Non-tobacco nicotine products that reproduce the nicotine delivery and behavioural characteristics of smoking, without the many other toxins in tobacco smoke, therefore have the potential to allow smokers to continue to use nicotine and avoid the significant harm to themselves and others that smoking causes*."[15] The UK National Institute for Health & Care Excellence stated in a 2013 report: "*Most health problems are caused by other components in tobacco smoke, not by the nicotine*."[16] This is also in line with UK National Health Service advice on using e-cigarettes to quit smoking, which states: "[m]*any people think nicotine is very harmful to health. In fact, although it is addictive, nicotine is relatively harmless: it's the thousands of other chemicals in tobacco smoke that cause almost all the harm from smoking*."[17]

4.15 As explained above, e-cigarettes do not contain tobacco and they do not rely on combustion. As a consequence no smoke is formed when the e-liquid is 'vaped' and no tobacco tar is formed. As such, e-cigarettes do not produce the vast majority of toxicants that are contained in tobacco smoke.

4.16 BAT has commissioned an expert report by Dr. Fagerström, a renowned expert in the study of tobacco, nicotine dependence, smoking cessation, and harm reduction, who states that:

"*e-cigarettes do not involve combustion of tobacco that leads to the formation of the many toxicants and carcinogens at levels found in cigarette smoke,"* and instead "*deliver nicotine in an aerosol or vapour of glycerol, rather than in smoke.*"[18]

4.17 Dr. Fagerström also explains in his report that:

"[…] *while long term epidemiological data with respect to e-cigarettes is not yet available* […] *evidence to date indicates that e-cigarettes are unlikely to present significant health risks to both users and non-users. The available evidence indicates that e-cigarette use is not a gateway to the uptake of cigarette smoking. The scientific evidence further demonstrates that e-cigarettes are as effective as nicotine replacement products in helping cigarettes*

15 Royal College of Physicians (2016), *Nicotine without smoke: Tobacco harm reduction* at p. 184.

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

17 https://www.nhs.uk/oneyou/for-your-body/quit-smoking/using-e-cigarettes-vapes-to-quit-smoking/.

18 See Fagerström Report at ¶ 18

smokers to quit smoking. It is my view, therefore, that the weight of the scientific evidence to date demonstrates that e-cigarettes are an important component of a public health and harm reduction strategy."

4.18 We also refer to paragraphs [2.1 – 2.6] of **Appendix 1** to this Response, which provide additional supporting materials from independent sources.

4.19 We acknowledge that there are some public health organisations that have voiced concerns that not enough is known about the long-term effects of e-cigarette use and we agree with public health stakeholders that continued research is an essential component of any sensible strategy to continue to monitor the impact of e-cigarettes on consumers and the population as a whole. However, even with the remaining uncertainty about long term health effects, there is general agreement in the scientific community that there is sufficient evidence to support the fact that exclusive use of e-cigarettes that are manufactured to robust quality and safety standards is likely to be substantially less hazardous than smoking conventional cigarettes and that these products have a significant potential to contribute to public health tobacco harm reduction. They are able to deliver nicotine to consumers without the vast majority of the hazardous constituents of tobacco smoke whilst simultaneously providing behavioural and sensory aspects of the smoking ritual.

4.20 Fairchild *et al* (2018)[19] opine that:

"[h]*arm reduction recognizes that the proposed alternatives carry uncertainties. It involves making a strategic determination: when the risks are considerable – as they surely are with cigarette smoking – moving forward in the face of uncertainty is unavoidable. But the extent to which policies actually reduce harm matters.* ***Opting for a harm-reduction approach in name isn't enough if the specific policies employed are so restrictive that e-cigarettes contribute very little to reducing smoking-related risks in the long term****. To be sure, a permissive approach demands continuous health and safety monitoring along with the will to change course if necessary. Yet if policymakers are serious about mounting a largescale attack on smoking, we believe they must be willing to consider strategies, by any name, that are true to the spirit of harm reduction and could have a population-level effect.*" (emphasis added)

4.21 **The evidence suggests that e-cigarettes have contributed to reduced smoking prevalence in countries with a more flexible regulatory landscape.**

4.22 Evidence indicates that countries with a more flexible regulatory landscape that facilitates consumer awareness of the availability and attributes of e-cigarettes have experienced reductions in smoking prevalence.

4.23 For example, in the UK, where there is reasonable means of product distribution and communication coupled with the support of the Ministry and public health authorities, there has been a significant decline in smoking prevalence following the introduction of e-cigarettes.

4.24 Beard et al. (2016)[20] estimated that e-cigarettes may have contributed about 18,000 additional long-term ex-smokers in the England in 2015. 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*".[21] Recent UK government statistics also show that the proportion of current smokers in the UK has fallen significantly from 20.2% in 2011 to 14.1% in 2019;[22]

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19 Fairchild, A. L., Lee, J. S. Bayer, R., Curran, J. (2018). E-Cigarettes and the harm-reduction continuum. New England Journal of Medicine, 378:216–219.

20 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.

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 Office of National Statistics Adult smoking habits in the UK: 2019

4.25 A study by Levy *et al*., (2018)[23] modelled the future population impact if more smokers in the US switched to e-cigarettes. They estimated that taking into account several parameters such as cessation, initiation and relative harm, switching cigarette smokers to e-cigarette use over a 10-year period would lead to 1.6 to 6.6 million fewer premature deaths in the US under pessimistic and optimistic scenarios respectively. The authors concluded that "*a strategy of replacing cigarette by e-cigarette use can yield substantial gains, even with conservative assumptions about related risks.*"

4.26 The experience from Sweden where snus (a reduced risk oral tobacco pouch product) has been available for some time also supports the concept that smokers can transition to alternative nicotine delivery systems, with associated decreases in smoking prevalence. In the March 2017 Eurobarometer survey on the attitudes of Europeans towards tobacco and electronic cigarettes,[24] the reported daily smoking prevalence for Sweden was 5%, by far the lowest national level in Europe in comparison with EU wide daily smoking prevalence of 24%.

4.27 We also refer to paragraphs [3.1 – 3.9] of **Appendix 1** to this Response, which provide additional supporting evidence from independent sources.

4.28 Applying plain packaging to e-cigarettes - a product category with an estimated substantially lower risk profile compared to cigarettes (as endorsed by many public health experts), and whose availability has been shown to be associated with reduced smoking prevalence - is wholly inappropriate and discriminatory, and is liable to have an adverse impact on public health.

4.29 **Concerns that e-cigarettes cause widespread established nicotine use among non-smokers (including youth) – are unsubstantiated.**

4.30 We acknowledge the concerns regarding youth nicotine and tobacco use which are stated in the government's National Prevention Agreement.[25] We agree that nicotine and tobacco products should be restricted to adults only. However, the evidence does not support the claim made in the National Prevention Agreement that the use of e-cigarettes cause widespread established nicotine use among non-smokers (including youth) and leads to young people smoking tobacco.

4.31 The Ministry has not provided a full assessment of youth vaping in the Netherlands in order to understand the products they are using (whether they are nicotine or nicotine free products), the characteristics of those youth that are vaping (including whether they are smokers, former smokers or non-smokers) and the reasons why they are vaping.

4.32 Furthermore, data from other jurisdictions does not support claims of e-cigarettes acting as a gateway to tobacco and nicotine use by youth or non-smokers. For example:

4.32.1 PHE's most recent 2020 evidence update[26] found that: "*current vaping [is] mainly concentrated in young people who have experience of smoking. Less than 1% of 11- to 18-year-olds who have never smoked are current vapers*" and "*vaping remains most common among smokers and former smokers, with less than 1% of people who have never smoked currently vaping.*" The report concludes: "***the data presented here suggest that vaping has not undermined the declines in adult smoking*" and "*increasingly incorrect perceptions among the public about the harms of vaping could prevent some smokers using vaping products to quit smoking***" (emphasis added).

4.32.2 A 2019 factsheet by UK Action on Smoking and Health ("**ASH**") on the use of e-cigarettes among young people in Great Britain found that "*while some people, particularly those who have tried smoking, experiment with e-cigarettes, regular*

23 Levy DT, Borland R, Lindblom EN, *et al* Potential deaths averted in USA by replacing cigarettes with e-cigarettes Tobacco Control 2018;27:18-25.

24 Eurobarometer, report 458, issued May 2017: March 2017 survey data.

25 The National Prevention Agreement: A healthier Netherlands

26 McNeill, A., Brose, L.S., Calder, R., Bauld, L., and Robson, D. (2020). Vaping in England: an evidence update including mental health and pregnancy, March 2020: a report commissioned by Public Health England. London: Public Health England.

use remains low." ASH also found that: "[v]*aping is much less common among young people who have never smoked. A large majority of never smokers aged 11-18, 93.8% in total, have either never used an e-cigarette (87.8%) or are not aware of them (6.0%). Of young people aged 11-18 years old who have never smoked, 5.5% have ever tried e-cigarettes, 0.8% are current vapers, only 0.1% vape more than once a week, and not a single never smoker reported vaping daily*."[27]

4.32.3 A 2019 factsheet by ASH on the use of e-cigarettes among adults in Great Britain similarly found that vaping behaviour in adult never smokers was negligible: "*the proportion of never smokers who vape is 0.8%, compared to 11.7% of ex-smokers and 19.5% of current smokers. A further 13.3% of ex-smokers report having tried e-cigarettes but are no longer using them*." ASH also found that: "[n]*ever smokers who have tried or currently vape are different to smokers both in their vaping behaviour and in their attitudes to vaping. Only a quarter of never smokers who reported trying vaping are current users. Only 4% of never smokers who say they currently or used to use e-cigarettes say they vaped daily. Over a third (36%) of never smokers who have tried vaping report never using a nicotine containing e-cigarette*."[28]

4.32.4 Claims that there are high levels of youth vaping in the US have also been shown to be unsubstantiated. For example, West et al (2019)[29] analysed the US National Youth Tobacco Survey data and found that in never-smokers, regular vaping was rare, nicotine addiction was minimal and the great majority of smokers used tobacco before trying vaping. The authors concluded: **"[d]*ata from the NYTS do not support claims of a new epidemic of nicotine addiction stemming from use of e-cigarettes*** *nor concerns that declines in youth tobacco addiction stand to be reversed after years of progress. Among current e-cigarette users who had never tried tobacco products, responses consistently pointed to minimal dependence*." (emphasis added).

4.32.5 We also refer to paragraphs [4.1 – 4.5] of **Appendix 1** to this Response, which provide additional supporting evidence from independent sources.

4.33 Whilst the studies that find that tobacco use among youth is declining as vaping product prevalence increases can only identify correlation rather than attribute causation, the finding of correlation raises the possibility that the use of vaping products may act as a diversion that can keep some youth away from cigarette smoking. This is perhaps not altogether surprising. Indeed, given that some studies suggest that nearly 80% of all adult smokers start regularly smoking by the age of 18, and that 90% do so before leaving their teens, if those who would have otherwise started smoking conventional cigarettes before reaching this age were to use vaping products it is possible that vaping products could prevent would-be smokers from ever starting in the first place. This is in addition to helping existing smokers switch to this potentially less risky form of nicotine consumption.

4.34 To be clear, we are not advocating for the promotion or sale of vaping products to youth. However, it is important as a first step to understand the nature of youth vaping behaviours in the Netherlands and to consider the possible impacts of plain packaging with other objectives in the Netherlands, such as adult (and youth) smoking. The Ministry has not done this.

4.35 The evidence also suggests that concerns that dual use of e-cigarettes and cigarettes might impede or delay attempts to quit smoking are unjustified. Dual use is often part of a transition to quitting smoking. Indeed, dual use of NRT is recommended as a means of increasing the

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27 ASH (2019), Use of e-cigarettes among young people in Great Britain. https://ash.org.uk/wp-content/uploads/2019/06/ASH-Factsheet-Youth-E-cigarette-Use-2019.pdf

28 ASH (2019), Use of e-cigarettes (vaporisers) among adults in Great Britain. https://ash.org.uk/wp-content/uploads/2019/09/Use-of-e-cigarettes-among-adults-2019.pdf

29 Robert West, Jamie Brown, Martin Jarvis. (2019). Epidemic of youth nicotine addiction? What does the National Youth Tobacco Survey reveal about high school e-cigarette use in the USA? (Preprint). Qeios. doi:10.32388/745076.3.

likelihood that smokers will attempt to quit smoking. Studies also indicate that dual users are more likely to quit smoking.[30] However, we agree that consumers should be informed that dual use eliminates the potential reduced risks that e-cigarettes offer. This underscores the importance of ensuring that consumers are fully informed regarding the attributes of cigarettes and the potential reduction in health risks of switching to the exclusive use of e-cigarettes compared to continued smoking of conventional cigarettes.

4.36 Accordingly, plain packaging is not justified by claims that e-cigarettes cause widespread established nicotine use among non-smokers or that they prevent smokers from quitting smoking.

