



PHILIP MORRIS LIMITED

Philip Morris Limited

Submission to the Senate Standing Committees on Economics on

Personal choice and community impacts

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Introduction

Smoking prevalence has declined in many countries, including Australia, over the last forty years. However, millions of adults choose to continue to smoke cigarettes. Recognising this, the policy of tobacco harm reduction – making safer products available to smokers who do not quit– is being put forward by a multitude of stakeholders, including public health organisations, healthcare professionals and regulators, to complement the other major strategies for reducing smoking-related harm (i.e., prevention of initiation and cessation).

Around the world, millions of adult smokers have switched from cigarettes to non-combustible alternatives such as e-cigarettes. Hundreds of thousands of Australians have done the same and will undoubtedly want to continue to do so. In most countries in the developed world, including the United States, United Kingdom and other countries of the European Union, Governments are supporting this change, allowing e-cigarettes to be sold as tobacco products or consumer products, not prohibiting them as poisons or unauthorised medicines.

However State and Federal Governments in Australia seem to be moving in the other direction, even though the Federal Government has tacitly made such products available in a limited way through the personal importation scheme.

It is therefore significant and timely that the Senate Standing Committee on Economics inquiry into Personal Choice and Community Impacts is examining the potential for nicotine products such as e-cigarettes, to reduce tobacco smoking prevalence and harms.

Philip Morris Limited and our ultimate parent company Philip Morris International (PMI), believe that tobacco harm reduction policies should complement State and Commonwealth policies designed to prevent initiation and encourage cessation. At the same time, we support regulatory oversight in the interests of public health for the development, marketing and sale of potentially less harmful alternatives to cigarettes.

This can be achieved through implementation of proportionate and reasonable rules governing product quality and safety, sales, marketing, public use and communication of substantiated product benefits. Regulation can help provide assurance that products introduced into the marketplace, and any claims made about them, are supported by scientific substantiation and ensure that product innovation and investment in scientific assessment of new products as well as smoker acceptance and switching are encouraged.

Harm Reduction

When a cigarette is lit, the burning of tobacco and other materials creates smoke, which contains nicotine and thousands of other chemicals. Some of these chemicals are widely recognised as being associated with the development of smoking-related diseases.ⁱ

At the same time, experts agree that nicotine, while addictive, is not the primary cause of smoking-related diseases. In 2007, Britain's Royal College of Physicians observed:

"...that smokers smoke predominantly for nicotine, that nicotine itself is not especially hazardous, and that if nicotine could be provided in a form that is acceptable and effective as a cigarette substitute, millions of lives could be saved."ⁱⁱ

E-cigarettes are not cigarettes, do not burn tobacco and do not generate smoke. They use battery-powered electronics to vaporise a nicotine-containing solution to create an aerosol, commonly referred to as vapour, with far fewer harmful chemicals than cigarette smoke.ⁱⁱⁱ

A growing number of public health authorities and experts view the emergence of e-cigarettes and other non-combustible alternatives to cigarettes as:

“among the most significant health innovations of the 21st Century – perhaps saving hundreds of millions of lives...”^{iv}

Providing adult smokers with reduced-risk alternatives to cigarettes is a priority for PMI. Our goal is to develop a portfolio of novel products, including e-cigarettes, which replicate the sensorial and taste attributes of cigarettes and deliver a nicotine-containing aerosol that is significantly less harmful than cigarette smoke.

In order for an alternative to cigarettes to benefit public health, it must satisfy three conditions:

- **First**, its potential to reduce risk in smokers who switch to it must be established by sound science and measured against a clear standard.
- **Second**, the product must be a satisfying alternative to conventional tobacco products.
- **Third**, the product’s marketing and use must not adversely impact initiation and cessation of overall conventional tobacco use.

The available evidence strongly suggests that, as a class, nicotine-containing e-cigarettes meet those three criteria.

First, nicotine-containing e-cigarettes are likely to present significantly lower risk of smoking related disease to individuals than combustible cigarettes. For example, a 2014 publication by the UK Royal College of Physicians noted that:

“Switching completely from tobacco to e-cigarettes achieves much the same in health terms as does quitting smoking and all nicotine use completely.”^v

A group of scientific and tobacco policy experts reviewed all the available scientific literature on e-cigarettes and concluded:

“based on the data available regarding the toxicant content of EC [electronic cigarette] liquid and aerosol, long-term use of EC, compared to smoking, is likely to be much less, if at all, harmful to users or bystanders. This is because unlike cigarettes, EC do not deliver combustion-generated toxicants that are linked to cancer, chronic lung disease and cardiovascular disease (CVD).”^{vi}

Although, to our knowledge, no individual e-cigarette has been subjected to the full set of studies that would be necessary to precisely quantify its specific risk profile, there is little doubt among the scientific and policy community that smokers who switch to e-cigarettes would likely significantly reduce their risk of smoking-related diseases.

