166 William Street
Woolloomooloo 2011
NSW Australia

Locked Bag 6000
Potts Point 1335
NSW Australia

Tel +61 2 9370 1500
Fax +61 2 9370 1188
www.bata.com.au

British American Tobacco Australia Limited's submission to the Select Committee on Tobacco Harm Reduction November 2020

Executive summary

British American Tobacco Australia limited (BATA) is pleased to take this opportunity to make a submission to the Senate Select Committee on Tobacco Harm Reduction (the **'Committee'**).

BATA believes that e-cigarettes, and other potentially reduced risk alternative non-combustible tobacco and nicotine products, that are manufactured to robust quality standards, have a significant potential to contribute to tobacco harm reduction. We call for a strong regulatory framework that facilitates awareness of, and appropriate adult access to a wide range of potentially reduced risk alternatives to combustible tobacco products, while protecting against underage usage of any tobacco or nicotine products.

BATA strongly encourages an approach to the legalisation of these products that includes:

- Robust quality standards, including manufacturing process requirements; product specifications and ingredients; and product packaging and labelling requirements
- Strong age verification practices;
- Hardware/device requirements adhering to Australian Standards;
- Flavours that appeal to adults are not limited to tobacco and menthol; and
- Controlled marketing and advertising rules aimed at adult consumers only

Vaping regulations should sit under the jurisdiction of the Australian Competition and Consumer Commission (ACCC).

BATA suggests that the Government look towards a strong regulatory approach to nicotine for Australians that supports smokers who want to switch to potentially reduced risk alternatives to conventional tobacco, while protecting against underage usage.

BATA suggests that the Committee takes note of the successful approaches taken by other countries such as the United Kingdom, and New Zealand in respect of the legalisation of potentially reduced risk alternatives to cigarettes.

Traditional oral smoke-free tobacco products such as Swedish-style snus and modern tobacco-free nicotine-containing pouches provide further potentially reduced-risk alternatives to cigarettes. Epidemiological evidence from Sweden over many decades shows that snus is a substantially less risky product compared to cigarettes when used exclusively.

These products allow nicotine to be absorbed through the oral mucosa (the mucous membrane lining the inside of the mouth). These products are preferred in countries such as Sweden, which has one of the lowest tobacco smoking rates in the world and correspondingly the lowest rates of tobacco related mortality in the EU.

Responses to Committee terms of reference

1. The treatment of nicotine vaping products (electronic cigarettes and smokeless tobacco) in developed countries similar to Australia (such as the United Kingdom, New Zealand, the European Union and United States), including but not limited to legislative and regulatory frameworks

Australia is one of the very few developed countries where vaping products that contain nicotine are illegal.

United Kingdom

In the UK, where nicotine e-cigarettes have been legally available for several years and are supported by the Government and public health authorities, there has been a significant decline in the smoking rate from 20.2% in 2011 to 14.1% in 2019[1].

A 2019 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..*"[2]

The potential use of e-cigarettes in a public health strategy was recognised in a guidance document on the use of e-cigarettes in public places and workplaces published by Public Health England (PHE). PHE concluded that "*We believe e-cigarettes have the potential to make a significant contribution to its achievement. Realising this potential depends on fostering an environment in which e-cigarettes can provide a route out of smoking for England's eight million smokers, without providing a route into smoking for children or non-smokers.*"[3]

The PHE report proposes 5 key principles intended to: *"guide the development of evidence-based policies that maximise the potential for e-cigarettes to improve public health while managing the risks in any particular setting."* These principles are:

1. Make a clear distinction between vaping and smoking.

E-cigarette use does not meet the legal or clinical definitions of smoking. Furthermore, international peer-reviewed evidence suggests that e-cigarettes carry a fraction of the risk of cigarettes and have the

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[1]Office for National Statistics (2019), Adult smoking habits in the UK: 2019, available at https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandlifeexpectancies/bulletins/adultsmokinghabitsingreatbritain/2019

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

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

potential to help drive down smoking rates, denormalise smoking and improve public health. So policies need to be clear on the differences between vaping and smoking.

