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5 November 2020

Department of the Senate
PO Box 6100
Parliament House
Canberra ACT 2600
tobaccoharmreduction.sen@aph.gov.au

RE: SELECT COMMITTEE ON TOBACCO HARM REDUCTION

INTRODUCTION

Imperial Brands Australasia (Imperial) welcomes the opportunity to participate in the Select Committee on Tobacco Harm Reduction. Imperial participates in a range of government consultations that are relevant to our business. We do this on the basis that our views will be considered in an objective manner and that the evidence and views we provide will be properly evaluated, with due regard given to relevant legal and legislative requirements and the principles of best practice regulation.

We would like to re-affirm that we recognise the role of Governments and Public Health Authorities in the regulation of tobacco and non-tobacco nicotine products and support those measures that are reasonable, proportionate and evidence based. Of paramount importance to us, is that our products are sold only to adult smokers and adult nicotine users who exercise free choice to use them. We support strong regulation to prohibit supply to or use of nicotine products by those underage.

We would be pleased to discuss any aspects of this submission with the Committee in more detail.

BACKGROUND

Imperial is an Australian-based wholly owned subsidiary of Imperial Brands PLC, an international fast-moving consumer goods company specialising in tobacco and non-tobacco brands. Imperial entered the Australian market in September 1999 at the request of the ACCC to ensure that competition was maintained following the global merger between British American Tobacco ("BAT") and Rothmans International.

We are a company with a strong heritage. At Imperial we understand society's concerns about the health risks of smoking and as a result, we are increasingly focusing our attention on our portfolio of nicotine alternatives.



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In late 2019, Imperial Tobacco Australia adopted the trading name Imperial Brands Australasia to better reflect a change in global focus from a traditional tobacco business to a more diverse brands business which includes the developing Next Generation Product (NGP) sector.

THE HARM REDUCTION APPROACH TO TOBACCO CONTROL

Reducing the health impacts of tobacco requires Governments, regulators and public health bodies to play a positive role, which includes a legislative framework that allows for a NGP category to develop, providing consumers the confidence to trial, and ultimately transition, to these less harmful products.

A public health approach that assumes more intensive regulation will drive behavioural change is condemned to fail. Tobacco harm reduction is based on a well-established public health concept which recognises that adults choose to participate in risky behaviours and focuses on modifying, rather than eliminating, these behaviours. Cigarettes are a known cause of serious disease in smokers and many countries have stated aims for future generations to be smoke-free. Yet over a billion adults around the world still choose to smoke and will continue to do so well into the future. There are just under 3 million adult smokers in Australia today¹.

NGPs – particularly vapour products, which do not contain tobacco; are seen as representing a less harmful alternative to cigarettes, thereby creating a huge global public health opportunity.

The remainder of this submission will focus on addressing the committee's terms of reference;

a. 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;

Globally, leading authorities are increasingly applying harm reduction thinking and strategies to their public health objectives. Australia has a strong track record on tobacco control but has unfortunately fallen behind in recent times. The UK, New Zealand, the US and many European countries have legalised and regulated nicotine containing e-cigarettes to allow adult consumers access to smoking alternatives. Australia has become increasingly at odds with the international general consensus on the potential of vaping products as a harm reduction tool. Today, Australia is one of only two OECD countries, the other being Turkey, to maintain a ban on these products².

¹ Roy Morgan Single Source MAT Sept. 2020

² <https://www.vapingpost.com/2020/06/25/australian-mps-launch-petition-against-the-health-ministrys-nicotine-ban/>



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The regulatory mechanisms that apply to vaping products globally include the use of existing regulations, new policies, amendments to existing policies, laws, decrees and combinations of new and amended regulations³. The legislative and regulatory frameworks provide guidance on the; manufacturing and quality standards, consumer communication, youth access prevention, accessibility, sale, marketing and use of electronic cigarette products.

In the UK, for example, the UK Tobacco and Related Products Regulations 2016 (“regulations”) came into force implementing the EU Tobacco Directive (EUTPD). The Regulations apply to electronic cigarettes, e-liquids and refill containers which can be used for the consumption of nicotine containing vapour. The UK Tobacco and Related Products Regulations implemented the EUTPD in the UK in full and came into force on 20 May 2016. They set out new requirements and administrative provisions on the manufacture, presentation and sale of tobacco and related products, including e-cigarettes. Article 20 of the EUTPD introduces new regulatory controls for nicotine containing electronic cigarettes and refill containers. The EUTPD does not cover nicotine-containing products that are authorised as medicines⁴. The requirements for vaping products cover product standards and nicotine strength, safety, labelling and packaging, notification and vigilance, advertising and annual reporting.

From a harm-reduction perspective, the EUTPD is not an ideal regulatory blueprint, since many of its provisions simply apply existing tobacco regulations to EVPs, thus conflating the product categories and undermining EVPs’ tobacco harm reduction potential.

In 2018, the Tobacco and Vaping Products Act (TVPA) became law in Canada. While continuing to govern tobacco products as was the case under the Tobacco Act which it replaced, the TVPA also applies to vaping products. Health Canada advises that the Act ‘*aims to protect Canadians from nicotine addiction and from inducements to use tobacco and, in particular for youth, from vaping products use.*’⁵ Key elements of the TVPA include directions on; Youth access prevention, manufacturing standards, product and package labelling and the promotion of vaping products.