4.37 **The overall weight of the evidence does not support the proposition that e-cigarettes have a "gateway effect"**

4.38 The evidence does not establish that the use of e-cigarettes causes an increase in consumption of traditional cigarettes.[31] To the contrary, as discussed above, the evidence suggests that they have provided a gateway out of smoking for millions of smokers (of all ages).

4.39 As described in the accompanying expert report by Dr. Fagerström, there is "*no meaningful data*" to support any such gateway concerns.[32] Instead, the evidence shows that "[r]*egular use of the devices is confined to current and ex-smokers and use amongst never smokers remains negligible*," and that "[r]*egular use of electronic cigarettes amongst children and young people is rare and is confined almost entirely to those who currently or have previously smoked*."[33]

4.40 A number of comprehensive reviews by independent organisations have also criticised 'gateway' arguments that have been made in relation to e-cigarettes and concluded that there is no reliable evidence of a gateway effect.[34] For example:

4.40.1 A study by Levy *et al*., (2018)[35] 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*

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30 For example, Etter et al., (2014) *A longitudinal study of electronic cigarette users.* Addict Behav. 2014 Feb;39(2):491-4. doi: 10.1016/j.addbeh.2013.10.028, which followed vapers over a 12 month period found that 22% of dual tobacco and e-cigarette users had stopped smoking after one month and 46% after one year.

31 Phillips C V. Gateway Effects: Why the Cited Evidence Does Not Support Their Existence for Low-Risk Tobacco Products (and What Evidence Would). *Int J Environ Res Public Health* 2015;12:5439–64; 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; Abrams *et al* (2018) Harm Minimization and Tobacco Control: Reframing Societal Views of Nicotine Use to Rapidly Save Lives, Annu. Rev. Public Health 2018. 39:193–213.

32 See Fagerström Report, ¶ 23.

33 ASH UK Fact Sheet May 2015, Use of electronic cigarettes (vapourisers) among adults in Great Britain; see also ASH UK Fact Sheet May 2015, Use of electronic cigarettes among children in Great Britain).

34 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; 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.

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

became popular. The results were consistent across different surveys, suggesting that the results are robust across different methods of data collection."

4.40.2 Public Health England in its 2018 report 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.

4.40.3 We also refer to paragraphs [5.1 – 5.3] of **Appendix 1** to this Response, which provide additional supporting evidence from independent sources.

4.41 Commenting on studies that purport to find a gateway effect, Gartner (2017)[36] 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 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."

4.42 Accordingly, while it remains important to monitor the use of e-cigarettes by youth, claims that e-cigarettes are causing an increase in cigarette smoking are not substantiated by the current evidence. As such, the Ministry cannot use such concerns to justify the implementation of plain packaging for e-cigarettes.

4.43 **Implementing plain packaging for e-cigarettes will undermine (and potentially extinguish) their potential public health benefits**

4.44 The success of e-cigarettes in potentially contributing to reductions in projected tobacco related diseases depends on their acceptance by smokers as a satisfactory alternative to combustible tobacco products. To achieve this, it is essential that the regulatory framework provides effective measures that inform consumers of these products and their potentially reduced risk, and that ensure the availability of a variety of options to suit the wide range of adult consumer preferences.

4.45 Imposing plain packaging will undermine the role of these products as part of a public health tobacco harm reduction strategy in a variety of ways, including:

4.45.1 **Conveying the message that e-cigarettes and combustible tobacco products confer the same risks to health, thereby exacerbating misperceptions**

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

regarding the comparative potential risks of these products and discouraging smokers from switching.

4.45.2 By mandating that e-cigarettes look the same as combustible tobacco products the Ministry would be conveying the message that the risks associated with e-cigarettes are the same as those associated with consuming combustible tobacco products.

4.45.3 As Kozlowski et al (2016) state: "[t]*he error of presenting products with no meaningful risk reduction as if they were safer cannot be redressed by committing the equally life threatening error of presenting products with large risk reductions as if they are not safer or by concealing this information" and: "[…] That reduced-harm products are not absolutely 'safe' and more dangerous than using no tobacco/nicotine product does not justify keeping potential consumers of legal products ignorant about this information any more than such arguments would for any other product or activity*."[37]

4.45.4 Studies show that a substantial portion of the public believes that e-cigarettes are just as dangerous as cigarettes. Even more troubling is that the public's views are growing less accurate as time goes by. For example, PHE's most recent March 2020 evidence update[38] found that: "[p]*erceptions of harm from vaping among smokers are increasingly out of line with the evidence. The proportion who thought vaping was less harmful than cigarettes declined from 45% in 2014 to 34% in 2019. These misperceptions are particularly common among smokers who do not vape*." The report also concluded that: "*increasingly incorrect perceptions among the public about the harms of vaping could prevent some smokers using vaping products to quit smoking*."

4.45.5 BAT has also commissioned an expert report from Professor Winer, the William Joyce Professor of Marketing and Deputy Chair of the Marketing Department at the Stern School of Business, New York University. Professor Winer provided his opinions on how the imposition of stringent marketing regulations on potentially reduced risk products, including e-cigarettes, may affect awareness of these products and their potential to reduce rates of smoking and smoking-related diseases for existing adult tobacco and nicotine users who do not want to stop using tobacco and/or nicotine.

4.45.6 Professor Winer explains:

> *"marketing communications are necessary to prevent and clear up consumer confusion and misperceptions about PRRPs. There is an increasing body of literature that consumers are confused and ill-informed about the relative risks of PRRPs in relation to combustible cigarettes, and that those misperceptions are growing. For example, a large number of consumers in many markets believe that PRRPs such as e-cigarettes and snus are as risky, if not more risky, than combustible cigarettes. Allowing firms that sell PRRPs to provide accurate information about the relative risks of these products compared to combustible cigarettes could serve a very important educational function and better align consumer beliefs about these products with the available scientific evidence. Moreover, restricting firms' abilities to market such products and inform consumers of their attributes have real potential to undermine public health efforts to move smokers who do not want to stop using nicotine towards PRRP use."*[39]

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37 Kozlowski LT, Sweanor D. Withholding differential risk information on legal consumer nicotine/tobacco products: The public health ethics of health information quarantines. Int J Drug Policy. 2016 Jun;32:17-23. doi: 10.1016/j.drugpo.2016.03.014. Epub 2016 Apr 1.

38 McNeil, A., Brose, L.S., Calder, R., Bauld, L., and Robson, D. (2020). Vaping in England: an evidence update including mental health and pregnancy, March 2020: a report commissioned by Public Health England. London: Public Health England.

39 Winer Report at ¶14.

4.45.7 We also refer to paragraphs [6.1 – 6.4] of **Appendix 1** which provide additional supporting evidence from independent sources.

4.46 **Creating barriers to product awareness and informed choice**

4.47 Plain packaging will restrict consumer information and awareness and thereby exacerbate existing misperceptions and undermine the ability of consumers to make informed choices. Plain packaging is also liable to deter smokers from considering e-cigarettes as an alternative to combustible tobacco products and limit the potential for smokers to transition away from cigarettes.

4.48 Indeed, due to their distinct nature, e-cigarettes do not lend themselves to immediate off-the-shelf consumption, as they are not as well known to consumers as traditional tobacco products. Accurate consumer education and widespread availability are key to enhancing smokers' awareness of e-cigarettes as an alternative to combustible cigarettes and facilitating the transition from cigarettes for those smokers that want to switch.

4.49 In his expert report, Professor Winer explains that marketing freedoms are critical to the growth of potentially reduced risk products, including e-cigarettes. He states:

> "*In new and growing product markets, such as the PRRP market, the first objective of marketing is to make consumers aware of the product including its function, how to use it, where to buy it and its cost. Simply put, the success of new and growing product categories rests and falls on the ability of firms to communicate with potential consumers (here, existing adult tobacco and nicotine users) about the existence of the product, its features and potential benefits. Without such communications, these consumers will remain "in the dark" about new products, and not avail themselves of these products due to their lack of awareness, information or confusion about them.*"[40]

4.50 Plain packaging would prevent trademarks from fulfilling their essential functions and prevent consumers of combustible tobacco from becoming aware of e-cigarettes. Although there is still room left for applying some limited word trademarks, the space left for displaying the trademarks is insufficient to effectively designate the product. This leaves the trademark without its function as an identification of the commercial origin and the quality of the underlying product. The function of trademarks is to indicate the source or origin of the product and to identify the product by distinguishing it from its competitors. Trademarks also symbolize a product's quality and features and guarantee that the goods or services measure up to expectation. Trademarks are essential for effective competition in the market, as they enable firms to uniquely identify and differentiate their products other than on the basis of price alone. They are an important tool to permit market penetration and facilitate local and international trade. Trademarks can only perform these functions if they can be effectively used as they were registered.

4.51 By implementing plain packaging for e-cigarettes the Ministry is conveying the message that the risks associated with e-cigarettes are the same as those associated with consuming combustible tobacco products. This denies consumers accurate information and is liable to deter consumers who smoke tobacco from switching to e-cigarettes. There is no ethical or rational justification for withholding accurate differential risk potential information, or for providing misleading information to consumers on legally available products.

4.52 One of the Ministry's stated objectives of plain packaging is to minimise the risk that the packaging design gives misleading information about the harmful health effects of tobacco. However, by applying plain packaging to e-cigarettes the Ministry is mandating the use of a misleading design by conveying the message that the risks associated with e-cigarettes are the same as those associated with consuming combustible tobacco products. As noted above, Kozlowski et al (2016) state: "*[t]he error of presenting products with no meaningful risk reduction as if they were safer cannot be redressed by committing the equally life*

[40] Winer Report at ¶14.

threatening error of presenting products with large risk reductions as if they are not safer or by concealing this information."[41]

4.53 **Creating increased costs and barriers to entry, and thereby stifling innovation and reducing the product options available for smokers who want to switch and undermining the tobacco harm reduction role that such products have.**

4.54 Plain packaging will also create barriers to entry and undermine innovation. The success of e-cigarettes, in general, depends on these products being seen by adult smokers as satisfactory alternatives to combustible cigarettes.

4.55 The impact of plain packaging would be particularly acute for the e-cigarette market, where consumers are less aware of the product (in contrast to combustible tobacco products which are well established). Without the ability to identify and distinguish products, and build consumer awareness, manufacturers will find it extremely difficult to gain market penetration and the product category may not survive at all. Indeed, one can think of few greater barriers to market entry for new products than plain packaging which is designed to create an 'ugly' product that consumers won't want to buy.

4.56 **Creating an illicit market for e-cigarettes**

4.57 Plain packaging for e-cigarettes will incentivise the illicit market, damaging consumers, governments and legitimate industry. If regulations make it harder to distinguish legal products from illicit products, and impede awareness of products, then the illicit market will develop to satisfy existing consumer demand (and illicit manufactures will obviously not comply with regulation).

4.58 Plain packaging will further facilitate the illicit trade, enabling illicit traders to take advantage of the unavailability of branding to induce consumers into purchasing illicit imitation products, which have not passed the relevant safety standards. Indeed, in Australia, where e-cigarettes are legally prohibited, government data shows that almost one-third (31%) of smokers reported in 2016 having tried e-cigarettes in their lifetime, and 4.4% of smokers and 1.2% of ex-smokers reported current use of e-cigarettes in 2016.[42]

4.59 An independent expert report commissioned by ASH New Zealand[43] states:

"*Black markets develop in response to restrictive or costly regulation or taxation. Black markets […] cause harms through trade, transit and handling of high strength liquids, product quality, poor labelling, inferior packaging. They may exacerbate risks the policy is designed to mitigate*."

4.60 This risk of excessive regulation, such as plain packaging was also underscored in a recent independent, peer-reviewed research publication which found that:

"[w]*ith a few exceptions, awareness and use of nicotine vaping products varied by the strength of national regulations governing nicotine vaping product sales/marketing, and by country income" and* "[i]*n contrast to many of the* [less restrictive policies] *and* [restrictive policies*] countries, rates of use were quite low in the* [most restrictive policies] *countries (Australia, Uruguay and Brazil), indicating that strict regulation and enforcement of* [nicotine vaping products] *laws in these countries may have limited smokers' access to these products and/or discouraged smokers from using them*".[44]

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41 Kozlowski LT, Sweanor D. Withholding differential risk information on legal consumer nicotine/tobacco products: The public health ethics of health information quarantines. Int J Drug Policy. 2016 Jun;32:17-23. doi: 10.1016/j.drugpo.2016.03.014. Epub 2016 Apr 1.

42 Australian Institute of Health and Welfare 2017. National Drug Strategy Household Survey 2016: detailed findings. Drug Statistics series no. 31. Cat. no. PHE 214. Canberra: AIHW.

43 Bates C, Beaglehole R, Laking G, Sweanor D, Youdan B. 2019. A Surge Strategy for Smokefree Aotearoa 2025: The role and regulation of vaping and other low-risk smokefree nicotine products. Auckland: ASH New Zealand and End Smoking New Zealand.

44 Gravely, et al (2019) Prevalence of awareness, ever-use and current use of nicotine vaping products (NVPs) among adult current smokers and ex-smokers in 14 countries with differing regulations on sales

This study thus indicates the relationship between restrictions on e-cigarettes and the levels of switching to these products by adult tobacco consumers – that is, between highly restrictive regulatory regimes and low uptake on the one hand, and between less restrictive regimes and higher switching on the other.