2. Ensure policies are based on evidence of harm to bystanders

[…] international peer-reviewed evidence indicates that the risk to the health of bystanders from secondhand e-cigarette vapour is extremely low and insufficient to justify prohibiting e-cigarettes. This evidence should inform risk assessments.

3. Identify and manage risks of uptake by children and young people

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

4. Support smokers to stop smoking and stay smokefree

E-cigarettes are used almost exclusively by smokers and ex-smokers and are now the most popular stop-smoking aid in England. To help smokers to stop smoking and stay smokefree, a more enabling approach to vaping may be appropriate to make it an easier choice than smoking. In particular, vapers should not be required to use the same space as smokers, as this could undermine their ability to quit and stay smokefree.

5. Support compliance with smokefree law and policies

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

There are also examples in the UK of hospitals selling vaping products to encourage patients to quit using combustible cigarettes.

1The vape store at Sandwell General Hospital, near Birmingham, UK

A 2019 expert review led by researchers at King's College London and commissioned by Public Health England found that "regular vaping among young people remains low in Britain and has plateaued among adults"[4].

Statements from this review include:

- Experimentation with vapour products 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;
- Vaping continues to be associated with smoking. The proportion of young people who have never smoked who use vapour products at least weekly remains very low (0.2% of 11-18-year olds in 2018);

Public Health England's most recent March 2020 evidence update[5] also found that for adults, "[v]aping remains most common among smokers and former smokers, with less than 1% of people who have never smoked currently vaping; and for youth "[c]urrent vaping is mainly concentrated in young people who have experience of smoking. Less than 1% of young people who have never smoked are current vapers".

Recently, the independent UK Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (the "COT") concluded that: "[t]he use of E(N)NDS products, produced according to

[4] Public Health England (2019), Regular e-cigarette use remains low among young people in Britain, available at https://www.gov.uk/government/news/regular-e-cigarette-use-remains-low-among-young-people-in-britain
[5] 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.

appropriate manufacturing standards and used as recommended, as a replacement for CC smoking, is likely to be associated with a reduction in overall risk of adverse health effects, although the magnitude of the decrease will depend on the effect in question.[6] Commenting on the report, the chairman of COT stated: "[o]ur assessment on e-cigarettes largely reinforces the scientific consensus to date on their relative safety, that while not without risk they are significantly less harmful than smoking."[7]

New Zealand

New Zealand recently passed specific legislation for vaping products and the Ministry of Health encouraged smokers to switch to e-cigarettes in June 2020 as a way of quitting combustible cigarettes[8].

New Zealand's Smokefree Environments and Regulated Products (Vaping) Amendment Act 2020 which comes into force from 11 November 2020, allows different advertising and marketing restrictions for vaping products than for tobacco and for special vape retailers to sell a full range of flavours[9].

The Ministry of Health's position statement on e-cigarettes states that, "[t]he Ministry of Health considers vaping products have the potential to make a contribution to the Smokefree 2025 goal and could disrupt the significant inequities that are present." The Ministry also states: "Smokers switching to e-cigarettes are highly likely to reduce their health risks and for those around them" and "When used as intended, e-cigarettes pose no risk of nicotine poisoning to users, but e-liquids should be in child resistant packaging. E-cigarettes release negligible levels of nicotine and other toxicants into ambient air with no identified health risks to bystanders."[10]

European Union

The European Union Tobacco Products Directive[11] ("**TPD**") is an example of a regulatory framework that enables e-cigarettes to remain available for commercial distribution while regulating the manufacture and sale of products and ensuring that post-market e-cigarette developments are reviewed by both regulators and manufacturers. This includes, amongst other things, the following regulatory requirements for e-cigarettes:

- A pre-market notification regime which requires notification to regulators by e-cigarette manufacturers and importers, in advance of introducing products to the market, addressing ingredients, toxicology, nicotine pharmacology, and production processes, amongst others;

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[6] The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment., *Statement on the potential toxicological risks from electronic nicotine (and non-nicotine) delivery systems (E(N)NDS – e-cigarettes)* July 2020 - A report commissioned by the Department of Health and Social Care and Public Health England.