Closer to home, the New Zealand Parliament passed *The Smokefree Environments and Regulated Products (Vaping) Amendment Bill*, which regulates vaping products and heated tobacco devices on August 5, 2020. Commenting on the legislation, Associate Health Minister Jenny Salesa said “*It ensures vaping products are still available to smokers who want to quit by switching to a less harmful alternative but also ensures they*

³ *Global Approaches to Regulating Electronic Cigarettes*, Kennedy RD et al, BMJ Journals Tobacco Control 2017

⁴ *The Regulation of E-Cigarettes*, briefing Paper, House of Commons Library 31 October 2017

⁵ <https://www.canada.ca/en/health-canada/services/smoking-tobacco/vaping/product-safety-regulation.html>



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cannot be sold or marketed to children... We know vaping is not without risks but it is 95 per cent less harmful than cigarette smoking.... Anything this Government can do to reduce the number of smokers and steer our kids towards a smokefree Aotearoa has got to be a good thing."

Regulations that give effect to *The Smokefree Environments and Regulated Products (Vaping) Amendment Bill* are yet to be finalised. Imperial is encouraged by the harm reduction approach of the New Zealand Government and support the Bill's intent to clarify and regulate the operating environment for NGP. There are however concerns that restrictions to the availability of flavours and the ability to communicate with adult consumers will ultimately counter the Bill's intent to support adult smokers' transition to less harmful alternatives. Effective regulation should support vaping products being made more attractive to adults to support them to transition to less harmful products. Practically, that requires; providing alternatives to consumers, enabling consumers to access those alternatives and providing consumers with advice around the use of alternatives.

Regulation continues to evolve for NGPs and there is a diverse set of views amongst governments in how best to legislate various product categories. We are in favour of regulation for all NGP. We support effective regulation that encourages NGP uptake by adult smokers and limits the ability of minors to access nicotine products. As EVPs and the vape category grow significantly in popularity the policy climate for vaping products is evolving rapidly. The vaping sector has gone from little/no regulation to a highly restrictive and burdensome regime in the EU particularly, following the introduction of the EUTPD which has created advertising bans, product restrictions and a slowdown in product innovation.

Effective regulation of EVPs should strike a balance. Government measures should not be so excessive that adult smokers find it too difficult to transition. Adult smokers will be discouraged if EVPs are more expensive, less appealing, or more difficult to buy and use. The way to strike this balance is to adopt 'risk-proportionate regulation' that imposes regulatory controls in proportion to the risk posed by the product—evidenced as tobacco harm reduction.

b. 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;



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// EFFECTIVE THR IN ACTION

Smoking rates are declining at an accelerated rate in countries where THR and NGPs are:

◆ Supported by public health experts, regulators and policymakers.

◆ Assisted by pragmatic, risk proportionate regulation which encourages innovation and high product standards.

◆ Marketed responsibly and widely available to adult smokers.



2. Public Health England (2018) Turning the Tide on Tobacco: Smoking in England Hits a New Low.
3. Office for National Statistics (2020) Adult Smoking Habits in Great Britain.
4. Clarke, E. et al. (2019) Snus: a compelling harm reduction alternative to cigarettes. Harm Reduction Journal 16, 62.
5. The European Commission (2017) Special Eurobarometer 458: Attitudes of Europeans towards tobacco and electronic cigarettes.
6. Cummings, M. et al. (2020) What is Accounting for the Rapid Decline in Cigarette Sales in Japan? Environmental Research and Public Health 17(10), 3750.



Australia has some of the most stringent plain packaging, display bans, point of sale restrictions and the highest cigarette prices in the world; what are widely considered to be the strictest tobacco controls in place globally. Nonetheless, the latest figures show that Australia is falling behind the rest of the world when it comes to reducing smoking incidence.

From 2013 to 2016 Australia experienced a statistically insignificant decline in smoking incidence of 0.6%⁶. Between 2016 and 2019 daily tobacco smoking declined 1.2%⁷. This is particularly concerning when viewed against the accelerated declines in many contemporary countries in Europe, the UK and the US where

⁶The Department of Health, national Drug Strategy Household Survey 2016 Key findings

⁷ Australian Institute of Health and Welfare, Alcohol Tobacco and Other Drugs in Australia, key findings
<https://www.aihw.gov.au/reports/alcohol/alcohol-tobacco-other-drugs-australia/contents/drug-types/tobacco>



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smoking rates have declined by between 3%-12% over the comparable period⁸. There is growing consensus that the successful experiences of these countries can be attributed to their harm reduction approach to tobacco control (in contrast to that taken in Australia). For example, the smoking rate in Norway fell by half from 22% to 11% between 2007-2017 supported by the widespread uptake of Swedish snus, a lower-risk, moist oral tobacco product, which is banned in Australia⁹. From 2013 to 2016 the UK witnessed a 3.2% decline in smoking rates¹⁰ coinciding with the introduction and growth of vaping products.