4.61 BAT has also commissioned an expert report by Professor Ian Irvine (Professor of Economics at Concordia University, Montreal), which explores the potential impact of the array of vaping policies currently under consideration by a number of regulators and governments. In his expert report, Professor Irvine, notes that:

"[e]-*cigarettes and traditional cigarettes differ dramatically in their toxicity and e-cigarettes are considered by multiple public health authorities to have dramatically lower risk profiles. Consequently policies that treat the two products the same way, as if they were identical, are anti-scientific and unlikely to contribute to public health*."[45]

4.62 Professor Irvine also highlights the need for balanced, proportionate policy, noting that: "*the potential public health gains that could be achieved with an effective vaping policy that encourages smokers to switch to vaping, have been substantially lost sight of by many advocates*."[46]

4.63 Professor Irvine concludes that the adoption of overly restrictive policies will undermine the harm-reducing potential of e-cigarettes, including:

4.63.1 "*The scientific evidence on plain packaging for cigarettes indicates that it had little if any discernable impact on smoking when introduced in Australia, and this begs the question of why there might be a different outcome in the case of vaping. Treating e-cigarettes in the same way as combustible tobacco products, including by banning all advertising and banning the retail display of products can also undermine consumer awareness and perceptions of the different risks of products, and thus deter some consumers who smoke tobacco from switching*."[47]

4.64 In sum, the success of e-cigarettes in potentially contributing to reductions in projected tobacco related diseases depends on their acceptance by smokers as a satisfactory alternative to combustible tobacco products. Applying plain packaging to e-cigarettes will undermine, and potentially extinguish, the potential role of these products as part of a public health strategy.

5. REQUIRING PLAIN PACKAGING FOR E-CIGARETTES IS NEITHER REQUIRED NOR AUTHORISED BY THE WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL

5.1 Firstly, the WHO in proposing regulatory measures for, *inter alia,* e-cigarettes, wrongly assumes that there is authority under the WHO FCTC to regulate these products.

5.2 However, the FCTC does not authorise the restrictive regulation of modern smoke and tobacco free products, including e-cigarettes The FCTC applies to combustible tobacco products. E-cigarettes are not "*tobacco products*" as they are not made of tobacco and nor are they smoked. Accordingly, the FCTC is not a legitimate basis for regulating these products.

5.3 Furthermore, even if the FCTC did apply to e-cigarettes, the FCTC itself recognises tobacco harm reduction as a part of the strategy for improving public health by reducing tobacco consumption and exposure to tobacco smoke. As noted above, the preamble to the FCTC recalls the right to health under international human rights agreements and states that Parties are "[d]*etermined to promote measures of tobacco control based on current and relevant, scientific, technical and economic considerations*." 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*

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and marketing of NVPs: cross-sectional findings from the ITC Project, Addiction. doi: https://doi.org/10.1111/add.14558.

45 Irvine Report at p17.

46 Irvine Report at p37.

47 Irvine Report at p40.

that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke". 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 risks, and eventually stop using it, this would represent a significant contemporary public health achievement.*"[48]

5.4 A proper application of the FCTC, if it did apply to e-cigarettes, would therefore require balanced, proportionate regulation that takes account of the relative risks of different products and seeks to **maximise** the potential of e-cigarettes to reduce the health burden associated with smoking, while minimising use by non-smokers (including youth).

5.5 BAT has commissioned an expert report from Professor Jan Wouters, a leading international trade law and public international law scholar, which argues conclusively for the lack of applicability of the FCTC to Alternative Nicotine Delivery Systems ("**ANDS**"), including e-cigarettes. Professor Wouters' opinion is based on his review of the customary international legal principles of treaty interpretation and counters the attempts to extend the FCTC beyond its limited coverage of traditional tobacco products, based on the following reasons:

5.5.1 The history of the FCTC confirms that ANDS (such as e-cigarettes) were not covered by the FCTC at the time of adoption, since they did not commercially exist at that time.

5.5.2 General rules of treaty interpretation confirm that, because they do not contain tobacco, e-cigarettes fall outside the scope of application of the FCTC based on (1) the ordinary meaning of the treaty's terms; (2) the current state of scientific knowledge; and (3) the FCTC's object and purpose.

5.5.3 No subsequent action by the FCTC Conference of the Parties ("**COP**") amounts to a subsequent agreement or subsequent practice that brings non-tobacco products such as e-cigarettes within the remit of the FCTC.

5.6 Professor Wouters also notes that the FCTC recognises tobacco harm reduction as a part of the strategy for improving public health by reducing tobacco consumption and exposure to tobacco smoke. Tobacco control and public health are furthered through reducing exposure to tobacco and smoke, which is equally recognized in Article 3 on the "*Objective*" of the treaty. He states:

"[i]*n sum, by prohibiting or severely restricting the sales of these new categories of products and/or by extending to them combustible regulations as would be the consequence of applying the strict requirements of the FCTC to ANDS, countries could unwillingly contribute to perpetuating smoking. The question arises whether such policies would be fully consistent with the harm reduction considerations of the FCTC*."[49]

5.7 Indeed, a proper interpretation of the FCTC that gives meaning and effect to the harm reduction principle enshrined in the plain language of its definition of tobacco control, and in line with the object and purpose of the treaty, requires that PRRPs including e-cigarettes be treated more favourably from a regulatory and taxation standpoint than combustible tobacco products (such as cigarettes). This would support adult consumers of combustible products who want to switch to PRRPs, including e-cigarettes.

5.8 Moreover, the WHO's position on harm reduction and new tobacco and nicotine technologies has been heavily criticised by a number of public health experts. For example, commenting on a WHO 2016 report on e-cigarettes, the UK Centre for Tobacco and Alcohol Studies, an independent network of 13 universities which conducts research, teaching and policy development regarding tobacco and alcohol, concluded that the WHO report*: "fails to deliver the equipoise required for dispassionate formulation of public health policy. The report also*

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48 WHO FCTC (2016), *Report on Electronic Nicotine Delivery Systems ("**PRRPS**") and Electronic Non-Nicotine Delivery Systems ("**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.

49 Wouters' expert report, at p23.

contains ***factual errors and misinterpretations of evidence*** *available in the public domain* […]*".*[50] (emphasis added).

5.9 Independent experts have also criticised a recent WHO Q&A on electronic cigarettes, stating that it is wrong and misleading – with one expert stating: "*The authors of this document should take responsibility for using blatant misinformation that is likely to prevent smokers from switching to a much less risky alternative*".[51] More significantly, the regulatory objectives proposed by the WHO are not part of the FCTC and, as such, do not have any legal force. In addition, they do not specify plain packaging for e-cigarettes).

5.10 It remains the case also that, in proposing regulatory measures, Governments must examine the evidence to determine whether proposed regulatory measures are effective or whether alternative less restrictive options should be preferred. Such an evidence base must be established by reliable science and empirical evidence that demonstrates the effectiveness of proposed measures. The Ministry has not done such an examination, or at least this is not apparent from the Proposal.

6. REQUIRING PLAIN PACKAGING FOR E-CIGARETTES IS UNLAWFUL

6.1 The Proposal engages a number of legal rights which call into question their legality. These include:

6.1.1 **Plain packaging for e-cigarettes lacks a legitimate legal basis under the TPD**.

6.1.2 The TPD requires the harmonisation of the regulation of tobacco and nicotine products across EU Member States, in order to facilitate free movement (see Article 1, and recitals 15 and 53). It identifies the particular restrictions on the sale of tobacco and nicotine products which the EU has concluded are justified in order to protect health, and requires all Member States to apply them. Those requirements do not include plain packaging.

Article 24(1) of the TPD guarantees the free movement of products which comply with the Directive. Article 24(2) and (3) only allow for possible limited exceptions to the guarantee of free movement of products that comply with the TPD – namely "*standardisation of the packaging of tobacco products*" under Article 24(2) (emphasis added) and the prohibition of "*a certain category of tobacco or related products*" under Article 24(3) (which is not relevant to the proposal to introduce plain packaging for e-cigarettes).

Because Article 24(2) only applies to "*tobacco products*" it cannot be relied on to introduce plain packaging for e-cigarettes (even if the requirements under Article 24(2) that a measure can only be introduced "*where it is justified on grounds of public health taking into account the high level of protection of human health achieved through the Directive*" and it is proportionate, could be met – which they can't in respect of plain packaging for e-cigarettes).

6.1.3 **Plain packaging for e-cigarettes restricts the free movement of goods between the Netherlands and other EU Member States**.

6.1.4 It is self-evidently the case that the Proposal will restrict the movement of goods within the EU. The Proposal will partition the internal market by imposing purely national conditions and requirements on the presentation and sale of these products in the Netherlands. In doing so, it will prevent the access of some products from other EU Member States into the Netherlands and impede market access of other e-cigarettes.

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50 Britton et al. (2016) *Commentary on WHO report on electronic nicotine delivery systems and electronic non-nicotine delivery systems*, Available at http://ukctas.net/news/commentary-on-WHO-report-on-ENDS&ENNDS.html.

51 Expert reaction to World Health Organisation Q&A on electronic cigarettes

6.1.5 Whilst it is open to a Member State to restrict free movement on the grounds of protection of public health, it is settled law that any measure inconsistent with Article 34 TFEU may only be justified on Article 36 TFEU grounds (including for the protection of human health) – if the measure complies with a strictly-applied test of proportionality.

6.1.6 However, the Ministry simply states that the proportionality requirement has been met but it has failed to conduct any such proper proportionality analysis, nor provide any evidence substantiating the efficacy of the proposed measures. Further, as discussed below, the Proposal is manifestly inappropriate, discriminatory and disproportionate.

6.1.7 We also note that, given the impact of the Proposal on the free movement of goods, the Government is required to notify the Proposal, or in any event the details of the plain packaging requirements which would be laid down in a ministerial regulation (Tabaks- en rookwarenregeling) to the EU Commission. This should be done before the Proposal (or, again, the details of the ministerial regulation) is finalised, so that any concerns raised by the Commission or other Member States can be addressed.

6.1.8 **Extending plain packaging to e-cigarettes is discriminatory and would infringe on smokers' personal choice.**

6.1.9 Extending plain packaging to e-cigarettes would deny adult smokers' access to accurate information to allow them to make informed choices with respect to their use of tobacco and nicotine products.

6.1.10 Consumers have 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. Plain packaging denies consumers accurate health information and thereby devalues individual autonomy and personal freedoms.

6.1.11 **Plain packaging for e-cigarettes violates free speech rights and the rights of consumers to receive accurate information about legal products, protected by Article 7 of the Constitution, Article 11 of the Charter of Fundamental Rights and Article 10 of the ECHR**.

6.1.12 The Proposal will restrict manufacturers' free speech rights and the right of consumers to receive accurate information about legal products in order to make informed decisions. In circumstances where e-cigarettes are already subject to a comprehensive advertising ban, plain packaging will ban one of the last remaining means of product communication that manufactures have. As discussed below, these restrictions cannot be justified.

6.1.13 **Plain packaging for e-cigarettes amounts to a complete deprivation of manufacturers valuable intellectual property rights, contrary to Article 14 of the Constitution, Article 17 of the Charter of Fundamental Rights and Article 1 of the First Protocol of the ECHR**.

6.1.14 The Proposal would prohibit manufacturers from using virtually all of their trademarks as registered (including logos and device marks). The value of these trademarks would be eliminated.

6.1.15 While the use of some word marks would still be allowed on packaging, they would be required to be in a standardised form – preventing them from being able to adequately serve their essential functions of differentiating products and uniquely identifying their origin and quality.

6.1.16 The result is that manufacturers would be unable to use and control their trademarks, which goes to the essence of the property rights protected the Constitution.

6.1.17 **Plain packaging for e-cigarettes is an unjustified restraint on the freedom to conduct a business in violation of Article 16 of the Charter of fundamental rights of the EU** .

6.1.18 The Proposal will restrict the freedom to conduct a business, protected under Article 16 of the Charter of fundamental rights of the European Union by restricting communication with adult consumers about legal products, and restricting competition, which are fundamental to the right to engage in lawful business.

6.1.19 The Proposal will severely restrict e-cigarette manufacturers' ability to compete with one another, and for the product category to compete with combustible tobacco products which are well established in the market, and distort market competition.

6.1.20 In addition, plain packaging for e-cigarettes would make it extremely difficult for new entrants to enter and remain present on the market because the ability to identify and differentiate their products through packaging, and (in the context where e-cigarettes are already subject to a comprehensive advertising ban) the ability to effectively communicate to consumers regarding their products, will be virtually eliminated.

6.1.21 **Violation of Prohibition of Arbitrariness (*verbod op willekeur*)**

6.1.22 The Government has also violated the prohibition of arbitrariness by failing to sufficiently take into account the interests of those who are disproportionately affected by the Proposal. As discussed below, the Government has failed to undertake any meaningful consultation process, or to identify and/or quantify the economic impact of the Proposal on retailers and legitimate manufacturers (i.e., those that will be most impacted by the Proposal). The Government's brief overview in the Proposal of estimated costs for retailers and manufacturers expressed only as the number of hours taken to get acquainted with the Proposal is clearly insufficient and does not address in any way the true economic impact of the Proposal.