[7] Tobacco Reporter (2019), 'U.K. Study Reiterates Relative Safety of Vaping' available at https://tobaccoreporter.com/2020/09/16/u-k-study-reiterates-relative-safety-of-vaping/.

[8] New Zealand Parliamentary Counsel Office 'Smokefree Environments and Regulated Products (Vaping) Amendment Act 2020' available at http://www.legislation.govt.nz/act/public/2020/0062/40.0/LMS313921.html

[9] Ibid.

[10] New Zealand Ministry of Health (2020), 'Position Statement on vaping' available at https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/vaping-smokefree-environments-and-regulated-products/position-statement-vaping

[11] Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC, Official Journal of the European Union, 29 April 2014.

- Requirements addressing technical design parameters (including volume limitations on pre-filled cartridges and dedicated refill containers and reasonable limitations on nicotine content);
- Restrictions on e-liquid manufacture to high purity ingredients;
- Limiting ingredients (aside from nicotine) to those that do not pose a risk to human health in heated or unheated form;
- Informational leaflet requirements addressing instructions for use and storage, contra-indications, warnings for specific risk groups, possible adverse effects, and addictiveness/toxicity;
- Warning requirements for external packaging;
- Requirements that e-cigarettes and refill containers be child and tamper proof, protected against breakage and leakage, and have a mechanism to ensure leak-free refilling;
- Post-market surveillance for adverse effects; and
- Submission of sales and marketing data to regulators.

Whilst the entire TPD regulatory regime would likely not benefit consumers (such as the prohibitions against e-cigarette communications and promotion, and the prescribed limit on the nicotine content of e-liquids), this approach demonstrates a more proportionate approach than the current approach in Australia.

United States

In the United States the Food & Drug Administration (FDA) regulates e-cigarettes and other smoke-free tobacco and nicotine alternatives to cigarettes.

In its announcement on July 28, 2017 of a new comprehensive plan for tobacco and nicotine regulation the FDA noted "*A key piece of the FDA's approach is demonstrating a greater awareness that nicotine — while highly addictive — is delivered through products that represent a continuum of risk and is most harmful when delivered through smoke particles in combustible cigarettes.*"[12]

Scott Gottlieb, M.D., also stated when FDA Commissioner, that the FDA "*see*[s] *the possibility for ENDS products like e-cigarettes and other novel forms of nicotine-delivery to provide a potentially less harmful alternative for currently addicted individual adult smokers who still want to get access to satisfying levels of nicotine without many of the harmful effects that come with the combustion of tobacco.*"[13]

Tobacco policy guidance principles from the American Association of Public Health Physicians state that, "Smoke-free tobacco/nicotine products, as available on the American market, while not risk-free, carry substantially less risk of death and may be easier to quit than cigarettes. ...Smokers who have tried, but failed to quit using medical guidance and pharmaceutical products, and smokers unable or uninterested in quitting, should consider switching to a less hazardous smoke-free tobacco/nicotine product for as long as they feel the need. Such products include pharmaceutical Nicotine Replacement Therapy (NRT)

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[12] FDA News Release (28 July 2017). FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death. Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm568923.htm

[13] FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on new enforcement actions and a Youth Tobacco Prevention Plan to stop youth use of, and access to, JUUL and other e-cigarettes, available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm605432.htm (dated April 24, 2018).

products used, off-label, on a long term basis, electronic "e" cigarettes, dissolvables (sticks, strips and orbs), snus, other forms of moist snuff, and chewing tobacco."[14]

2. The impact nicotine vaping products have had on smoking rates in these countries, and the aggregate population health impacts of these changes in nicotine consumption

Tobacco free nicotine products and smokeless tobacco products present potentially less risk for lung cancer, oral cancer, respiratory disease and heart disease than combustible tobacco products.