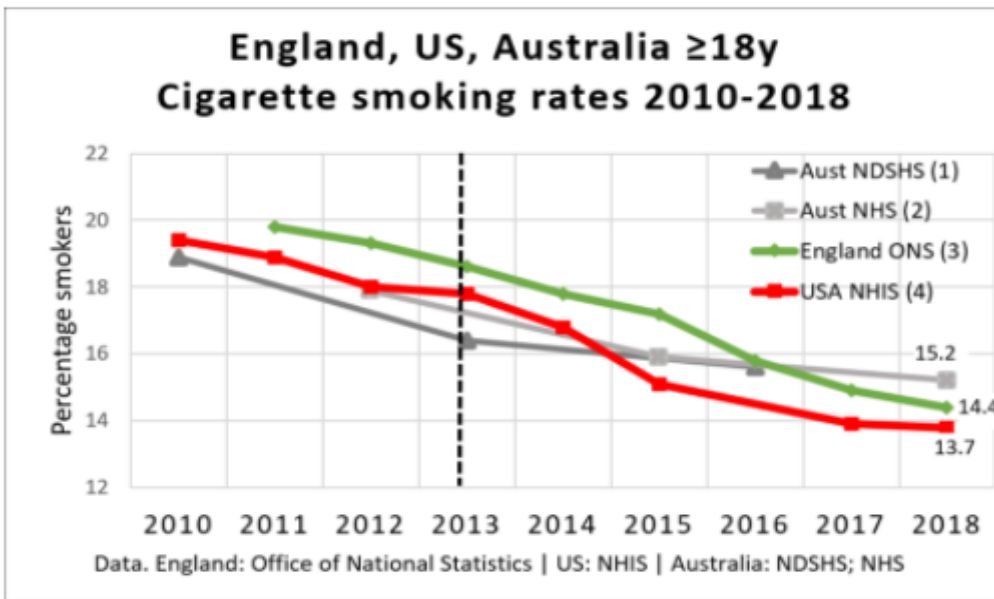


Chart source: Australian Tobacco Harm Reduction Australia

The chart above highlights the accelerated decline in smoking rates since the introduction of EVP around 2013 in the US and the UK charted against the stagnated decline experienced in Australia.

Leading international public health bodies have drawn attention to the correlation between access to vaping products and a reduction in the smoking incidence. In 2018, Public Health England published an independent expert evidence review that included in the main findings that; “*e-cigarette use is associated with improved*

⁸ Source: Australian Tobacco Harm Reduction Association, <https://au.news.yahoo.com/australia-highest-priced-cigarettes-world-arent-people-quitting-012023457.html>

⁹ <https://www.reuters.com/article/us-norway-smoking/snus-tobacco-on-the-rise-as-norway-smoking-halved-in-a-decade-idUSKBN1F70R1>

¹⁰ Office for National Statistics, <https://www.ons.gov.uk/>



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quit success rates over the last year and an accelerated drop in smoking rates across the country” and “e-cigarettes could be contributing to at least 20,000 successful new quits per year and possibly many more”¹¹.

A number of EU countries are also seeing great progress in terms of smokers using vaping to completely replace tobacco consumption. An EU-wide study in 2016 found that 6.1 million vapers in Europe had managed to quit combustible cigarettes completely, while another 9.2 million had reduced their smoking¹².

In the US there has also been a rapid decline in smoking coinciding with the rise of vaping. Adult smoking prevalence fell from 19.4% in 2010 to 15.1% in 2015¹³. A study published in the British Medical Journal examined whether the increase in use of EVPs in the USA, which became noticeable around 2010 and increased dramatically by 2014, was associated with a change in overall smoking cessation rate at the population level. The authors found the substantial increase in EVP use among US adult smokers was associated with a statistically significant increase in the smoking cessation rate at the population level¹⁴.

A study published in Tobacco Control entitled “Potential deaths averted in USA by replacing cigarettes with e-cigarettes” estimated that vaping could save the lives of up to 6.6 million U.S. smokers over a 10 year period and on the basis of this evidence, recommended that public health organizations adopt a strategy of encouraging smokers to switch to vaping¹⁵.

The evidence to date indicates that the risks are much lower than continued cigarette smoking. Estimations of long-term public health impact of vaping have indicated significant reductions in smoking-attributable deaths¹⁶, even when conservative assumptions were made for the relative health risk versus conventional cigarettes and for transitions between smoking, vaping and non-use¹⁷.

¹¹ <https://www.gov.uk/government/news/phe-publishes-independent-expert-e-cigarettes-evidence-review>

¹² Farsalinos, K. E et al: “Electronic cigarette use in the European Union”, Addiction, 2016

¹³ National Center for Health Statistics, National Health Interview Survey (<https://www.cdc.gov/nchs/nhis/releases.htm>), Sample Adult Core component. Figure 8.1. Prevalence of current cigarette smoking among adults aged 18 and over: United States, 1997–2016.

¹⁴ Zhu, S.-H., Y.-L. Zhuang, S. Wong, S. E. Cummins and G. J. Tedeschi (2017). “E-cigarette use and associated changes in population smoking cessation: evidence from US current population surveys.” BMJ 358

¹⁵ Levy, D. T., R. Borland, E. N. Lindblom, M. L. Goniewicz, R. Meza, T. R. Holford, Z. Yuan, Y. Luo, R. J. O’Connor, R. Niaura and D. B. Abrams (2017). Potential deaths averted in USA by replacing cigarettes with e-cigarettes. Tobacco Control.

¹⁶ Hill, A. and O. M. Camacho (2017). “A system dynamics modelling approach to assess the impact of launching a new nicotine product on population health outcomes.” Regul Toxicol Pharmacol 86: 265-278.

¹⁷ Levy, D. T., R. Borland, A. C. Villanti, R. Niaura, Z. Yuan, Y. Zhang, R. Meza, T. R. Holford, G. T. Fong, K. M. Cummings and D. B. Abrams (2017). “The Application of a Decision-Theoretic Model to Estimate the Public Health Impact of Vaporized Nicotine Product Initiation in the United States.” Nicotine & Tobacco Research 19(2): 149-159.



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Considering the growing consensus among public health specialists that vapour products can contribute greatly to tobacco harm reduction and therefore offer significant potential public health benefits, the sale and supply of nicotine e-cigarettes and liquids containing nicotine should be permitted.

c. the established evidence on the effectiveness of e-cigarettes as a smoking cessation treatment;

Many regulators and public health bodies across the world have independently concluded that vaping is significantly less harmful than smoking and has significant potential for reducing tobacco consumption. Current tobacco control strategies in most countries focus on supply and demand measures intended to prevent initiation, reduce consumption and encourage cessation of cigarettes. While these measures have resulted in a slow decline in smoking prevalence in many countries, they are highly unlikely to eliminate smoking altogether or help countries achieve their public health goals within stated timeframes.