7. REQUIRING PLAIN PACKAGING FOR E-CIGARETTES IS INAPPROPRIATE AND DISPROPORTIONATE

7.1 The Proposal is inappropriate because it fails to take account of relevant evidence.

7.2 Ultimately, the Ministry, whether by failure of investigation or by failure to take account of relevant (and disregard irrelevant) information, has issued the Proposal when there was no rational basis for a conclusion that implementing plain packaging for e-cigarettes would fulfil a legitimate public health objective. In doing so, the Ministry has reached a decision which is beyond the range of responses open to a reasonable decision-maker.

7.3 It is demonstrably inappropriate to apply a measure intended to suffocate, and potentially eliminate, the development of e-cigarettes, thereby perpetuating the use of more hazardous combustible tobacco products.

7.4 The Ministry has fundamentally failed to take reasonable steps to acquaint itself with the relevant information necessary to properly assess the Proposal, including the implications for public health.

7.5 Plain packaging is disproportionate.

7.6 The principles of proportionality require that administrative acts meet the following requirements:

7.6.1 There must be a legitimate aim for the proposal;

7.6.2 The proposal must be suitable or appropriate to achieve the objective pursued;

7.6.3 The proposal must be necessary to achieve the aim; and

7.6.4 The burden imposed by the proposal must not be disproportionate, *stricto sensu*.

7.7 The proportionality requirement is reflected in the Dutch Instructions for Regulations ("aanwijzing 2.2. van de Aanwijzingen voor de regelgeving":

> *"Regelgeving is noodzakelijk indien aannemelijk is dat het concrete voorstel een effectieve, efficiënte en evenredige reactie vormt op het maatschappelijke probleem dat aanleiding geeft voor die regelgeving. Daarvoor is dus vereist dat voldoende zekerheid bestaat dat de voorgestelde regeling werkelijk zal leiden tot het oplossen of verminderen van dat probleem, dat er geen minder bezwarende alternatieven zijn, en dat de kosten en lasten daarvan gerechtvaardigd worden door de ernst van het probleem. Indien niet aan elke van deze voorwaarden is voldaan, bestaat onvoldoende grond om tot regelgeving (in de voorgenomen vorm) over te gaan. Eventueel kan in zo'n geval een alternatief, minder bezwarend sturingsinstrument worden ingezet, of dient simpelweg van overheidsingrijpen te worden afgezien."*

7.8 The Ministry has the burden of showing that plain packaging of e-cigarettes can be justified and meet the requirements of proportionality. This is particularly pertinent in this case in light of the transposition of the TPD. The Ministry provides no proper assessment of the measures introduced under the TPD nor explains, much less demonstrates, that since its transposition of TPD, the situation in the Netherlands has changed so as to now require the introduction of the Proposal. Given the absence of a defined problem with the current regulatory regime, requiring plain packaging is disproportionate as it cannot be shown to be necessary.

7.9 The interference resulting from plain packaging goes to the very essence of a number of fundamental rights, including rights of privacy and liberty, property, freedom of expression and free and equal access to trade, meaning that the requisite thresholds for justification and proportionality are at their highest.

7.10 Plain packaging must also be considered in the context where e-cigarettes are still relatively new to the market (in contrast to combustible tobacco products which are well established) and many smokers are not yet fully aware of their availability or familiar with their features. As such, (in the context where e-cigarettes are already subject to a comprehensive advertising ban) the ability of manufacturers to communicate on packaging with consumers regarding their products is critical to the potential success of the category.

7.11 The Royal College of Physicians stated in its 2016 Report: "*proportionality in nicotine regulation must also incorporate the consideration that regulation that discourages or delays the development and use of non-tobacco nicotine is likely, in effect, to sustain tobacco smoking and hence perpetuate harm to smokers and wider society.*"

7.12 The Proposal is being advanced (i) without a proper regulatory impact assessment; (ii) in the absence of evidence demonstrating that the Proposal is appropriate to promote public health and would in fact do so; and (iii) despite the potential contribution to tobacco harm reduction offered by e-cigarettes (as endorsed by leading independent health experts around the world).

7.13 As the Ministry has not demonstrated an adequate and evidence-based basis for the Proposal, and since the evidence shows that plain packaging would be likely to undermine public health, there is no basis – and certainly no proportionate basis – to justify the Proposal.

7.14 Furthermore, the Proposal cannot be shown to be appropriate, necessary, or proportionate based on the available evidence.

7.15 **The Ministry has incorrectly applied the Precautionary Principle**

7.16 The Proposal mentions that it is brought on the basis of the precautionary principle and that the Dutch public health is best served by disincentivising the use of e-cigarettes. The Ministry, however, has not further elaborated on its basis for applying the precautionary principle and it incorrectly applies the principle.

7.17 Given the real-world experience suggesting that e-cigarettes can be an important tobacco harm reduction tool for smokers who are wanting to quit cigarettes, the lack of scientific certainty as to the absolute level of risk of e-cigarettes is not a justification for implementing plain packaging. The application of the precautionary principle must be reasoned and involve an examination of the full range of alternatives, including the impact of inaction – which in this case includes denying consumers information and access to acceptable e-cigarettes with the potential public health benefits that this carries.

7.18 Professor John Britton, the Director of the UK Centre for Tobacco and Alcohol Studies, University of Nottingham, recently stated: "**[t]*hose who cite the precautionary principle as justification to discourage or prohibit electronic cigarettes ignore the fact that for the great majority of users, the counterfactual is premature death from tobacco smoking. Smoking kills. So does denying smokers opportunities to quit***."[52] (emphasis added).

7.19 Invoking the precautionary principle does not provide the Ministry with a *'free pass*' for the implementation of plain packaging for e-cigarettes. It has been recognised that the precautionary principle can never justify arbitrary decisions.[53] Guidance provided by the European Commission states that the precautionary principle may only be invoked when the following three preliminary conditions are met:

7.19.1 Identification of potentially adverse effects;

7.19.2 Evaluation of the scientific data available; and

7.19.3 The extent of scientific uncertainty.

7.20 Furthermore, the precautionary principle shall be informed by three specific principles:

7.20.1 The fullest possible scientific evaluation, the determination, as far as possible, of the degree of scientific uncertainty;

7.20.2 A risk evaluation and an evaluation of the potential consequences of inaction; and

7.20.3 The participation of all interested parties in the study of precautionary measures, once the results of the scientific evaluation and/or the risk evaluation are available.

7.21 In addition, the general principles of risk management remain applicable when the precautionary principle is invoked. These are the following five principles:

7.21.1 Proportionality between the measures taken and the chosen level of protection;

7.21.2 Non-discrimination in application of the measures;

7.21.3 Consistency of the measures with similar measures already taken in similar situations or using similar approaches;

7.21.4 Examination of the benefits and costs of action or lack of action; and

7.21.5 Review of the measures in the light of scientific developments.[54]

7.22 An expert report commissioned by ASH New Zealand[55] emphasises that of particular relevance in considering the application of the precautionary principle to e-cigarettes and other low-risk smoke-free nicotine products is the requirement to assess consequences of both action and inaction: "[…] *in other words, to take account of plausible harms that would arise from restricting what are likely to be far less harmful products in a market dominated by cigarettes. There is no avoiding a risk assessment based on what is known, looking not only at the risks of the product, but also risks that might arise from policies justified on supposedly precautionary grounds*."

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52 John Britton: Electronic cigarettes and the precautionary principle

53 European Commission Communication (COM(2000) 1final) on the precautionary principle

54 Ibid.

55 Bates C, Beaglehole R, Laking G, Sweanor D, Youdan B. 2019. A Surge Strategy for Smokefree Aotearoa 2025: The role and regulation of vaping and other low-risk smokefree nicotine products. Auckland: ASH New Zealand and End Smoking New Zealand.

7.23 The Ministry has not undertaken any appropriate consideration of these issues and its application of the precautionary principle is therefore arbitrary and unjustified.

7.24 **Plain packaging is not appropriate to achieve the objective pursued because**:

7.24.1 Rather than improving public health, plain packaging would be likely to result in significant adverse public health effects by perpetuating the use of more hazardous combustible tobacco products. As discussed above, the weight of current scientific evidence points in favour of allowing adult smokers access to the information necessary to choose and differentiate between tobacco and nicotine products, as an important component of a public health harm reduction strategy. Plain packaging will constrain, or possibly eliminate altogether, the potential for e-cigarettes to contribute to tobacco harm reduction, if e-cigarette brands cannot compete with cigarettes (the market incumbent) and smokers are discouraged from considering e-cigarettes as an alternative to cigarettes.

7.24.2 **Plain packaging will create an illicit market for e-cigarettes which would further undermine the public health objective.** As explained above, plain packaging will incentivise the illicit market, by, *inter alia,* making it harder to distinguish legal products from illicit products, and impeding awareness and access to legal products.

7.24.3 The illicit trade would further undermine public health by increasing consumer (including youth) access to unregulated products with no controls on standards and ingredients, or compliance with other product regulation; as well as undermine government revenues and adversely impact on society in general through increased criminal activity.

7.24.4 **Plain packaging would also have a number of other unintended impacts which would undermine public health**. Plain packaging is more likely to undermine public health than improve it. It will severely undermine the potential of e-cigarettes to displace smoking with the likelihood of foreclosing the market for these products entirely, along with the corresponding loss of substantial public health gains that e-cigarettes may provide.

7.25 **Plain packaging is not necessary because there are more effective and less onerous alternatives.**

7.25.1 There are a number of alternative regulatory options that are more properly targeted to reducing youth access and initiation, and which could provide significant public health gains through tobacco harm reduction.

7.25.2 Rather than requiring plain packaging for e-cigarettes, a more appropriate regulatory framework would provide that these products meet appropriate criteria with regards to quality and safety and are not marketed to youth, whilst remaining available to adult smokers.

7.25.3 The following regulations are more effectively targeted to reducing youth initiation and youth access:

(A) Strong enforcement measures to ensure retailers and third parties obey the law and do not provide e-cigarettes or tobacco products to youth;

(B) Penalties for any person caught providing e-cigarettes or tobacco products to youth;

(C) Mandatory training programmes for all e-cigarette and tobacco product retailers;

(D) Implementing education and awareness programmes to ensure that adults are not buying and providing e-cigarettes to youth;

(E) A requirement that online vendors implement a robust third-party age verification process before accepting any online orders for e-cigarettes or tobacco products;

(F) at preventing young people from taking up tobacco and nicotine products; while informing adult smokers of the relative risk of different products and the benefits of switching from smoking to e-cigarettes.

7.25.4 There is no indication that the Ministry has considered these or any other alternatives to achieve its public health objectives.

7.26 **Plain packaging is disproportionate because:**

7.26.1 Plain packaging will severely undermine the potential of e-cigarettes to displace smoking with the likelihood of foreclosing the market for these products entirely, along with the corresponding loss of substantial public health gains that e-cigarettes may provide.

7.26.2 Plain packaging will convey the message that e-cigarettes and cigarettes confer the same health risks and thereby deny consumers accurate information and perpetuate current misperceptions regarding the comparative potential risks of these products and discourage smokers from switching.

7.26.3 Plain packaging would expropriate manufactures' brands and trademarks, eviscerate product communication and risks destroying the vaping market altogether, with no demonstrable benefit to public health.

7.26.4 Plain packaging will distort market competition and incentivise the illicit trade.

7.26.5 It is impossible on the evidence currently available to justify plain packaging and the Ministry offers insufficient evidence to support its introduction.

8. REQUIRING PLAIN PACKAGING FOR E-CIGARETTES WOULD VIOLATE THE NETHERLANDS' INTERNATIONAL OBLIGATIONS

8.1 Imposing plain packaging on e-cigarettes would violate the Netherlands' international obligations under WTO Agreements such as the TRIPS Agreement, the TBT Agreement and GATT, which are vital for the fair treatment of domestic exports.

8.2 Plain packaging undermines intellectual property rights by impairing the essential functions performed by trademarks and the enforcement of associated trademark rights. As a result, it would violate the fundamental principles of trademark protection contained in the TRIPS Agreement.

8.3 In particular, plain packaging imposes special requirements that encumber the use of trademarks, thus violating Articles 15, 16, and 20 of the TRIPS Agreement and trademark-related provisions of the Paris Convention, such as Article 10bis.

8.4 Plain packaging would also amount to technical regulations that are more trade restrictive than necessary to achieve the legitimate policy objective of protecting public health and thus violate obligations under Article 2.2 of the WTO TBT Agreement.

9. THE MINISTRY HAS FOLLOWED A FLAWED AND INADEQUATE PROCESS

9.1 The procedure followed by the Ministry to-date raises serious concerns.

9.2 The failure to undertake and/or publish a proper regulatory impact assessment or undertake any meaningful consultation before the substantive decisions were made means that the decisions were taken without proper analysis of the costs and benefits of the Proposal and without consideration of alternative policy options.