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. An evidence update by Public Health England in 2020 reiterated that: "*Vaping regulated nicotine products has a small fraction of the risks of smoking, but this does not mean it is safe*."[15] A large-scale systematic review of the scientific literature undertaken by the US National Academies of Sciences, Engineering, and Medicine for the Food and Drug Administration[16] also concluded that: "*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*".

There is also a general scientific consensus that, while not risk free, snus is dramatically less dangerous than combustible tobacco.[17] As stated by the United Kingdom's Royal College of Physicians, "*it is very clear that, for most of the major health effects of tobacco, smoking is many times more dangerous than smokeless tobacco use*".[18] Similarly, the WHO Scientific Advisory Committee on Tobacco Product Regulation has concluded that "[a]*mong the smokeless tobacco products on the market, products with low levels of nitrosamines, such as Swedish snus, are considerably less hazardous than cigarettes*."[19]

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[14] American Association of Public Health Physicians 'Principles to Guide AAPHP Tobacco Policy' available at https://www.aaphp.org/Tobacco

[15] 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.

[16] NASEM (2018), Public Health Consequences of E-Cigarettes.

[17] For example, see 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; WHO (2008), The scientific basis of tobacco product regulation: second report of a WHO study group (WHO technical report series; no. 951); Broadstock (2008) Systematic review of the health effects of modified smokeless tobacco products. NZHTA Report 2007; 10(1); Kozlowski and Sweanor, "Withholding differential risk information on legal consumer nicotine/tobacco products: The public health ethics of health information quarantines", *International Journal of Drug Policy*, 32: 17-23 (2016).

[18] 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 (2007) (**RCP 2007**).

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

United Kingdom

There is strong evidence in the United Kingdom suggesting that vaping has contributed to the decline in the smoking rate from 20.2% in 2011 to 14.1% in 2019[20].

West et al. (2014)[21] estimated that the availability of e-cigarettes resulted in between 16,000 and 22,000 long-term quitters in England during 2014. Similarly, Beard et al. (2016)[22] estimated that e-cigarettes may have contributed about 18,000 additional long-term ex-smokers in the England in 2015. Referring to these studies, the 2018 Public Health England Report concluded that: "[w]*hile caution is needed with these figures, the evidence suggests that e-cigarettes have contributed tens of thousands of additional quitters in England.*" [23]

According to the UK Government's Office of National Statistics ("ONS"), "E-cigarettes are increasingly being used by smokers to help quit smoking. In a recent evidence review, Public Health England found that vaping poses a small fraction of the risk of smoking and that when e-cigarettes are used as part of a quit attempt, success rates are comparable with or higher than licensed medication alone."[24] The ONS 2019 survey of adult smoking habits in the UK found that 5.7% of survey respondents in the UK were current users of e-cigarettes, up significantly from 3.7% in 2014 when data collection of e-cigarette users began[25].

[20] Office for National Statistics (2019), Adult smoking habits in the UK: 2019, available at https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandlifeexpectancies/bulletins/adultsmokinghabitsingreatbritain/2019

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

[22] 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.