Second, evidence from places where e-cigarettes are widely available shows that e-cigarettes are a satisfying alternative to conventional tobacco products for millions of smokers and they are not used by never smokers. For example, a recent briefing paper by Action on Smoking and Health–UK noted that *“there are currently 2.6 million adults in Great Britain using electronic cigarettes. Of these, approximately 1.1 million are ex-smokers while 1.4 million continue to use tobacco alongside their electronic cigarette use. Regular use of the devices is confined to current and ex-smokers and use amongst never smokers remains negligible.”^{vii}* Similarly, a government-funded monthly survey of thousands of UK smokers and non-smokers found that *“E-cigarettes may have helped approximately 20,000 smokers to stop last year who would not have stopped otherwise.”^{viii}*

Third, evidence shows that the availability of e-cigarettes has not adversely impacted smoking initiation and cessation rates. Again, the UK’s robust data are instructive, showing that the advent and growth in e-cigarette use *“has been accompanied by an increase in smoking cessation rates, a*

continued reduction in [smoking] prevalence and no increase in smoking uptake” and “by a decrease rather than increase in smoking uptake by children.”^{ix}

Evidence also shows that e-cigarettes more likely to be gateways out of smoking than gateways into smoking. The same review concluded, “[A]lthough there have been claims that EC [electronic cigarettes] are acting as a ‘gateway’ to smoking in young people, the evidence does not support this assertion. Regular use of EC by non-smokers is rare and no migration from EC to smoking has been documented (let alone whether this occurred in individuals not predisposed to smoking in the first place).”^x

Action on Smoking and Health in the United Kingdom (ASH UK) recently released research from the ASH Smokefree GB Youth Survey which was published in the journal Public Health^{xi} finding no evidence that young people are being recruited to smoking through their use of electronic cigarettes. Their press release^{xii} titled **Latest data finds no evidence that electronic cigarettes are a gateway to smoking for young people** quoted a number of experts including Hazel Cheeseman, Director of Policy at ASH UK:

These results should reassure the public that electronic cigarettes are not linked with any rise in young people smoking. Although more young people are trying electronic cigarettes and many more young people are aware of them, this has not led to widespread regular use or an increase in smoking.

Prof Kevin Fenton, National Director for Health and Wellbeing at Public Health England said:

This survey provides further confirmation that regular use of electronic cigarettes is still low and largely confined to young people who are already smokers. The new law prohibiting the sale of electronic cigarettes to young people under the age of 18 - which is due to take effect on 1 October - will further reduce teenagers’ access to these products and will reinforce the message that they are intended for adult smokers who want to cut down or stop smoking.

Internationally renowned Australian tobacco control, cancer and smoking cessation expert Professor Ron Boland, the Nigel Gray Distinguished Fellow in Cancer Prevention at Cancer Council Victoria has stated:

If you take the most pessimistic scenario and say they might be 10% as harmful as smoking, and you could get rid of nearly all smoking, then more than the entire population would have to take them up before you’d be having a net public health loss... So the maths says it’s almost impossible there wouldn’t be a public health gain — if these products will get people off smoking.^{xiii}

Regulatory Measures

Laws and policies at the State and Commonwealth level should support and encourage the development, assessment, commercialisation and use of potentially reduced risk non-combustible products by adult smokers as alternatives to combustible cigarettes.

The United States, United Kingdom and other countries of the European Union have already adopted, or are in the process of adopting such dedicated legislative and regulatory frameworks. In the EU, for example, e-cigarettes will be regulated under the 2014 Tobacco Product Directive (2014/40EU). As the EU Commission stated:

“The new legislation does not ban e-cigarettes, nor was there ever a plan to ban such products. Not only will consumers still be able to buy and use e-cigarettes, but they will benefit from improved safety and quality requirements.”^{xiv}

Therefore we recommend that the Commonwealth establish a new framework for e-cigarettes and other such nicotine containing products, and encourage the States and Territories to amend those aspects of their regulations which are required to enable this. In particular, we would recommend a framework that includes:

- Regulating them in a dedicated category or as tobacco-related products, not as medicines;
- Prohibiting their sale to minors;
- Subjecting e-cigarettes and e-cigarette ingredients (including nicotine) to quality and safety requirements;
- Regulating the advertising and marketing practices for e-cigarettes in a balanced way to minimise exposure of non-smokers and minors while ensuring smokers and e-cigarette users are informed about their availability and benefits;
- Prohibiting therapeutic claims unless the product and claims are authorised as medicines;
- Prohibiting comparative claims of reduced risk or reduced exposure unless substantiated by product-specific clinical studies and other data;
- Prohibiting the use of candy or confectionary brands and marketing, such as the use of cartoon character trademarks.