9.3 **The Proposal is proceeding without a proper regulatory impact assessment**

9.4 As outlined above, plain packaging is unlawful. However, even if the Proposal could proceed, a regulatory impact assessment that undertakes a thorough analysis of the Proposal, including whether it is necessary and whether there are less burdensome means of achieving the regulatory objective, ought to be undertaken, to enable the Ministry to properly scrutinise the Proposal.

9.5 The Ministry has not published any proper regulatory impact assessment or studies in respect of the Proposal. No substantive reasoning or evidence supporting why it is considered necessary and appropriate to introduce plain packaging for e-cigarettes has been provided, nor has the Ministry provided an appropriate proportionality analysis.

9.6 A regulatory impact assessment is the cornerstone of internationally accepted principles of Better Regulation, such as those defined by the OECD, to which the Netherlands is a member. It is also an essential part of a transparent, accountable and empirically-based regulatory system.

9.7 Regulatory impact assessments are important because, if properly approached and effectively implemented, they enhance the rigour, transparency and accountability of the decision-making process, including strengthening consultation. They provide a formal method for ensuring that Government action is justified and based on a clear understanding of cause and effect. They help decision-makers assess alternative policy interventions (including no regulatory action) explicitly. They highlight the impacts of regulatory decisions on different stakeholder groups and promote strategies that maximise the net benefits of government action.

9.8 The use of robust, balanced and evidence-based regulatory impact assessment is particularly important in emotive areas like tobacco and nicotine regulation to avoid bureaucratic and political 'knee-jerk' regulation where measures might otherwise be adopted even in the absence of any supporting evidence or where the costs of the measure significantly exceed the benefits.

9.9 The importance of conducting a regulatory impact assessment 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*."[56] 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*."[57]

9.10 The need for a proper evidence-based regulatory impact assessment is even more pressing in this case given the requirements of the TPD and the right to free movement of goods under the TFEU. Any additional measures and restrictions on free movement, even if legally permissible (which, as explained above, is not the case with the Proposal), are only permitted

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56 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.

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

"*where it is justified on grounds of public health taking into account the high level of protection of human health achieved through the Directive*" and it is proportionate. This assessment can only properly be performed on a case-by-case basis, whereby the incremental benefit to public health of each 'further requirement' is assessed against the benefit to public health achieved by TPD. The Ministry has not undertaken this assessment.

9.11 The explanatory memorandum does not include any evidence and analysis to support policy development and it is an inadequate basis on which to conclude that the Proposal is necessary, appropriate and proportionate. For example:

9.11.1 The explanatory memorandum does not include any analysis of the efficacy of current tobacco measures or identify a problem which specifically requires the Proposal as opposed to other measures. Again, this is particularly pertinent in this case where Parliament, in transposing the TPD in 2016, did not introduce the Proposal. The Ministry provides no assessment of the measures introduced under TPD nor has it explained, much less demonstrated, that, since its transposition of TPD, the situation in the Netherlands has changed so as to now require the introduction of the Proposal in respect of e-cigarettes.

9.11.2 The explanatory memorandum does not provide any evidence or assessment of the use of e-cigarettes in the Netherlands, including by smokers as an alternative to smoking, and the nature of use by youth (and what is driving such use) and fails to identify a problem with the existing measures that now requires the Proposal.

9.11.3 The explanatory memorandum asserts that the Proposal will be effective without any analysis of the evidence, much less any evidence in relation to e-cigarettes. This does not satisfy the onus on the Ministry to show that the Proposal is appropriate for securing the attainment of the objective and does not go beyond what is necessary to attain it.

9.11.4 While acknowledging that the Proposal will have economic consequences for businesses, the explanatory memorandum does not even attempt to identify, let alone monetise or quantify, those impacts and the costs of the Proposal, including its impact on businesses and the value of manufactures brands and related intellectual property. The lack of any analysis of the impacts makes the Proposal entirely arbitrary and unjustified.

9.11.5 The explanatory memorandum does not consider any unintended consequences of the Proposal, including the potential impact on public health in deterring smokers from switching to e-cigarettes, and the impact on the illicit trade and on manufactures and retailers.

9.12 Since the explanatory memorandum does not include the elements of what a regulatory impact assessment should be, it cannot fulfil the purpose of a regulatory impact assessment and cannot be relied on to provide proportionate, evidence-based policy recommendations.

9.13 The Ministry's failure to undertake an evidence-based regulatory impact assessment, means that the Proposal cannot be shown to be justified as necessary, appropriate and proportionate, or to comply with the obligations under the TPD and the TFEU, and WTO Agreements such as the TRIPS Agreement and the TBT Agreement, to "*ensure*" that requirements do not violate internationally protected intellectual property rights or constitute an "*unnecessary obstacle to trade*".

9.14 Accordingly, even if the Proposal could proceed, a proper regulatory impact assessment should be carried out before proceeding further with the Proposal.

9.15 **Lack of meaningful consultation**

9.16 The Ministry did not seek any views from stakeholders or allow them the opportunity to comment on the analysis and evidence used to justify the imposition of plain packaging before the Proposal was published. Furthermore, the consultation now being run after the Proposal has already been published indicates an intent to press ahead and calls into question the purpose of the Consultation.

9.17 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. This 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.[58] The process being conducted by the Ministry does not meet any of these standards.

9.18 Article 5.3 of the FCTC cannot be used to disregard industry evidence and submissions. Article 5.3 of the FCTC 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) only talks about protecting tobacco control policies from the interests of the tobacco industry and does not make it clear what concrete result is to be achieved …" (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 the right to fully participate in the Consultation.

9.19 Nor do the Guidelines on Article 5.3 of the FCTC 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 of the FCTC to say that somehow this provision now requires Governments to exclude tobacco industry evidence or afford it less weight as a matter of principle.

9.20 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, these submissions and evidence are being presented in an open and transparent manner.

10. CONCLUSION

10.1 For the reasons set out above, BAT Nederland believes that the Proposal should be rejected. In summary, those reasons include:

10.1.1 The Proposal is more likely to undermine public health than improve it. The Proposal is proceeding without any rational basis or scientific evidence. The Ministry's failure to consider evidence demonstrating the role that e-cigarettes can play in public health underscores that the Proposal is not evidence based.

10.1.2 Requiring plain packaging for e-cigarettes would convey the message that e-cigarettes and cigarettes confer the same health risks and thereby deny consumers accurate information and perpetuate current misperceptions regarding the comparative potential risks of these products; and discourage smokers from switching.

10.1.3 Plain packaging amounts to a wholesale expropriation of manufactures' brands and trademarks, represent an unprecedented assault on commercial expression, and risks destroying the vaping market altogether, with no demonstrable benefit to public health.

10.1.4 The Ministry has failed to demonstrate that plain packaging is justified and the weight of evidence shows that plain packaging is not necessary, appropriate or proportionate.

10.1.5 Plain packaging would distort market competition and incentivise the illicit trade; and would have a number of other unintended consequences that would undermine public health.

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

10.1.6 The Proposal is neither required nor authorised by the WHO FCTC.

10.1.7 The Proposal infringes consumers' personal choice, violates manufacturers' and retailers' freedom to conduct a business and fundamental property rights and freedom of expression. In addition, the Proposal would violate the Netherlands' international obligations under WTO Agreements.

10.1.8 There are a number of alternative regulatory options that are more properly targeted to reducing youth access and use while still ensuring that adult smokers have awareness of, and appropriate access to, a wide range of potentially reduced risk alternatives to combustible tobacco products and that they are empowered to switch to such products if they want to.

10.1.9 Even if the Proposal could proceed, neither a proper evidence based regulatory impact assessment nor a meaningful consultation process has been undertaken in order to establish that it is necessary and to properly consider the impacts, costs and benefits of the Proposal.

10.2 Rather than stifling the e-cigarette category and potentially eliminating it altogether, the Ministry should focus on developing a balanced regulatory regime that supports the e-cigarette market, so that adult smokers have awareness of, and appropriate access to, a wide range of potentially reduced risk alternatives to conventional tobacco, while protecting against youth usage of any tobacco or nicotine products. The Ministry should do so immediately, rather than perpetuating misconceptions about e-cigarettes and undermining their potential by regulating them in the same way as combustible tobacco products.

10.3 We strongly urge the Ministry to consider our comments on the Proposal. We would also welcome the opportunity to work with the Ministry in establishing an appropriate framework for the regulation of e-cigarettes. We are also able to make our research and development scientists available for any further questions or comments regarding e-cigarettes and other smoke and tobacco free alternatives.

APPENDIX 1: ADDITIONAL THIRD PARTY SOURCES

This Appendix supplements our Response with references to additional third party sources, which are provided for the Ministry's review and consideration. Copies of any of the studies referred to in our Response or this Appendix 1 can be provided upon request.

1. **Additional sources supporting the role of tobacco harm reduction as a public health strategy.**

1.1 The World Health Organization ("**WHO**") has stated that "[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 risks, and eventually stop using it, this would represent a significant contemporary public health. achievement."[1] We note that the WHO's opposition to e-cigarettes as part of a tobacco harm reduction policy, notwithstanding this position, has been criticised as being non-evidence based , and is driven by a flawed political ideology of an 'abstinence-only' approach to tobacco and nicotine that devalues individual autonomy and health.

1.2 The ex-director of UK anti-smoking charity ASH UK, Clive Bates has stated that: "[i]f there is to be an overarching public health goal, it should be focussed on a 'smoke-free society' not a 'nicotine-free society'. However, in pursuit of an overarching goal, the *means*, are as important as the *ends* and we should never pursue public health goals by imposing a tyranny against a particular group. Policymakers should resist excessively coercive and punitive measures, reject prohibitionist approaches and take a more enlightened approach to nicotine by suppressing the authoritarian reflexes that have served society so badly in other areas of public health."[2]

1.3 A submission by Associate Professor Colin Mendelsohn (2017) in the inquiry into the use of marketing and e-cigarettes and personal vaporisers in Australia stated: "Tobacco harm reduction (THR) aims to reduce the health risks in continuing smokers. This involves switching from combustible tobacco to a lower risk alternative that delivers the nicotine smokers are addicted to, but without smoke. E-cigarettes meet many of the criteria for an ideal tobacco harm-reduction product. They can replace smoking by delivering high doses of nicotine without the vast majority of harmful constituents of tobacco smoke, and provide the behavioural and sensory aspects of the smoking ritual."[3]

1.4 The UK Royal College of Physicians (2007) stated: "[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*."[4]

1.5 In October 2018, a group of 72 independent specialists in nicotine science, policy and practice called on the WHO to embrace technology innovation in the fight against diseases caused by smoking, stating: "[i]*n the field of tobacco control and 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*

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1 WHO FCTC (2016), *Report on Electronic Nicotine Delivery Systems ("**PRRPS**") and Electronic Non-Nicotine Delivery Systems ("**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.

2 Bates (2020), Nicotine Science and Policy Q&A

3 Associate Professor Colin Mendelsohn (2017), Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia; and Supplementary submission

4 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.

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)."[5]

1.6 A letter to the Lancet medical journal in February 2020, signed by 33 public health professionals,[6] states: "*Equating the dangers of vaping with those of smoking ignores dozens of studies that show substantial differences in the risks associated with cigarette and e-cigarette use. The evidence of efficacy of e-cigarettes in helping smokers quit is not weak; the results of a randomised controlled trial have shown two times higher quit rates by people using e-cigarettes than in people using medicinal nicotine replacement therapy, confirming similar findings from population data.* ***E-cigarettes have an important role to play in preventing death and disability from tobacco use, and, while remaining vigilant over potential adverse effects is vital, the effect on public health of denying smokers the choice to use e-cigarettes could be devastating***." (emphasis added).

2. **Additional sources demonstrating that there is increasing agreement amongst health experts that exclusive use of e-cigarettes exposes consumers to significantly reduced toxicants and is estimated to pose substantially reduced risks of harm as compared to continued smoking of cigarettes.**

2.1 An independent expert review commissioned by Public Health England (2018),[7] which updates the evidence from its landmark 2015 report, found, *inter alia*, that: "[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*. "[8]

2.2 An evidence update by Public Health England in 2019 similarly finds that whilst e-cigarettes are not risk free, "*the evidence suggests that* [e-cigarettes] *are substantially less harmful to health than smoking.*"[9] This was reiterated in a further evidence update by Public Health England in 2020, which states: "*Vaping regulated nicotine products has a small fraction of the risks of smoking, but this does not mean it is safe*."[10]

2.3 A large-scale systematic review of the scientific literature undertaken by the US National Academies of Sciences, Engineering, and Medicine ("**NASEM**") for the Food and Drug Administration[11] also concluded, inter alia, that:

2.3.1 "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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5 https://clivebates.com/documents/WHOCOP8LetterOctober2018.pdf at p1.

6 Shahab L, Britton J, Brown J, Hajek P, McNeill A, on behalf of 33 signatories. The need for an evidence-based and rational debate on e-cigarettes. *Lancet* 2020; **395:** 688.