Over the past three decades, the effectiveness of medically licensed Nicotine Replacement Therapy (NRT) products in facilitating adult smoker cessation has been limited. Many stakeholders, including public health organisations, healthcare professionals and regulators now recognise traditional NRTs are failing to encourage enough adult smokers to stop smoking quickly enough, and new tobacco harm reduction policies are required to complement existing prevention and cessation strategies.

A 2016 Cochrane Review concluded EVPs with nicotine can help people quit smoking with no increased health risks associated with short-to-medium term (two years) use¹⁸. Cochrane Reviews are systematic reviews of primary research in human health care and health policy, and are internationally recognised as the highest standard in evidence-based health care resources.

A recent study published in the New England Journal of Medicine concluded that “E-cigarettes were more effective for smoking cessation than nicotine replacement therapy”. The clinical trial involved nearly 900 participants and found that the 1-year abstinence rate was 18% for the e-cigarette group compared to 9.9% for the NRT group¹⁹.

In 2018, the UK Royal College of general Practitioners issued a position statement stating amongst other things that based on the evidence to date, vaping is a lot less harmful than smoking tobacco; the evidence so far that EVPs are a gateway to smoking is not convincing; the evidence on passive vaping is that it is not

¹⁸ http://www.cochrane.org/CD010216/TOBACCO_can-electronic-cigarettes-help-people-stop-smoking-and-are-they-safe-use-purpose

¹⁹ The New England Journal of Medicine, A Randomized Trial of E-cigarettes versus Nicotine-Replacement Therapy, February 14 2019



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harmful...and it is not something we should be overly concerned about; and the evidence to date suggests that EVPs are more effective than NRT over-the-counter or willpower alone²⁰.

The Government of Canada advises on its health page that “*some evidence suggests that using e-cigarettes is linked to improved rates of success*”²¹ while the New Zealand Ministry of health similarly informs that “*vaping products have the potential to make a contribution to the Smokefree 2025 goal and could disrupt the significant inequities that are present*”²². In France, the High Council on Public Health endorsed EVP as a cessation tool²³ in further evidence of the international acknowledgement of the harm reduction potential of e-cigarettes.

in February 2019 Public Health England (‘PHE’) published an update to their evidence review on vaping products. The report looked at the prevalence of vaping in the UK, particularly amongst young people and found that, amongst 11-18 year olds who also smoked, regular use (at least once a week) of e-cigarettes remained very low at 1.7%. Within its main findings were that the proportion of young ‘never smokers’ who use vape products at least weekly remains very low at 0.2% of 11-18 year olds with youth smoking rates at an all-time low. The UK now has Europe’s second-lowest smoking rate and declines in youth smoking are the largest on record.

The updated 2020 Cochrane review *Electronic Cigarettes for Smoking Cessation* published on 14 October 2020 evaluated the effect and safety of using EVPs to help people who smoke achieve long-term smoking abstinence.

Cochrane considered 50 studies in 12,430 adults who smoked and compared EVPs with nicotine replacement therapy, varenicline, nicotine-free EVPs, behavioural support or no support for stopping smoking. The studies took place in the USA, the UK, Italy, Australia, New Zealand, Greece, Belgium, Canada, Poland, South Korea, South Africa, Switzerland and Turkey. Cochrane found more people stop smoking for at least six months using nicotine EVPs than using nicotine replacement therapy or nicotine-free EVPs and nicotine EVPs may help more people to stop smoking than no support or behavioural support only. For every 100 people using nicotine EVPs to stop smoking, 10 might successfully stop, compared with only six of 100 people using NRT

²⁰ https://www.cancerresearchuk.org/sites/default/files/rcgp_e-cig_position_statement_approved_060917_clean_copy.pdf

²¹ <https://www.canada.ca/en/health-canada/services/smoking-tobacco/vaping/smokers.html>

²² <https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/vaping-smokefree-environments-and-regulated-products/position-statement-vaping>

²³ <http://www.hcsp.fr/explore.cgi/avisrapportsdomaine?clefr=541>



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or nicotine-free EVP, or four of 100 people having no support or behavioural support only²⁴. The review asserts that nicotine containing e-cigarettes;

- do help people to stop smoking (even amongst those who do not intend to quit smoking at the outset) and work better than NRT and nicotine-free e-cigarettes;
- are better for smoking cessation than no support, or behavioural support alone;
- and are not associated with serious unwanted effects or harm with up to 2 years product use.

Harm reduction without consumer appeal provides little in the way of public health benefits. Traditional nicotine replacement therapies - many of which have been available for decades - are simply not satisfying enough for adult smokers and have failed to encourage behavioural change on a global scale. Unsurprisingly, most countries are therefore struggling/failing to meet their smoking reduction targets. It is of critical importance that NGPs are accepted by adult smokers if they are to fulfil their role in tobacco harm reduction. If adult smokers cannot accept, and therefore do not adopt, next generation cigarette alternatives this precious opportunity will be lost.

d. the established evidence on the uptake of e-cigarettes amongst non- smokers and the potential gateway effect onto traditional tobacco products;

“E-cigarette use among never smokers in Great Britain remains very rare at less than 1%” –
Public Health England

“There is no international evidence that vaping products are undermining the long-term decline in cigarette smoking among adults and youth, and may in fact be contributing to it” –
New Zealand Ministry of Health.