Research and Evidence

On 25 March 2015, the CEO of National Health and Medical Research Council (NHMRC) issued a statement on electronic cigarettes about the current status of the evidence, which concludes:

There is currently insufficient evidence to conclude whether e-cigarettes can benefit smokers in quitting, or about the extent of their potential harms. It is recommended that health authorities act to minimise harm until evidence of safety, quality and efficacy can be produced. NHMRC is currently funding research into the safety and efficacy of e-cigarettes for smoking cessation.^{xv}

This is an extraordinarily conservative approach, ignoring scientific and empirical evidence from countries in which e-cigarettes have been legally sold for years. A press release dated 19 August 2015 from the Government of the United Kingdom's Public Health England titled ***E-cigarettes around 95% less harmful than tobacco estimates landmark review*** notes:

An [expert independent evidence review](#) published today by Public Health England (PHE) concludes that e-cigarettes are significantly less harmful to health than tobacco and have the potential to help smokers quit smoking.

Key findings of the review include:

- *The current best estimate is that e-cigarettes are around 95% less harmful than smoking*
- *nearly half the population (44.8%) don't realise e-cigarettes are much less harmful than smoking*
- *there is no evidence so far that e-cigarettes are acting as a route into smoking for children or non-smokers*

The approach by NHMRC is representative of the approach of the Department of Health and other members of the public health 'establishment' in Australia, on what it characterised as the precautionary principle and needs to recognise the cost of denying less harmful alternatives to millions of adult smokers in Australia. A more rational, reasonable, evidence-based approach is warranted by the Commonwealth, even if that evidence is not locally produced in Australia.

ⁱ <http://www.fda.gov/downloads/tobaccoproducts/publichealthsciencesresearch/hphcs/ucm435035.pdf>.

ⁱⁱ Royal College of Physicians, HARM REDUCTION IN NICOTINE ADDICTION: HELPING PEOPLE WHO CAN'T QUIT Preface (2007) available at <http://www.tobaccoprogram.org/pdf/4fc74817-64c5-4105-951e-38239b09c5db.pdf>.

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- ⁱⁱⁱ See, for example, Britton, J. Bogdanovioca I, Electronic cigarettes: A Report Commissioned by Public Health England (2014). https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311887/Ecigarettes_report.pdf. (“Producing nicotine vapour from a solution rather than by burning tobacco means that electronic cigarette vapour is free from almost all of the many toxic chemicals that accompany nicotine in cigarette smoke.”)
- ^{iv} Letter from Specialists in Nicotine Science and Public Health Policy, to Dr. Margaret Chan, WHO Director General (May 26, 2014) at 1, available at <http://nicotinepolicy.net/documents/letters/MargaretChan.pdf>.
- ^v Ilze Bogdanovica, et al., Royal College of Physicians, *What You Need to Know About Electronic Cigarettes*, COMMENTARY, Mar. 20, 2014, available at <http://www.rcplondon.ac.uk/commentary/what-you-need-know-about-electronic-cigarettes>.
- ^{vi} Hajek, P., Etter, J.-F., Benowitz, N., Eissenberg, T. and McRobbie, H. (2014), Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. *Addiction*. doi: 10.1111/add.12659. <http://onlinelibrary.wiley.com/doi/10.1111/add.12659/abstract>.
- ^{vii} ASH Fact Sheet, Use of electronic cigarettes (vapourisers) among adults in Great Britain, May 2015, http://www.ash.org.uk/files/documents/ASH_891.pdf.
- ^{viii} Trends in electronic cigarette use in England (STS140122), updated 23 April 2015, <http://www.smokinginengland.info/latest-statistics>.
- ^{ix} Hajek, P., Etter, J.-F., Benowitz, N., Eissenberg, T. and McRobbie, H. (2014), Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. *Addiction*. doi: 10.1111/add.12659. <http://onlinelibrary.wiley.com/doi/10.1111/add.12659/abstract>.
- ^x Hajek, P., Etter, J.-F., Benowitz, N., Eissenberg, T. and McRobbie, H. (2014), Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. *Addiction*. doi: 10.1111/add.12659. <http://onlinelibrary.wiley.com/doi/10.1111/add.12659/abstract>.
- ^{xi} Eastwood, B., Dockrell, M., Arnott., D, Britton, J., Cheeseman, H., Jarvis, M., McNeill, A. (2015) Electronic cigarette use in young people in Great Britain 2013–2014. *Public Health*. DOI: <http://dx.doi.org/10.1016/j.puhe.2015.07.009>.
- ^{xii} ASH UK Media Release: <http://www.ash.org.uk/media-room/press-releases/latest-data-finds-no-evidence-that-electronic-cigarettes-are-a-gateway-to-smoking-for-young-people>.
- ^{xiii} The Mandarin, Policy in a puff of smoke: vexed options on vaping regulation. <http://www.themandarin.com.au/18371-whatever-done-e-cigarettes-health-outsources-policy-work>.
- ^{xiv} European Commission, E-cigarettes Myth Buster, http://ec.europa.eu/health/tobacco/docs/tobacco_mythbuster_en.pdf.
- ^{xv} National Health and Medical Research Council, updated on 23 March 2015. <https://www.nhmrc.gov.au/health-topics/electronic-cigarettes>.