7 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.

8 McNeill A, Brose LS, Calder R, Bauld L & Robson D., *Evidence review of e-cigarettes and heated tobacco products 20*18. A report commissioned by Public Health England. London: Public Health England, 2018.

9 McNeill *et al*., (2019), Vaping in England: an evidence update February 2019 – A report commissioned by Public Health England. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/821179/Vaping_in_England_an_evidence_update_February_2019.pdf.

10 McNeill, A., Brose, L.S., Calder, R., Bauld, L., and Robson, D. (2020). Vaping in England: an evidence update including mental health and pregnancy, March 2020: a report commissioned by Public Health England. London: Public Health England.

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

2.3.2 "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."

2.3.3 "Taken together, the evidence … suggests that e-cigarette aerosol contains fewer numbers and lower levels of toxicants than smoke from combustible tobacco cigarettes."

2.3.4 "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".

2.4 The 2018 United States Annual Review of Public Health states: "Most reviews of toxicological, clinical, and epidemiological evidence indicate that the chemicals found in e-cigarettes, when used as intended, are far fewer and well below levels seen in cigarette smoke. According to the Royal College of Physicians in the United Kingdom, '[T]he available data suggest that they are unlikely to exceed 5% of those associated with combusted tobacco products'. Studies in humans have also documented improved physiological outcomes, including reduced blood pressure, improved lung function, and lower disease symptoms, among smokers who switched to e-cigarettes. E-cigarettes are much less dependence-producing than are cigarettes. Thus, the potential harm of e-cigarettes falls in the low range on the continuum. Harm levels do differ among e-cigarettes. Lab studies have documented some potentially toxic constituents in some devices, e-liquids, and flavors, especially when overheated to produce aldehydes (such as acrolein and formaldehyde) and an acrid "dry puff condition" unlikely to be tolerated by actual users. Nonetheless, prudent product standards can readily eliminate these unnecessary risks and ensure quality control over devices and liquids."[12]

2.5 The recent UK House of Commons Science and Technology Committee Report finds that whilst "[t]here are uncertainties…especially about any long-term health effects, because the products have not yet had a history of long use…any judgement of risks has to take account of the risk of not adopting e-cigarettes – that is, continuing to smoke conventional cigarettes, which are substantially more harmful."[13]

2.6 A study funded by Cancer Research UK (2017),[14] analysed the nicotine, carcinogen, and toxin exposure in long-term e-cigarette and nicotine replacement therapy users over a year. This study, which is the first long-term study of its kind, found that people who swapped smoking regular cigarettes for e-cigarettes or nicotine replacement therapy for at least six months, had much lower levels of toxic and cancer causing substances in their body than people who continued to smoke conventional cigarettes.

3. **Additional sources that suggest that e-cigarettes have contributed to reduced smoking prevalence in countries with a more flexible regulatory landscape.**

3.1 A recent factsheet by UK Action on Smoking and Health ("**ASH**") on the use of vaping products among adults in Great Britain found that "*an estimated 7.1% of the adult population amounting to 3.6 million people in Great Britain currently use e-cigarettes … Over half (54.1%) of current vapers are ex-smokers, and the proportion has grown year on year*" and "[a]*s in previous years the main reason given by ex-smokers for using e-cigarettes is primarily to help them quit (31%) and secondly to prevent relapse (20%)."* The report also noted: "[t]*he Annual Population Survey found that smoking prevalence among adults aged 18 and over in England declined by 5.4 percentage points from 2011 to 2018. In 2011 19.8% of adults smoked, falling to 14.9% in 2017 and to 14.4% in 2018; equivalent to a drop from 7.7 million smokers in 2011 to 6.1 million in 2017 and 5.9 million in 2018.."*[15]

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12 Abrams *et al* (2018) Harm Minimization and Tobacco Control: Reframing Societal Views of Nicotine Use to Rapidly Save Lives, Annu. Rev. Public Health 2018. 39:193–213.

13 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.

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

15 ASH (2019), Use of e-cigarettes (vapourisers) among adults in Great Britain.

In contrast, in Australia, where there is a *de facto* ban on tobacco-free vapour products there was no statistically significant decline in smoking prevalence in the three years from 2013-2016 (despite standardised packaging having been introduced for cigarettes in 2012, together with significant and repeated excise increases).[16]

3.2 In the US, where there have been substantial marketing and distribution freedoms for e-cigarettes, smoking rates among adults have dropped to record low levels in 2018, declining from 20.9% in 2005 to 13.7% in 2018 according to the Centres for Disease Control and Prevention's National Center for Health Statistics.[17]

3.3 Zhu *et al*., (2017)[18] assessed the relationship between e-cigarette use and smoking cessation in a representative sample of the US population. They found that e-cigarette users were more likely than non-e-cigarette users to make a quit attempt (65.1% v 40.1%), and 70% more likely to succeed in quitting (8.2% v 4.8%); and the overall population smoking cessation rate increased between 2010-2011 (4.5%) and 2014-15 (5.6%) representing approximately 350,000 additional US smokers who quit in 2014-15.

3.4 A study by Levy *et al*., (2018)[19] also found that tobacco use among youth is declining as e-cigarette use increases, stating that their findings "*paint a consistent picture of accelerated reductions in youth and young adult smoking prevalence as vaping became more widespread*."

3.5 Kalkhoran *et al*., (2019)[20] found in a longitudinal cohort study of U.S. adult cigarette smokers, that daily e-cigarette use was associated with higher odds of prolonged cigarette smoking abstinence over two years, compared to no e-cigarette use. The authors concluded: "*Daily use of e-cigarettes may help some smokers to stop smoking combustible cigarettes*".

3.6 Farsalinos *et al*., (2016)[21] assessed relationships between e-cigarette use and changes in smoking status in the EU in 2014. They found that smoking cessation with the help of e-cigarettes was reported by 35.1% of current e-cigarette users, while a further 32.2% reported smoking reduction. Being a current or former smoker was the strongest correlate of whether a participant had ever used e-cigarettes. The authors stated: "[a]*n estimated 6.1 and 9.2 million EU citizens had quit and reduced smoking with the help of e-cigarettes, respectively."*

3.7 Giovenco *et al*., (2018)[22] assessed e-cigarettes' effects on smoking cessation. They found that *"over half of daily e-cigarette users (52.2%) quit smoking in the last 5 years, a higher prevalence than any other demographic or behavioural subgroup. After adjusting for all covariates, this group was three times more likely than never e-cigarette users to quit at the time of the survey."* While the study also found that infrequent e-cigarette users were the least likely subgroup to quit smoking, the authors stated: "[p]*ossibly, current smokers who are using e-cigarettes on some days are dually using the products in an attempt to cut back on and eventually eliminate cigarette use. That is, they may have been interviewed in the middle of an attempt at smoking reduction or cessation*."

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

17 https://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.htm.

18 Zhu *et al*., (2017) E-Cigarette use and associated changes in population smoking cessation: evidence from US current population surveys.

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

20 Sara Kalkhoran, Yuchiao Chang, Nancy A Rigotti, Electronic Cigarette Use and Cigarette Abstinence Over 2 Years Among U.S. Smokers in the Population Assessment of Tobacco and Health Study*, Nicotine & Tobacco Research*, , ntz114, https://doi.org/10.1093/ntr/ntz114

21 Farsalinos KE, Poulas K, Voudris V, Le Houezec J. Electronic cigarette use in the European Union: analysis of a representative sample of 27 460 Europeans from 28 countries. Addiction. 2016;111(11):2032-40

22 Giovenco DP, Delnevo CD (2018), Prevalence of population smoking cessation by electronic cigarette use status in a national sample of recent smokers. Addict Behav. Pergamon; 2018 Jan 1;76:129–34.

3.8 A *study* by Hajek *et al*., (2019)[23] which conducted a randomized trial of e-cigarettes versus nicotine-replacement therapy, found that "[e]-*cigarettes were more effective for smoking cessation than nicotine-replacement therapy in this randomized trial. This is particularly noteworthy given that nicotine replacement was used under expert guidance, with access to the full range of nicotine-replacement products…*" The authors also note that "[t]*he trial provides some indications of why e-cigarettes had better results than nicotine-replacement treatments. As in previous studies, e-cigarettes were more effective in alleviating tobacco withdrawal symptoms and received better ratings than nicotine-replacement therapy. They may also have allowed better tailoring of nicotine dose to individual needs.*"

3.9 A study by Beard et al., (2019)[24] found a positive link between the number of people in England giving up smoking when using e-cigarettes to try and quit. The study, led by UCL researchers and funded by Cancer Research UK, found that prevalence of e-cigarette use among current smokers was positively associated with quit success rate and prevalence of e-cigarette use during a quit attempt was positively associated with the overall quit rate. This led the team to estimate that in 2017 around 50,700 to 69,930 smokers in England had stopped smoking as a consequence of the use of e-cigarettes.

4. **Additional sources demonstrating that concerns that e-cigarettes cause widespread established nicotine use among non-smokers (including youth) are unsubstantiated.**

4.1 The Public Health England report (2018)[25] found that: "[d]espite some experimentation with these devices among never smokers, [e-cigarettes] are attracting very few young people who have never smoked into regular use" and that "[e-cigarettes] use among never smokers in [Great Britain] remains very rare at less than 1%, similar to the level of use of [nicotine-replacement therapy]. Among never smokers who have ever used [e-cigarettes], a minority have used nicotine-containing liquids and the vast majority have not progressed to regular use." These findings were reinforced by the 2019 Public Health England evidence update[26], which found that: "[i]n England and in Great Britain as a whole, experimentation with [e-cigarettes] 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 [e-cigarettes] at least weekly remains very low (0.2% of 11 – 18 year olds in 2018) […]."

4.2 Analysis of the U.S. 2018 National Youth Tobacco Survey data by Professor Brad Rodu, a Professor of Medicine at the University of Louisville, found that the proportion of students in the U.S. who were regular vapers and never used tobacco products was only 0.6%. Professor Rodu states: “It is true that frequent vaping among underage high school teens increased substantially from 26,660 in 2017 to 95,316 in 2018. These numbers translate into an increase from less than 0.2 to 0.6% of all high school students. In summary, the oft-cited teen vaping epidemic involves not three million youths, but rather 95,000 underage teens who vaped frequently but never used other tobacco products – or 0.6% of the nation’s 14.8 million high school students.” [27]

4.3 Professor Rodu also presents the following chart of the prevalence of current smoking and vaping among young adults in the US from 2014 to 2018 based on the US Center for Disease Control’s National Health Interview Survey. The chart’s shows that exclusive smoking prevalence dropped in half, from 13.3% to 6.1%, as did dual use. Vaping increased, but only from 1.7% to 5.9%. In fact, all use went from 18.3% in 2014 down to

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23 Hajek *et al*., (2019) A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy

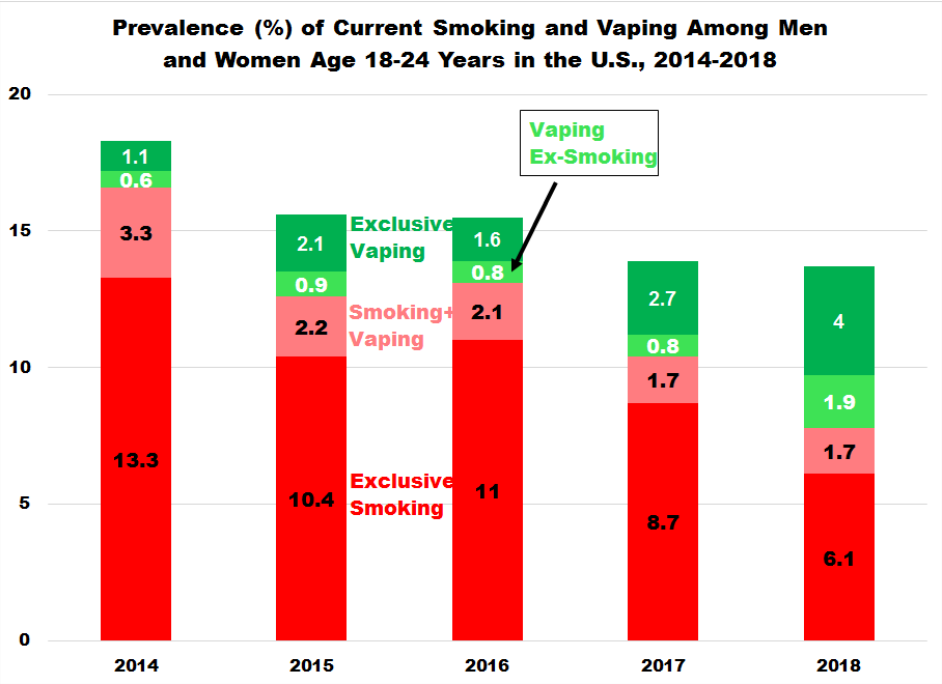
24 Beard et al., (2019) Association of prevalence of electronic cigarette use with smoking cessation and cigarette consumption in England: a time-series analysis between 2006 and 2017

25 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.