Some regulators have expressed fears that electronic vapour products could act as a ‘gateway’ to tobacco use among non-smokers, or that vaping could ‘renormalise’ the act of smoking. These fears are not justified, primarily because the statistics to date do not support the view that non-smokers are regularly vaping, and secondly, because most available data shows the opposite is occurring and EVPs are acting as a gateway away from tobacco, accelerating declines in smoking rates.

²⁴ <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub4/full>



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Action on Smoking and Health (ASH), an organization that has been conducting year-on-year research in the UK since 2012, found, in May 2017, that less than 0.3% of vapers are people who have never smoked²⁵. This figure is comparable to the use of NRT products by UK nonsmokers. A recent analysis of EVP uptake amongst UK youth from various separate studies revealed that, although there is some experimentation amongst never-smokers, there is no evidence that this group of young people regularly use EVPs; regular use is almost entirely concentrated in young people who already smoke²⁶.

The 2018 annual ASH survey found that an estimated 3.2 million adults in Great Britain currently vape and that there were now more ex-smokers (1.7 million) who use EVPs than current smokers (1.4 million). This means that over half of e-cigarette users are ex-smokers with another 44% being current tobacco smokers. Only 0.5% of never smokers report being a current EVP user²⁷.

Scotland introduced new rules for the purchase and supply of vapour products in April 2017 following consultations on potential measures. At the time NHS Scotland stated that there was “agreement based on the current evidence that vaping e-cigarettes is definitely less harmful than smoking tobacco”²⁸. The 2018 Scotland Tobacco Control Plan acknowledged that the use of e-vapour products had settled at around 7%, in both 2015 and 2016 and “the vast majority of vapers are former smokers (37%) or current smokers/dual users (60%), very few start the habit without smoking cigarettes first (3%)”²⁹.

We recognise significant public health benefits can only be fully achieved at a population level when many adult smokers transition from cigarettes to less harmful NGPs, while significant numbers of non-smokers and youth do not begin using these products. That’s why we’re clear only adult smokers and current adult NGP users should use our products, and why the notion of consumer acceptance needs to include elements addressing unintended use. NGPs should be targeted at - and only used by - adult smokers who would otherwise continue to smoke. The unintended use groups are, simply, everyone else.

e. 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;

²⁵ <http://ash.org.uk/download/use-of-e-cigarettes-among-adults-in-great-britain-2017/>

²⁶ Bauld, L et al: “E-Cigarette Uptake Amongst UK Youth: Experimentation, but Little or No Regular Use in Nonsmokers”, Nicotine & Tobacco Research, 2016

²⁷ <https://bit.ly/2p5V3sr>

²⁸ <https://www.ukvia.co.uk/nhs-scotland-backs-vaping-for-smoking-cessation/>

²⁹ <http://www.gov.scot/Resource/0053/00537031.pdf>



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The use of e-vapour products is largely concentrated among adult smokers, most of whom report using e-vapour for the purpose of smoking reduction or to quit smoking. While teens who engage in 'risky behaviours' - meaning they experiment with different substances - are more likely to experiment with both tobacco and EVPs, it's worth noting that this experimentation is being accompanied by continuing, even accelerating, declines in youth smoking. In the USA, for example, youth smoking has steadily declined since the late 1990s. The Monitoring the Future (MTF) survey shows that smoking peaked at 28.3% in 1996 and fell to 5.9% by 2016. In fact, since 2011 when EVP use began to rapidly rise in the USA, there has been a particularly marked decline in teen cigarette smoking, from 11.7% to 5.9%³⁰.

The UK Royal College of General Practitioners released a position statement in 2018 which asserted that the evidence so far that e-cigarettes are a gateway to smoking were not convincing and that youth smoking rates in the UK continue to decline³¹.

The World Health Organisation acknowledges "renormalization as measured by smoking prevalence of smoking is not occurring currently"³² and Public Health England found "no evidence so far that e-cigarettes are acting as a route into smoking for young people."

In the UK, youth use of e-cigarettes is monitored regularly by Government and public health organisations. In general, uptake is largely experimental, with regular use confined largely to those who currently or previously smoked, with only 0.8% of young people aged 11-18 who have never smoked using e-cigarettes more than once or twice .

The Canadian Tobacco, Alcohol and Drugs Survey 2017 showed that although a substantial number of Canadian youth have tried an e-vapour product (i.e. ever-use), regular daily use remains rare³³. Another recent Canadian research paper on Canadian youth and e-cigarette use concluded; only 0.2% of all youth — and 2% of those who had tried e-vapour — reported daily use³⁴.

³⁰ Johnson, L et al (2016) Monitoring the Future: National Survey Results on Drug Use, 1975-2016: 2016 Overview, <http://www.monitoringthefuture.org/pubs/monographs/mtf-overview2016.pdf>

³¹ <https://athra.org.au/uk-royal-college-of-general-practitioners-advises-gps-to-recommend-vaping/>

³² http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10Rev1-en.pdf

³³ Canadian Tobacco, Alcohol and Drugs Survey (CTADS) 2017. <https://www.canada.ca/en/health-canada/services/canadian-tobacco-alcohol-drugs-survey/2017-summary.html>.

³⁴ Khoury M, Manlhiot C, Fan CPS, et al. Reported electronic cigarette use among adolescents in the Niagara region of Ontario. CMAJ 2016; 188:794-800.



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Evidence suggests that vaping products are actively contributing to declining smoking rates as increasing numbers of smokers move away from tobacco. The research does not support the 'gateway' theory and in fact points to the opposite trend; that EVPs are acting as a 'roadblock' to combustible tobacco products.