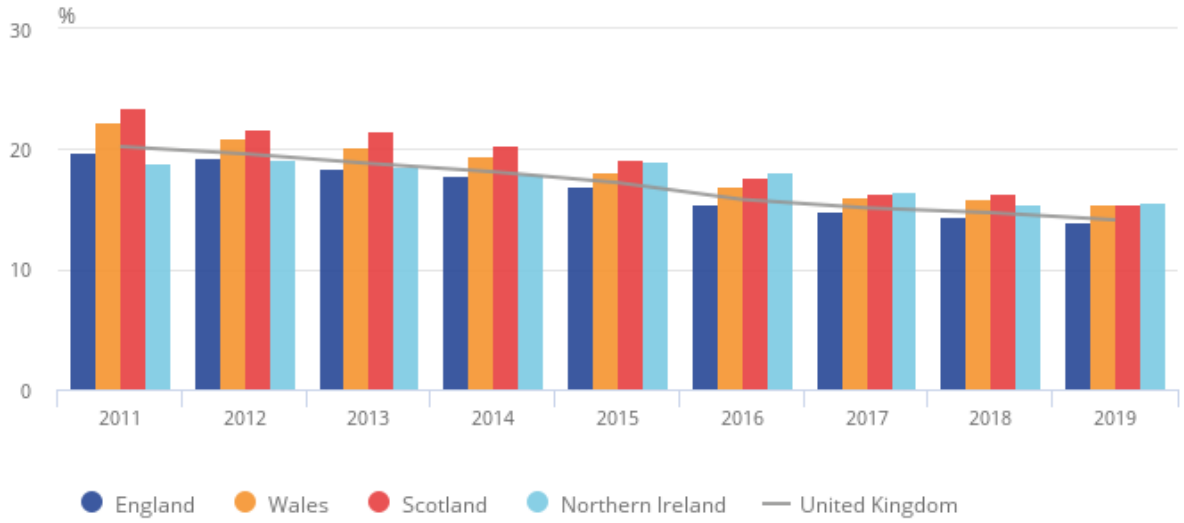
[23] Public Health England (2018), Public Health Matters (Blog) - Turning the tide on tobacco: Smoking in England hits a new low. Available at: https://publichealthmatters.blog.gov.uk/2018/07/03/turning-the-tide-on-tobacco-smoking-in-england-hits-a-new-low/.

[24] Office for National Statistics (2019), Adult smoking habits in the UK: 2019, available at https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandlifeexpectancies/bulletins/adultsmokinghabitsingreatbritain/2019#the-use-of-electronic-cigarettes-e-cigarettes-great-britain.

[25] Ibid.

Figure 1: Smoking prevalence has fallen in all four countries of the UK since 2011

Proportion who were current smokers, all persons aged 18 years and over, UK, 2011 to 2019



Source: Office for National Statistics – Annual Population Survey

United States

Similarly, in the US, where there have been substantial marketing and distribution freedoms for potentially reduced risk products, smoking rates among adults have dropped to record low levels in 2018, declining to 13.7% according to the Centres for Disease Control and Prevention's National Center for Health Statistics.[26]

Kalkhoran *et al*., (2019)[27] 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*".

The outbreak of vaping-related lung injury (EVALI) cases in the US in 2019 has been subject to much misreporting in the media. The facts clearly demonstrate that a major cause of the US cases is linked to vaping products containing THC and/or vitamin E acetate, in particular illicit products. This highlights the

[26] Centres for Disease Control and Prevention (2019), 'Cigarette Smoking Among U.S. Adults Hits All-Time Low' available at: https://www.cdc.gov/media/releases/2019/p1114-smoking-low.html.

[27] 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

need for Australia to adopt robust, workable regulations for e-cigarettes to bring them out of the current black market.

New Zealand

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.*"[28] 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, 24.6% (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).*"

European Union

Although all EU member states have transposed the European Tobacco Products Directive (TPD 2014/40/EU) into their national tobacco regulation, the treatment of vaping varies across Member States in certain areas i.e. domestic advertising, point of sale, internet sales and flavours.

Farsalinos et al., (2016)[29] assessed relationships between of e-cigarette use and changes in smoking status in the European Union ("**EU**") Member States 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 ever e-cigarette use. 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.*"

Sweden

The experience in Sweden where snus 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.

The daily tobacco smoking rate in Sweden in 2018 was just 7% - the lowest in the EU[30]. One of the reasons for this very low number is due to the widespread use of snus and other smokeless alternatives to combustible cigarettes. As one study reports: "[s]*nus has both contributed to decreasing initiation of smoking and, when used subsequent to smoking, appears to facilitate smoking cessation. All these effects suggest that the availability and use of snus has been a major factor behind Sweden's record-low prevalence of smoking and the lowest level of tobacco-related mortality among men in Europe*."[31] In