26 Vaping in England: evidence update summary February 2019, available at https://www.gov.uk/government/publications/vaping-in-england-an-evidence-update-february-2019/vaping-in-england-evidence-update-summary-february-2019.

27 Rodu (2019) The 2018 American Teen Vaping Epidemic, Recalculated

10.1% in 2018. He states: "**The clear takeaway is that smoking is evaporating among young Americans.**"[28]



4.4 A group of independent UK public health professionals also recently stated:[29]" […] *experimentation with e-cigarettes occurs predominantly among young people who have already started smoking or are at increased risk of smoking, thus representing a rational choice over the far more hazardous tobacco product. Most importantly, smoking rates among teenagers in the US and UK are falling. The same is true of adult smoking, which is falling in both countries, particularly rapidly in the UK as increasing numbers of adult smokers switch to e-cigarettes. Moreover, parental smoking is one of the main drivers of child smoking uptake, so as e-cigarette use enables more adults to quit so fewer children will have smoking parents as role models and more children will be protected from in utero and passive smoke exposure*."

4.5 In New Zealand, evidence also suggests that e-cigarettes might be displacing smoking. A government funded cross-sectional study on the use of e-cigarettes and smoked tobacco in youth aged 14-15 years, found that "[t]*he overall decline in smoking over the past 6 years in New Zealand youth suggests that e-cigarettes might be displacing smoking.*"[30] The authors note: "*In absolute numbers, over the past 5–6 years, most students who had ever tried e-cigarettes were non-smokers, but very few were daily e-cigarette users. In 2019, 6% (5349 of 21 776) of non-smokers reported ever trying an e-cigarette, but only 0·8% (175 of 21 385) were daily users of e-cigarettes. In comparison, almost all regular or daily smokers in 2019 had tried an e-cigarette and about a third of daily smokers also used e-cigarettes daily (equivalent to 0·6% [159 of 27633] of all Year-10 students surveyed).*"

5. **Additional sources demonstrating that the overall weight of the evidence does not support the proposition that e-cigarettes have a gateway effect.**

5.1 Phillips (2015)[31] examined what evidence and research strategies would be needed to empirically detect a gateway effect and explains that the evidence that is typically cited in

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28 Rodu (2019) As Young Adult Smoking Evaporates, "Teen Vaping Epidemic" Appears Overblown

29 Britton et al. (2020) A rational approach to e-cigarettes - challenging ERS policy on tobacco harm reduction. Eur Respir J 2020; in press (https://doi.org/10.1183/13993003.00166-2020).

30 Walker *et al*., (2020) Use of e-cigarettes and smoked tobacco in youth aged 14-15 years in New Zealand: findings from repeated cross-sectional studies (2014-19).

31 Phillips (2015), *Gateway Effects: Why the Cited Evidence Does not support Their Existence for Low-Risk Tobacco Products (And What Evidence Would).*

support of gateway claims is invalid. He notes: "[i]*t is often claimed that low-risk drugs still create harm because of "gateway effects", in which they cause the use of a high-risk alternative. Such claims are popular among opponents of tobacco harm reduction, claiming that low-risk tobacco products (e.g., e-cigarettes, smokeless tobacco) cause people to start smoking, sometimes backed by empirical studies that ostensibly support the claim. However, these studies consistently ignore the obvious alternative causal pathways, particularly that observed associations might represent causation in the opposite direction (smoking causes people to seek low-risk alternatives) or confounding (the same individual characteristics increase the chance of using any tobacco product). Due to these complications, any useful analysis must deal with simultaneity and confounding by common cause. In practice, existing analyses seem almost as if they were designed to provide teaching examples about drawing simplistic and unsupported causal conclusions from observed associations.*"

5.2 While the 2018 US National Academies of Sciences, Engineering and Medicine (NASEM) Report concluded that there is substantial evidence that e-cigarette use by youth and young adults increases their risk of ever using conventional cigarettes, this is not a finding of causation. Maciej 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*…"[32] Dr. Nancy A. Rigotti of Harvard Medical School and Massachusetts General Hospital, who was also on the committee for the NASEM review, has also stated: "*what we are not actually saying here is that it leads to young youth smoking, something that has been sometimes lost in translation*." Dr. Rigotti clarified that there is an "*enormous amount of ecological data*" showing that as youth vaping increased cigarette smoking decreased, which makes it "*hard to argue that there is a gateway there*".[33]

5.3 Levy *et al*., (2018)[34], also critiques 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.*"

6. **Additional sources demonstrating existing misperceptions regarding the comparative risk of e-cigarettes.**

6.1 A study funded by Cancer Research UK also found that in the UK "[t]he relative harms of EC [e-cigarettes] and NRT [nicotine replacement therapy] compared to smoking tobacco cigarettes and the role of nicotine in the main health harms of smoking were overestimated by large proportions of smokers and ex-smokers. These misperceptions have increased over time, and those who have never vaped are more likely to have misperceptions about relative harmfulness"[35] The Public Health England 2018 Report[36] also concluded that "[m]isperceptions of nicotine and different nicotine-containing products need to be addressed. These have deteriorated further since the PHE report in 2015 which called for clear and accurate information on relative harms."

6.2 Research from King's College London[37] also finds smokers and ex-smokers in the UK overestimate the harm from vaping, with fewer than 6 out of 10 accurately believing that e-

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

33 Rigotti, Nancy A. "U.S. National Academies of Sciences, Engineering and Medicine Report: Summary and Relevance to Clinicians." E-cigarette Summit. April 30, 2018. https://vimeo.com/268310971.

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

35 Wilson S., Partos T., McNeill A., and Brose L. S. (2019) Harm perceptions of e-cigarettes and other nicotine products in a UK sample, Addiction. 114, 879–888, doi: 10.1111/add.14502.

36 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.*

37 Wilson et al, (2019) 'Harm perceptions of e-cigarettes and other nicotine products in a UK sample' Addiction, DOI: 10.1111/add.14502.

cigarettes are less harmful than tobacco cigarettes. When asked about the relative harms of e-cigarettes and tobacco cigarettes only 57.3% correctly said vaping was less harmful than smoking, while 21.8% said equally harmful, 3.3% said more harmful and 17.6% didn't know. Lead researcher Dr Leonie Brose from the Institute of Psychiatry, Psychology & Neuroscience at King's College London stated: "[i]**t is possible that smokers may not try e-cigarettes or NRT [nicotine replacement therapy] due to inaccurate beliefs about nicotine and vaping. A lot of public discussion and media reporting focuses on harms from vaping, but we rarely see any reports on how deadly smoking is – 1500 people die from smoking-related illness every week in England alone. Correcting misperceptions around nicotine may help smokers move towards less harmful nicotine delivery methods**." (emphasis added).

6.3 In the US, Huang et al., (2019) found that: "the proportion of adults who perceived e-cigarettes as equally harmful as cigarettes more than tripled from 11.5%...in 2012 to 36.4%...in 2017."[38] The authors also found that "the proportion of adults who perceived e-cigarettes to be more harmful than cigarettes also more than tripled from 1.3%...in 2012 to 4.3%...in 2017."[39] The authors concluded that their results: "imply that at least some smokers may have been deterred from using or switching to e-cigarettes due to the growing perception that e-cigarettes are equally harmful or more harmful than cigarettes. Our results underscore the urgent need for accurate communication of the scientific evidence on the health risks of e-cigarettes and the importance of clearly differentiating the absolute harm from the relative harm of e-cigarettes."[40]

6.4 A study carried out by Perski et al. (2020)[41] reviewed the association between changes in harm perceptions and e-cigarette use among current tobacco smokers in England between 2014 and 2019. The authors found that between 2014 and 2019, at the population level, there was a decline in the proportion of tobacco smokers who endorsed the belief that e-cigarettes are less harmful than combustible cigarettes. There was also a decline in the proportion of tobacco smokers who reported the use of e-cigarettes during this time period. After adjusting for potential confounders and underlying trends, the decline in the belief among current smokers that e-cigarettes are less harmful than combustible cigarettes was strongly associated with declines in the use of e-cigarettes among current tobacco smokers in England. For every 1% decrease in the mean prevalence of current tobacco smokers who endorsed the belief that e-cigarettes are less harmful than combustible cigarettes, the mean prevalence of e-cigarette use decreased by 0.48%. The authors state: "[…] our results highlight the need for an increase in media portrayals and public health campaigns focusing on the reduced health harms by switching from combustible tobacco to e-cigarettes".

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38 Huang et al., (2019) Changing perceptions of harm of e-cigarette vs cigarette use among adults in 2 US National Surveys from 2012 to 2017. Available at: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2729471

39 Ibid.

40 Ibid.

41 Perski O., Beard E., and Brown J., "*Association between changes in harm perceptions and e-cigarette use among current tobacco smokers in England: a time series analysis*" BMC Medicine (2020) 18:98

APPENDIX 2: SCIENTIFIC INFORMATION FOR VYPE ELECTRONIC NICOTINE DELIVERY SYSTEMS

Prepared by British American Tobacco

17th September 2020

Contents

1 INTRODUCTION

The impact of smoking on population health is well known as it is a key risk factor for CVD, COPD and cancer [US Department of Health & Human Services 2014]. The combustion of tobacco in cigarettes at temperatures in excess of 900^{O}C forms smoke which is comprised of more than 6500 compounds [Rodgman 2013], of which around 150 are known as toxicants [Fowles 2003]. It is generally accepted that it is these toxicants in cigarette smoke that are the cause of smoking related diseases and not nicotine [The Royal College of Physicians 2016].

The US Institute of Medicine suggested that a tobacco harm reduction approach could reduce the burden of smoking on health at a population level through the concept of Potentially Reduced Exposure Products (PREPs) which would (i) result in the substantial reduction in exposure to one or more tobacco toxicants and (ii) could reasonably be expected to reduce the risk of one or more specific diseases or other adverse health effects [Stratton 2001]. More recently the FDA introduced a framework outlining their approach for determining a Modified Risk Tobacco Product (MRTP), either through demonstration of reduced toxicant exposure or a reduction in health risks [FDA 2012]. We recently outlined a framework for the assessment of products such as e-cigarettes that includes four key assessment phases: stewardship science, exposure reduction, individual risk reduction and population risk reduction. This integrated approach proposes the use of pre-clinical, clinical and population studies to assess the risk reduction potential of new products at the individual and population level [Murphy 2017a].

E-cigarettes are products that have come into widespread use in many countries around the world as they can replicate many of the sensorial, ritualistic and pharmacological aspects of cigarettes. On account of their popularity, they present a unique opportunity for tobacco harm reduction. In 2015, Public Health England (PHE), an executive agency of the UK Department of Health, reported that their findings from reviewing data from over 180 multidisciplinary studies led them to conclude that; 'best estimates show e-cigarettes to be 95% less harmful to your health than cigarettes' [McNeill 2015;].

Furthermore, in 2016, the UK Royal College of Physicians (RCP) published their report 'Nicotine without smoke: tobacco harm reduction', which sought to reassure smokers on the safety of e-cigarettes and encourage their use. They concluded that; 'e-cigarettes were not a gateway to smoking nor did they renormalize smoking and they would likely lead to quit attempts that may not have happened otherwise'. They added that; 'although any long-term harm effects could not be dismissed, the available data suggested that they are unlikely to exceed 5% of those associated with smoked tobacco products (and could be substantially lower than this figure)'[The Royal College of Physicians 2016].

In 2018 PHE prepared an additional report and concluded 'vaping poses only a small fraction of the risks of smoking and switching completely from smoking to vaping conveys substantial health benefits over continued smoking. 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 does not mean e-cigarettes are safe' [McNeill 2018].

In 2018 the National Academies of Sciences (NAS) [National Academies of Science 2018] also reviewed available scientific data and concluded that 'while e-cigarettes are not without health risks, they are likely to be far less harmful than conventional cigarettes'.

More recently in 2020, the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) made the following statements with regards to e-cigarettes/E(N)NDS [Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT)Physicians 2020]: 'overall the COT agreed that the evidence on the toxicity of E(N)NDS[1] aerosol indicates that use of E(N)NDS products may be associated with a reduced risk compared with CC[2], but this should not be taken as meaning that these products are risk-free' and 'Considering the comparison of E(N)NDS use with CC smoking, the Committee concluded that the relative risk of adverse health effects would be expected to be substantially lower from E(N)NDS'.

[1] electronic nicotine (and non-nicotine) delivery systems (E(N)NDS – e-cigarettes
[2] combustible cigarette

In this document, we describe peer reviewed scientific data that British American Tobacco generated to enable the risk profile of Vype e-cigarettes to be assessed relative to cigarettes. For laboratory studies, 3R4F [Roemer 2012] or 1R6F scientific reference cigarettes, from the University of Kentucky, were adopted as they have a history of use in tobacco assessment studies and are used by regulatory and public health scientists globally. In clinical/human/ consumer tests, commercial cigarettes were used as a control, the exact product is detailed in the referenced publication.