Imperial would like to reiterate our firm belief that vapour products are for adult smokers and current vapour users only –we fully support the prohibition of sales (and proxy sales) to minors and heavy sanctions for violations.

At Imperial we have an important role to play in assuring that minors do not have access to vapour products. In international markets, Imperial Brands' has one of the best-selling e-cigarette products, blu®. blu® is, and always has been, marketed as an adult brand. We are clear and passionate about our commitment to youth access prevention as set out in our E-Vapour Products Marketing Standard:

- i) we shall not market our vapour products to minors; and
- ii) we will not market or design liquids in flavours that will appeal primarily to youth.

We design all flavour marketing in ways intended to appeal to adult smokers. We are unequivocal about the need for manufacturers to act responsibly regarding product marketing and promotion of flavours. We do not use any names, descriptors, packaging or labelling intended to target minors and at the same time make clear that the product is designed for adult smokers only.

Imperial has designed a robust and proactive set of programs aimed at preventing the underage use of and access to blu® products. Our commitment to youth access prevention is exemplified in our Youth Access Prevention Policy.

We would strongly support regulation which requires that:

- Advertising – should not appear in or on channels that are intended for minors
- Online sales – should only be permitted on registered websites with advanced age verification technology
- Naming conventions – restrictions to prevent the use of names that may appeal to minors
- Child-resistant measures – devices and liquids should be sold in tamper evident and child resistant packaging

f. access to e-cigarette products under Australia's current regulatory frameworks;



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Nicotine for human consumption is listed in the SUSMP (The Poisons Standard) as a prescription-only medicine in the schedule 4 (S4) classification, except when used as an aid in the withdrawal from tobacco smoking in preparations intended for oromucosal or transdermal use (e.g. nicotine patches, gum or mouth sprays). In the schedule 7 (S7) classification, nicotine is listed as a poison, except in preparations for human therapeutic use or in tobacco prepared and packed for smoking.

Nicotine used for e-cigarettes will fall within S7 classification if it is not treated as a therapeutic good. It is not an offence to import nicotine e-liquid into Australia. However, it is an offence to take possession of imported nicotine without a prescription or if other requirements of the TGA Personal Importation Scheme are not met. In all Australian states and territories, it is an offence to manufacture, sell or supply nicotine as an S7 poison without a licence or specific authorisation. This means e-cigarettes containing nicotine cannot be sold in any Australian state or territory.

In practical terms, an Australian adult smoker who is looking to quit smoking, is required to find a registered Australian medical practitioner willing and able to provide a prescription for nicotine liquid. The consumer is then legally allowed to import nicotine containing liquids for personal use. In this manner, the nicotine is classified as a Schedule 4 product (prescription only) and it is permissible to possess or use it for personal use.

Anecdotally, many of the hundreds of thousands of Australian e-cigarette users import liquid nicotine from overseas retailers without possession of a prescription. It is likely that this is to avoid the complicated process involved with the compliance to current regulations. Estimates indicate that no more than 1-2% of vapers have a prescription and there are less than a dozen GPs in Australia who are willing write nicotine prescriptions³⁵.

We are discouraged by recent moves from the Department of health to ban the import of nicotine containing EVPs and believe the widespread backlash, including from some members of the Federal Health Minister's own backbench, is evidence of the broad support for the legalisation and regulation of EVP in Australia. The implementation of the ban was delayed by six months to January 1, 2021 following broad and vocal opposition to the proposal.

There are also clear indications of a domestic nicotine black market emerging. For example, ABC News has previously reported that NSW health inspectors visited 227 retailers selling e-liquids from November 2015 to April 2018 and found that over 40 per cent of these retailers were selling products that contained nicotine³⁶.

³⁵ <https://www.athra.org.au/blog/2020/09/18/why-greg-hunts-plan-to-ban-nicotine-imports-and-medicalise-vaping-will-not-work/>

³⁶ Flint Duxfield, 'NSW Health Department finds not all e-juices are as nicotine free as they claim', *ABC News* (online, 12 June 2018)



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That same article also reported that vape users 'agree it is possible to buy nicotine from retailers if you know who to ask' and quoted one vaper as having experienced shops who sold nicotine 'under the table'.

Another ABC News article quoted one tobacco control expert as saying 'it was an "open secret" that you could buy e-liquid containing nicotine' and that he had been told 'there's a fair amount of amateur, backyard lab production of e-juices which are being sold'³⁷. The *Daily Telegraph* has also previously reported that liquid nicotine products 'remain widespread in Victoria due to under-the-counter sales and products purchased over the internet'³⁸.

The nicotine black market wholly disregards fundamental safety matters surrounding the use of nicotine including its toxicity, potential for abuse, appropriate and lawful dosage, formulation, labelling, packaging and presentation. Indeed, it may be anticipated that the nicotine black market would operate much like the illicit tobacco black market in that it may be more easily accessible for underage users, bypass health information on packaging, and present nicotine products with vastly more dangerous health risks than those manufactured by reputable regulated industries.³⁹

The reality is that many people import nicotine into Australia to use in e-cigarettes for at least two reasons:

- they know that use is significantly less harmful to their health than using combustible tobacco products; and/or
- nicotine e-cigarettes are more appealing than the nicotine replacement products registered on the Australian Register of Therapeutic Goods.