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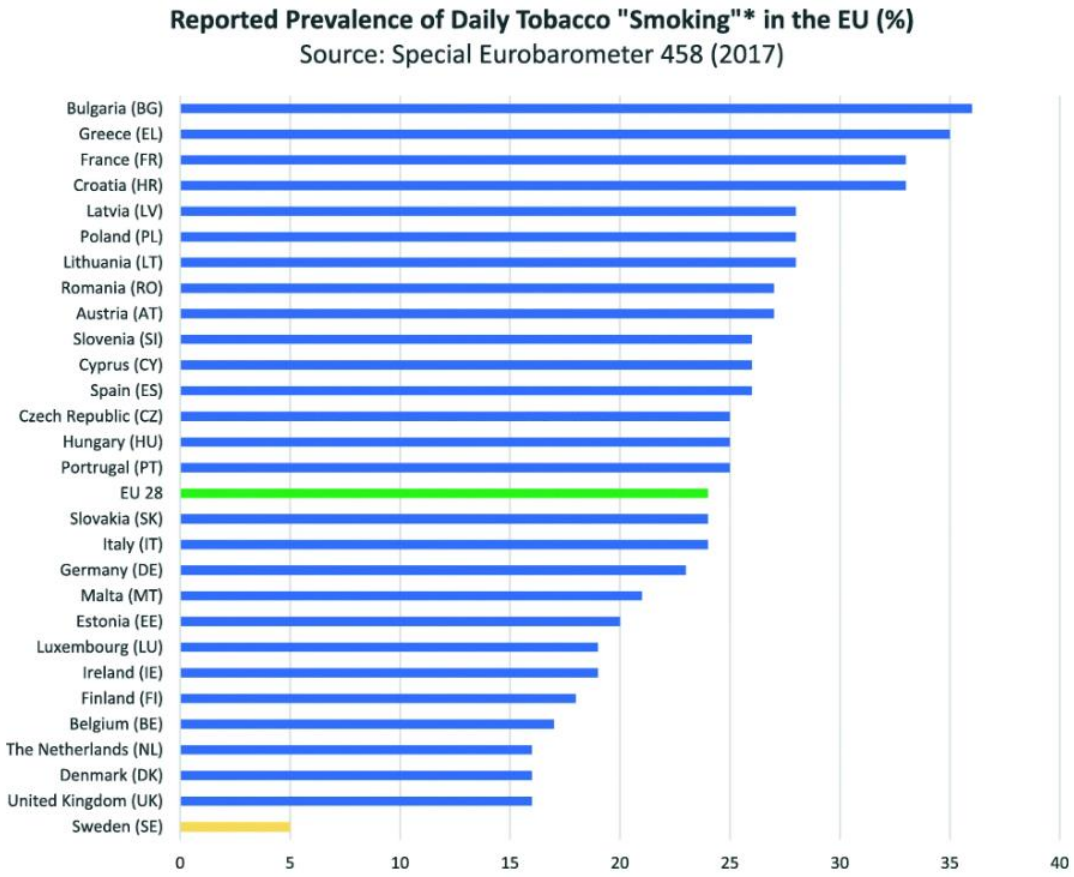
[28] Walker *et al*., (2020) Use of e-cigarettes and smoked tobacco in youth aged 14-15 years in New Zealand: findings from repeated cross-sectional studies (2014-19).

[29] 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

[30] World Health Organisatioon (2019), 'WHO report on the global tobacco epidemic' available at: https://www.who.int/tobacco/surveillance/policy/country_profile/swe.pdf?ua=1

[31] Ramström L., (2016) *Patterns of Smoking and Snus Use in Sweden: Implications for Public Health* Int. J. Environ. Res. Public Health 2016, 13(11), 1110

2017, Eurobarometer[32] published data collected from national surveys showing that Swedish respondents reported the lowest rate of daily smoking by a considerable margin (5%) compared with the EU wide daily smoking prevalence of 24%. The figure below was prepared by Clark et al[33] (in a study funded by tobacco product manufacturers) using data from the Eurobarometer report.