2 EMISSIONS

It is possible to use standardised testing methods to measure mainstream emissions from Vype e-cigarettes, but because the levels of many of the targeted toxicants are so low it is very important to also measure laboratory air blanks to avoid false readings [Margham 2016]. The composition of the aerosol generated by Vype e-cigarettes are fundamentally different from that of cigarette smoke, containing large levels of humectants and water, and so for untargeted emissions analysis analytical techniques need to be modified. It is not possible to measure sidestream smoke emissions as none are generated by Vype e-cigarettes.

On account of their design, the toxicants of concern in e-cigarette aerosols are typically carbonyl containing (aldehydes and ketones) and metals. We measured the levels of these two categories of compounds in Vype e-cigarettes aerosol and compared them to the levels in smoke from a scientific reference cigarette [Margham 2016].

Further to these studies, we conducted a specific study looking a much broader range of chemical classes. Classic markers of combustion, such as carbon monoxide, which are found in abundance in cigarette smoke were found to be below the limits of quantification. Several other toxicants that are listed on lists of compounds of importance to health from various authorities, including the World Health organisation, the US FDA and Health Canada, were found to be present in the cigarette smoke but were found to be below the level of quantification in the Vype e-cigarettes emissions, including 1,3-butadiene, benzene and benzo(a)pyrene [Margham 2016]. This was as expected as these toxicants are generated by tobacco being burnt.

Nicotine is present in Vype e-cigarettes emissions, but at levels lower than found in the reference cigarette. Other toxicants, including acetaldehyde and formaldehyde were found in the Vype e-cigarettes emissions, but at substantially reduced levels compared to the reference cigarette. Focusing on the emission levels for three flavoured variants, taking the WHO's priority 9 toxicants for lowering in cigarette smoke [Burns 2008], we calculate an overall reduction in toxicant levels for Vype e-cigarettes of the order of 99% relative to the scientific reference cigarette [Margham 2016]. In the same manner, Vype e-cigarettes had overall reductions in toxicant levels in the order of 98% relative to the reference cigarette.

As newer variants came to market, we repeated the above experiments to ensure toxicant levels were comparable or lower than previous launched products. In a recent study, comparing toxicant emissions from five e-cigarettes and a reference cigarette, levels of the nine WHO TobReg priority cigarette smoke toxicants were more than 99% lower in the aerosols of the e-cigarette products [Cunningham 2020].This study has confirmed that despite continuing evolution in design, components and ingredients, Vype e-cigarettes continue to offer significantly lower toxicant exposure alternatives to cigarette smoking [Cunningham 2020].

3 TOXICOLOGY

We have used traditional toxicological tests such as the Bacterial Reverse Mutation Test [Thorne 2016 and Thorne 2017b], as defined by the OECD, and the Neutral Red Uptake [Azzopardi 2016] test for cytotoxicity, both of which gave none or little response to the Vype e-cigarettes aerosol, whereas the reference cigarette induced dose dependent mutagenic and cytotoxic responses. Additional toxicological tests for oxidative stress [Taylor 2016a], genotoxicity [Thorne 2017a], tumour promotion [Breheny 2016], wound healing (a cell migration test likely relevant to cardiovascular disease) [Taylor 2016b] and blood vessel cytotoxicity [Bozhilova 2020] all showed much reduced response or no response with the Vype e-cigarettes aerosol compared to the cigarette smoke. A series of dosimetric studies were undertaken to ensure that equivalent amounts of aerosol were delivered to the cellular systems during both cigarette and Vype e-cigarettes exposure [Adamson 2016]. These results are consistent with the chemical analysis of the Vype e-cigarettes emissions [Margham 2016] and provide pre-clinical support for

the emissions of Vype e-cigarettes to be associated with reduced toxicity in laboratory tests compared to cigarette smoke.

Furthermore, studies that define the disease pathways and underlying mechanisms were investigated using a global and holistic systems science approach. In these studies [Banerjee 2016 and Haswell 2017], a reconstituted 3D human respiratory tissue, Muclilair™, was exposed to 3R4F reference cigarette smoke or Vype e-cigarettes aerosol followed by transcriptomic analysis. When this biologically relevant 3D cell system was exposed to cigarette smoke, a number of genes associated with disease relevant end-points (e.g. tissue damage, inflammation, respiratory damage) were up regulated. When the cellular system was exposed to Vype e-cigarettes aerosol, the same endpoints showed substantially reduced responses. An advantage of this approach was that mechanistic insights could be gained into the drivers of disease responses, for example inflammation damage. In this case, the cytokines which underpin the inflammatory response were measured for both smoke and e-cigarette aerosol exposure. It was found that a significant number of cytokines were expressed in the 3D tissue when exposed to cigarette smoke but with Vype e-cigarettes exposure there was little to no cytokine expression [Banerjee 2016]. Such findings are in accordance with the PHE, RCP, NAS and COT's predictions of the significantly reduced relative risk of e-cigarette use compared to smoking.

4 IMPACT ON INDOOR AIR QUALITY

The design principle of e-cigarettes also makes a fundamental difference on air quality when the product is used indoors compared to a cigarette. Much of the toxicant levels and odour created when cigarettes are smoked indoors results from the side stream smoke which is emitted at the lit end of the cigarette, particularly between puffs. With Vype e-cigarettes, because there is no tobacco and no combustion and the product only operates under user actuation, there is no side stream smoke. The only impact that a Vype e-cigarettes user will have on air quality will come from what aerosol is exhaled, and much of this will be humectants (glycerol and/or propylene glycol) and water, resulting in an aerosol with low odour and that dissipates quickly from the air.

We have tested the impact on indoor air quality of using Vype e-cigarettes compared to smoking at an independent laboratory (the Building Research establishment) in the UK [Murphy 2017b]. In carefully controlled rooms with air changes set to represent, home, hospitality and office conditions, we asked volunteers to either use Vype e-cigarettes or smoke cigarettes for a period of four hours while the air was monitored for particulate matter and other toxicants. The results found a substantial difference between Vype e-cigarettes use and cigarette smoking [Murphy 2017b; Azzopardi 2020]. In fact, the levels of particulate matter in the air during Vype e-cigarettes use did not exceed WHO air quality standards [WHO 2006, 2010 and 2016]. In additional testing, we found that the use of Vype e-cigarettes had much reduced impact on odour on hand, hair and fabric compared to cigarette smoking (unpublished data).

5 HUMAN USAGE, BEHAVIOUR AND CONSUMPTION STUDIES

A study was performed [Cunningham 2016] to measure daily consumption and consumer puffing behaviour with a variety of e-cigarette products. The puffing behaviour study measured the topography of 60 users of the Vype e-cigarette, which was found to comprise an average puff volume of 52.2-83ml, an average puff duration of 2.0-2.2 seconds and an average interval between puffs of 23.2-29.3 seconds. For laboratory testing of e-cigarettes, the CORESTA (Cooperation Centre for Scientific Research Relative to Tobacco) organisation have recently recommended a machine puffing regimen of a 55ml puff, with a 3 second duration and a puff interval of 30 seconds between puffs (CORESTA Method 81). Our study confirmed that consumer's behaviour was reflective of the laboratory machine regimen recommended by CORESTA. The second part of the study measured the daily consumption of over 1000 subjects using both 'cigalike' e-cigarettes (products that have a similar format and appearance to conventional cigarettes) and refillable tank systems. These data are important for calculating average daily exposure, which for Vype e-cigarette was found to be 7.2 puffing sessions per day; with typically 10 puffs per session. Consumer use-behaviour and consumption data as detailed in Cunningham et al. 2016 help give context to toxicological risk assessments and ensure that laboratory-based product testing is reflective of real-world consumers.

We have recently published a study which compares consumers use behavior across different product categories, including e-cigarettes. These studies further support the need to understating consumers' product interaction and that toxicological risk assessment should be assessed as exposure *per day* when conducting cross-category evaluations [Jones 2020].

6 CLINICAL DATA

Studies were conducted to measure the uptake of nicotine from both a commercially available cigarette and Vype e-cigarettes. A clinical based nicotine pharmacokinetic study was conducted with 18 subjects who used both a cigarette and Vype e-cigarettes sequentially in an ad libitum manner for 5 minutes [Fearon 2017]. Nicotine concentrations in blood were measured at a range of time-points from one minute post commencement of puffing and up to 60 minutes. First, the subjects smoked the cigarette and the average maximum concentration (Cmax) of nicotine was 7.2 ng/ml (CV 130.8%), with a median time to reach this maximum concentration (Tmax) of 6 minutes. Next, when the subjects used Vype e-cigarettes, the average maximum concentration of nicotine was 8.8ng/ml, with a median time to reach this concentration of 6 minutes also. When compared there was not a statistical difference between cigarette smoking and the e-cigarette values. The study illustrated that it was possible for consumers to get similar blood nicotine concentrations with Vype e-cigarettes and cigarettes and, importantly, in similar time frames which will increase the likelihood of product acceptance [Fearon 2017].

To understand consumer acceptance of our products and their reduced risk potential, we continue to conduct clinical studies when new variants or e-liquids formulations are developed. A 2020 study confirmed that a Vype e-cigarette, with different concentrations of nicotine salts, delivered nicotine more efficiently with the potential to increase product acceptance relative to earlier devices [Ebajemito 2020].

To understand reduced exposure to tobacco toxicants, biomarkers of exposure levels were measured in consumers breath and urine after they switched to Vype e-cigarettes for 5 days [McEwan 2020]. Compared to levels in smokers, biomarker levels were significantly reduced in Vype e-cigarettes user's breath and urine [McEwan 2020]. Some biomarkers levels were also at the level observed in subjects that had quit smoking. This data suggest that Vype e-cigarette have the potential to be reduced risk products.

Other clinical studies have also confirmed the reduction of tobacco smoke toxicants and biomarkers of exposure in subjects that switch to e-cigarettes. In Round et al 2019 [Round 2019] 23 biomarkers were measured in subjects that switched to using an e-cigarette. All biomarkers , apart from nicotine, significantly decreased in subjects that switched to the e-cigarette.

A cross sectional study conducted in the UK has also shown that former smokers, with more than 6 months exclusive e-cigarette use, were exposed to substantially reduced levels of carcinogens and toxins compared to cigarette smokers [Shahab 2017].

All of the above mentioned clinical studies support the conclusions made by PHE, RCP, NAS and COT [McNeill 2015; The Royal College of Physicians 2016; McNeill 2018; National Academies of Science 2018, Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT)Physicians 2020], that exclusive e-cigarettes use results in reduced exposure to tobacco toxicants and thus should have a beneficial public health impact.

7 POPULATION STUDIES

Historically, epidemiological studies have been used to substantiate the effects of smoking on population health. This can take up to a generation (*ie.* 25 years or more) to gather the required datasets. In the absence of epidemiology, the immediate impact of e-cigarettes on population health could be assessed using mathematical modelling.

Using publicly available data from the UK, Hill *et al* [Hill 2017] modelled the potential population health outcomes of introducing e-cigarettes into the marketplace. Mortality over a 50-year period (2000–2050) was the health outcome of interest, and was compared between two scenarios, with and without e-cigarettes being introduced. The model projected that by 2050, smoking prevalence in adults would be 12.4% in the core model and 9.7% (including dual users) in the counterfactual base model. Smoking-

related mortality was projected at 8.4% and 8.1%, respectively. The projections suggest an overall beneficial effect from launching e-cigarettes.

Levy and colleagues [2018a] used two birth cohorts of smokers (1962 and 1982) to compare the classic status quo scenario of only cigarette smoking against several scenarios in which cigarettes were replaced by e-cigarettes at different rates per year. In the status quo model, smoking was calculated to cause 390,632 cumulative premature deaths and 4,577,882 life-years lost in men and 135,468 premature deaths and 1,628,491 life-years lost in women. In the 1982 birth cohort, under the most pessimistic conditions, the model projects a decrease of 69,585 premature deaths and 1,048,763 life-years lost in men and 26,104 and 433,872, respectively, in women. Similarly, for the 1962 cohort, under the same assumptions, the model projects fewer premature deaths and fewer life-years lost.

In another model using a 2001 birth cohort, Levy et al [2018b] assessed scenarios in which vaping reducing smoking prevalence to 5% (optimistic) or 10% (pessimistic) by 2026. In the pessimistic scenario, cumulative reductions of 19.5 million premature deaths and 161.9 million fewer life-years lost were projected compared to results if there were no e-cigarettes available. In the optimistic scenario, the projected values were 24.4 million fewer premature deaths and 227.8 million life-years lost avoided.

8 OVERALL CONCLUSIONS

Public Health authorities in the UK and the US have reported that available data shows that exclusive e-cigarette use results in reduced exposure to tobacco toxicants and thus should have a beneficial public health impact. We have conducted a series of chemical, in vitro biological and a range of human studies on Vype e-cigarettes in comparison to scientific reference cigarettes or commercial cigarettes. The results from these studies when considered in their totality are in line with the findings of PHE, RCP, NAS and COT and they demonstrate that Vype e-cigarettes have the potential to be a reduced risk product in comparison to cigarettes. Longer term clinical studies will help to further substantiate Vype e-cigarette potential to contribute to harm reduction on a population level.

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