The Therapeutic Goods Administration has provided a notice and invitation to comment on an interim decision to amend the current Poisons Standard in relation to nicotine (Dated 23 September 2020). This consultation is not related to the proposed prohibition on importing e-cigarettes containing vaporiser nicotine which is the subject of a completely separate process. The amendments proposed do not meaningfully change the scheduling of nicotine, and we believe do not represent the positive role required from governments, regulators and public health bodies giving adult smokers the confidence to trial, and ultimately transition to less harmful NGPs.

g. tobacco industry involvement in the selling and marketing of e-cigarettes; and

³⁷ Olivia Willis, 'Nicotine found in 'nicotine-free' e-cigarette liquids sold in Australia, study finds, *ABC News* (online, 14 January 2019) <<https://www.abc.net.au/news/health/2019-01-14/nicotine-found-in-nicotine-free-e-cigarette-liquids/10709786>>.

³⁸ Grant McArthur, 'Retailers still pushing banned liquid nicotine products', *The Daily Telegraph* (online, 10 March 2020).

³⁹ Black Economy Taskforce (Final Report, October 2017) 305.



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Imperial Brands Australasia does not market or sell any e-cigarette or other next generation products in Australia. We believe NGPs are more likely to succeed at transitioning adult smokers if they aren't perceived to be medical treatments for smoking, unlike NRTs. Our broad portfolio of NGPs enables the transition to be successful through offering consumer choice.

We have continually evolved to embrace changing market dynamics and develop new consumer experiences. We are currently witnessing the biggest consumer shift in our history, with millions of smokers around the world choosing to switch to less harmful Next Generation Products. As a result, we are increasingly focusing our attention on developing and expanding our NGP portfolio. We want to reduce the health impact of tobacco by encouraging smokers to switch to products with lower health risks.

We understand society's concerns about the health risks of smoking and recognise that we have an important role to play in reducing the harm caused by cigarettes. Since establishing our first research and development (R&D) laboratory in the early 1950s, we have invested substantial sums in tobacco research and will continue to do so in the future. We uphold high standards, rigorously testing and analysing our products to ensure we continually build our knowledge and are able to meet our standards of care for consumers. In recent years we have increasingly focused our innovation and R&D work on Next Generation Products, while further enhancing our capabilities with value creating acquisitions. Innovation remains important in the NGP space alongside continued investment in trusted brands, best-in-class manufacturing, the highest quality standards and rigorous scientific research.

In 2019 Imperial Brands was among the European Patent Office's (EPO) top 100 applicants. We are excited with our work on next-generation batteries and charging; heated tobacco innovations; next generation heating; oral nicotine delivery platforms; and sustainable materials and packaging. It's an ongoing process but we are confident our investment in R&D will help us validate NGPs with regulators, and importantly offer more adult smokers more satisfying choices to combustible tobacco.

Our blu®, brand is one of the best-selling in the world with strong established positions in the USA and UK, the world's two largest vape markets, and available in an increasing number of international markets. We offer consumers exceptional nicotine and nicotine-free vaping experiences.

h. any other related matter.

Tobacco harm reduction represents one of the most promising global public health policies available, with the potential to save many lives if fully embraced. The concept of tobacco harm reduction is simple and



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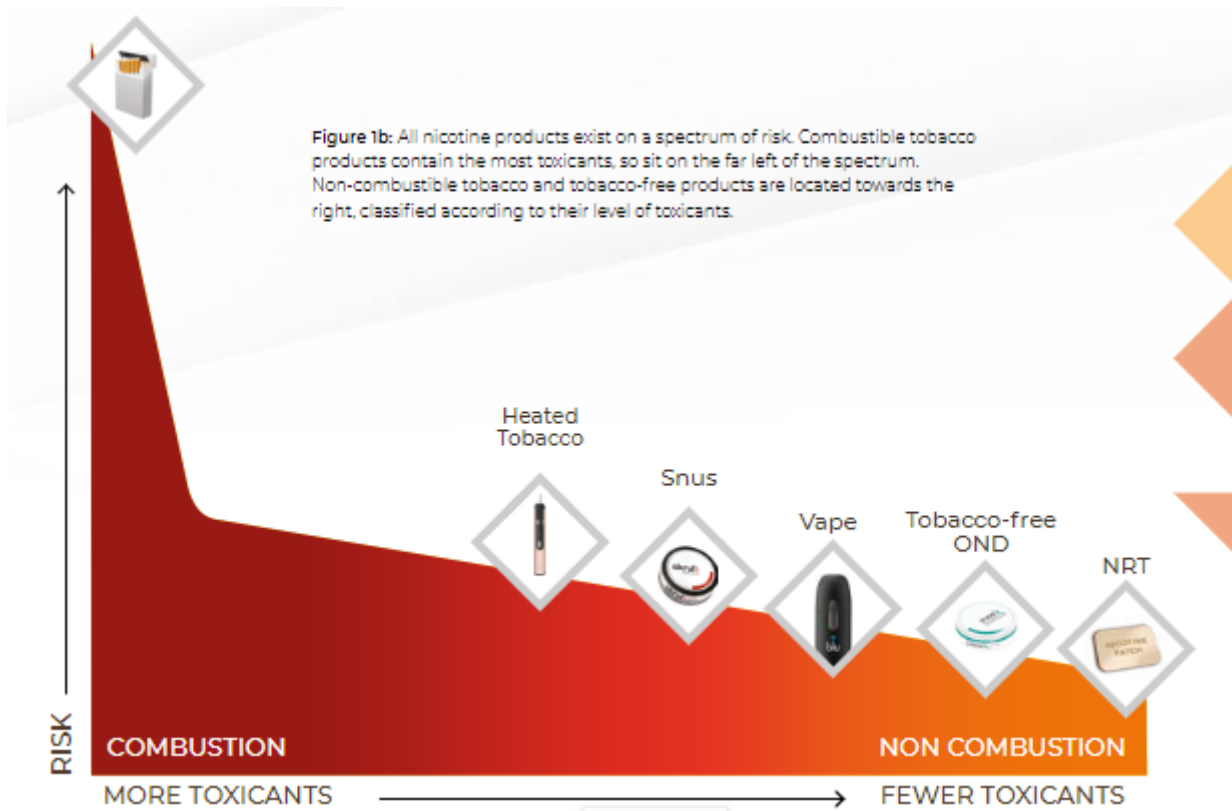
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compelling: to encourage adult smokers who would otherwise continue to smoke to transition to less harmful products that deliver nicotine, but with fewer and substantially lower levels of toxicants associated with burning tobacco.