3. The established evidence on the effectiveness of e-cigarettes as a smoking cessation treatment

BAT does not market e-cigarettes as cessation products, but as potentially reduced risk alternatives to combustible tobacco.

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[32] The European Commission. Special Eurobarometer 458. Attitudes of Europeans towards tobacco and electronic cigarettes. 2017. http://ec.europa.eu/commfrontoffice/publicopinion/index.cfm/Survey/getSurveyDetail/instruments/SPECIAL/surveyKy/2146. [Accessed 29 July 2020].

[33] Clarke et al "Snus: a compelling harm reduction alternative to cigarettes", *Harm Reduction Journal*, 16(2), (2019).

4. The established evidence on the uptake of e-cigarettes amongst non-smokers and the potential gateway effect into traditional tobacco products

We acknowledge concerns regarding youth nicotine and tobacco use and we agree that nicotine and tobacco products should be restricted to adults only. However, the evidence does not support the claim that the use of e-cigarettes causes widespread established nicotine use among non-smokers (including youth).

A 2019 factsheet by UK 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 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*."[34]

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*."[35]

As noted above, Public Health England's most recent 2020 evidence update[36] also 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).

Claims that there is an 'epidemic' of youth vaping in the US have also been shown to be unsubstantiated. For example, 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 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*

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[34] 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

[35] 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

[36] 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.

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." [37]

West et al (2019)[38] also analysed the US National Youth Tobacco Survey (NYTS) 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). The 2020 US NYTS data also shows 1.8 million fewer U.S. youth are currently using e-cigarettes compared to 2019.[39]

The New Zealand Ministry of Health's position statement on vaping states that, '"There is no international evidence that e-cigarettes are undermining the long-term decline in cigarette smoking among adults and youth, and may in fact be contributing to it."[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.[41]

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.

Similarly, there is no reliable data that supports the proposition that snus has a "gateway effect" that leads to increased uptake of cigarette smoking. The European Union Scientific Committee on Emerging and Newly Identified Health Risks concluded, in its opinion on 6 February 2008 that "[t]*he Swedish data, with its prospective and long-term follow-up do not lend much support to the theory that smokeless tobacco (i.e. Swedish snus) is a gateway to future smoking*."[42]

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[37] Rodu (2019) The 2018 American Teen Vaping Epidemic, Recalculated

[38] 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.

[39] Centres for Disease Control and Prevention (2020), 'Youth e-cigarette use is down, but 3.6 million still use e-cigarettes' available at: https://www.cdc.gov/media/releases/2020/p0909-youth-e-cigarette-use-down.html.

[40] https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/vaping-smokefree-environments-and-regulated-products/position-statement-vaping

[41] 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.

[42] Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) Opinion on: Health Effects of Smokeless Tobacco Products. Available at https://ec.europa.eu/health/node/42468_en

5. Evidence of the impact of legalising nicotine vaping products on youth smoking and vaping rates and measures that Australia could adopt to minimise youth smoking and vaping

There are several regulatory options that are properly targeted to reducing youth access, while still allowing e-cigarettes (along with other potentially reduced risk alternative products to cigarettes) to be available to adult consumers. These include:

- Implementing strong age verification requirements for in store and online sales. To minimise under 18s vaping and smoking not only must there be strong rules, but enforcement of age verification needs to increase to discourage youth smoking and vaping.
- Implementing quality standards, including with respect to flavours. Our view is that all ingredients should be subject to a thorough toxicological risk assessment and we support the ban of ingredients that are shown by sound scientific evidence to increase the toxicological effects of the products;
- implementing targeted youth education programmes aimed at preventing young people from taking up smoking;
- Requiring the responsible marketing of products (including the description and marketing of flavours) that is only directed at adults, both in terms of the content of such communications and by virtue of media placement. This would protect against advertising directed at youth while also ensuring that adult smokers can make fully informed choices and allowing e-cigarettes to be a visible, available and accessible alternative for adult smokers.

We also propose that strong product quality standards covering e-liquid labelling and packaging adopted to support appropriate use of these products. The standards should include requirements for product labelling, packaging and usage instructions on e-liquids encompassing: -

- child resistant packaging,
- tamper evident packaging,
- consumer labelling statements/warning statements, and
- requirements for over 18 usage only labelling.

6. Access to e-cigarette products under Australia's current regulatory frameworks

The present regulatory framework in Australia makes it illegal to sell e-cigarettes that contain nicotine; however, the sale of non-nicotine e-cigarettes is legal[43].

Despite the lack of legal sale of nicotine containing e-liquids, significant numbers of smokers in Australia are switching to e-cigarettes. According to the Australia Tobacco Harm Reduction Association (ATHRA), there were over 520,000 vapers in Australia in 2019[44].

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[43] Australian Government Australian Institute of Health and Welfare (2019) 'National Drug Strategy Household Survey 2019' available at: https://www.aihw.gov.au/getmedia/7ebfd47a-9063-4ae0-b22f-1aeff56a30dc/aihw-phe-270-Chapter2-Tobacco.pdf.aspx

[44] Australian Tobacco Harm Reduction Association (2020) 'Over 500,000 vapers in Australia now, according to Government study' available at: https://www.athra.org.au/blog/2020/07/22/over-500000-vapers-in-australia-now-according-to-government-study/?_sm_nck=1

According to Legalise Vaping's August 2020 survey (n=6,733) less than seven per cent of vapers get their nicotine from a GP[45].

According to the survey, if products were legal and regulated in Australia, 60 per cent of respondents would access their nicotine containing vape products and refills both online and in-person[46]. This underscores the need for both physical stores and e-commerce sites to be made available in any regulated approach to legalising vaping.

In regards to the system of requiring a doctor's prescription to purchase e-cigarettes or refills , University of NSW Associate Professor Dr Colin Mendelsohn said that 'in fact it is not a workable solution, the way that this is set up now is that there is a, onerous, convoluted process by which Doctors can write the prescriptions which require Doctors to get approval to get importation permits, to import the nicotine, pay for it and sell it to patients. It's just crazy and it won't happen. Doctor's won't do it'[47]

It is clear that the current approach for nicotine products in Australia is not fit for purpose. Australian smokers are acting outside regulation to access e-cigarettes, which many globally recognised public health bodies believe offer significant health benefits compared to smoking tobacco. A practical and regulated solution that allows Australian smokers ready access to nicotine containing e-liquids (along with other potentially reduced risk alternative products to cigarettes) without the need for a prescription, is urgently required.

7. Tobacco industry involvement in the selling and marketing of e-cigarettes

British American Tobacco (BAT) is the manufacturer of various forms of e-cigarettes around the world. Our e-cigarette products include Vuse, formerly Vype.

BAT has invested over $4 billion into the development, manufacture and commercialisation of our e-cigarette products since 2013.

These products have the consumer appeal capable of providing smokers who wish to continue using nicotine with a potentially reduced risk alternative to cigarettes. They can provide many of the enjoyable aspects of smoking with the potential for smokers to reduce their risk if they completely substitute e-cigarettes for cigarettes. As such they have the potential to make a significant contribution towards tobacco harm reduction and improving the health for individual smokers and improving public health at a population level.

BAT complies with the relevant local laws wherever we market e-cigarettes.

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[45] Legalise Vaping (2020), 'Vaping Legalisation Survey' available at: https://drive.google.com/file/d/1gh6oKXipvF5_bZY7Ddkp4YirekujUYGN/view

[46] Ibid.

[47] 2GB (2020) 'Ban on importing e-cigarettes a 'death sentence' for vapers' https://www.2gb.com/ban-on-importing-e-cigarettes-a-death-sentence-for-vapers/?fbclid=IwAR0JfSYeF9EJdI1-mTCXAKMgcDzVQszEDSo900ry3poLeJbDcOD1h6NQ26E

Vuse is currently being sold in various markets around the world and recently started being sold in New Zealand with strong sale controls, including age verification processes.