Public health experts worldwide have concluded it is the toxicants in cigarette smoke, not the nicotine, which is the cause of smoking-related diseases. Today, driven by the availability of new and emerging technologies, we're able to de-couple nicotine from burning tobacco and revolutionise how nicotine is enjoyed by adult smokers. Our responsibility as a multi-category NGP industry leader is to create better experiences and maximum choice for adult smokers who would otherwise continue to smoke.

Complete cessation of all tobacco and nicotine use is undoubtedly the best action adult smokers can take to improve their health. However, many public health bodies and scientific organisations are clear: encouraging and assisting smokers who aren't interested or willing to quit smoking to transition to potentially harm reduced NGP alternatives is the next best option.

Aligned with tobacco harm reduction, our goal is to offer adult smokers who would otherwise continue to smoke the widest possible opportunity to choose a product - or range of products -less harmful for their health. From a tobacco harm reduction perspective, the least harmful products are likely to be those where nicotine (without tobacco) is delivered with no harmful or potentially harmful constituents via a route that doesn't involve inhalation. Technology now allows nicotine to be delivered through products along a spectrum of risk, with cigarettes at one end and medically licensed NRT products at the other.



Imperial Brands is developing and commercialising a range of nicotine-containing NGPs which replicate many, or all, of the sensorial, pharmacological and behavioural elements of the smoking/tobacco experience. Aside from technologically advanced devices, other forms of NGP - specifically oral nicotine delivery - demonstrate significant harm reduction potential.

Oral Nicotine Delivery (OND) is an umbrella term for a number of different oral products, including Snus. Snus is a smokeless, moist sachet placed between the gum and the lip. Snus originated in Sweden where it has been used since the 18th century. Since the introduction of portion sized pouches in the 1970's. Snus use has significantly increased in Sweden. Today, more Swedes use Snus than they do cigarettes. In Sweden, snus has been reported to be the most effective quitting aid when compared to nicotine replacement therapy or any other treatment. Adult smokers who use snus as a cessation aid have a substantially higher success rates than other therapies. Modern snus is the most popular quitting aid in Sweden and Norway especially among men, and has been a major contributor to reducing smoking rates in those countries. The daily smoking rate in Sweden is now 5%⁴⁰.

⁴⁰ <https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-019-0335-1>



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Imperial's OND product portfolio includes both tobacco-containing and tobacco-free products. The All white category are OND products that are tobacco-free and consist of nicotine which has been added to plant fibres and come in a variety of flavours. The nicotine in an all-white pouch is transferred to the blood stream under the lip through the lining of the gum. Tobacco-free nicotine pouches completely decouple nicotine from tobacco, whilst providing for a similar delivery mechanism to that of traditional Snus.

Both the emerging, and established science on OND, including our own research, has demonstrated the potential for harm reduction.

Based on the decades of evidence available, many reviews conclude that snus is a reduced harm product

<p>"Snus users have been estimated to have at least 90-95% less tobacco-related mortality than cigarette smokers"</p> <p><i>Independent Scientists</i></p>	<p>"Long-term population studies indicate that Swedish snus is SUBSTANTIALLY less harmful than cigarettes"</p> <p><i>SCENIHR (European Commission)</i></p>	<p>"The health benefits of those who quit smoking for snus, are reported to be similar to those who quit tobacco completely"</p> <p><i>Swedish Academic</i></p>	<p>"Snus has not been demonstrated to increase the risk of cancer or heart disease, if any risk does exist, it is probably about 1% of that from smoking"</p> <p><i>Industry Consultant</i></p>
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All smokeless tobacco products, including snus, are banned from sale in Australia. The use and supply of snus is regulated under Federal law and differently in each state and territory. Offering innovative smoke free and tobacco free alternatives to adult smokers is an important complement to existing tobacco control strategies. Effective policies and regulation should enable adult consumers to be educated on this new category and access oral nicotine products.

CONCLUSION

Electronic Vapour Products represent a huge public health opportunity. There is a growing international consensus that e-cigarettes are significantly less harmful than conventional cigarettes⁴¹ and lead to an accelerated decline in both youth and adult smoking rates in markets where sold⁴².

The consumer-led demand for something better requires Governments, regulators and public health bodies to play a positive role, which includes a legislative framework that allows the Electronic Vapour Product

⁴¹ See for example; <https://www.gov.uk/government/news/phe-publishes-independent-expert-e-cigarettes-evidence-review>, or; <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction>

⁴² Australian Tobacco Harm Reduction Association



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category to develop and gives consumers the confidence to trial, and ultimately transition, to these less harmful products.

Effective regulation should support vaping products being made more attractive to adults to support them to transition to less harmful products. Practically, that requires:

- providing attractive alternatives to consumers;
- enabling consumers to access those alternatives; and
- providing consumers with advice and education around the use of alternatives.

Imperial Brands Australasia recognises the important role we have to play in reducing the harm caused by cigarettes and as such, we would welcome the opportunity to discuss this submission in further detail and clarify any questions that you might have.