

15 January

Mr/Ms XXX

[Title]

[Street Address]

[City] [State] [Postcode]

Via email: Check

Dear 

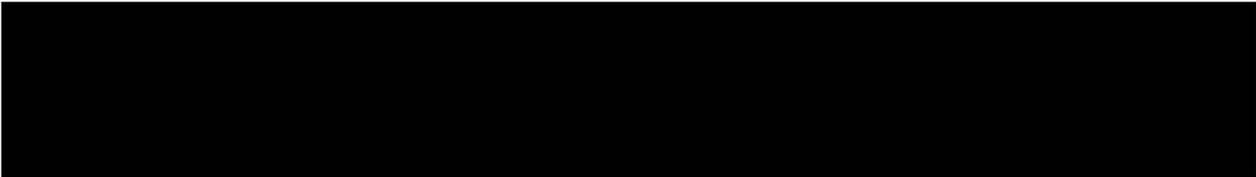
Re: Application to the Therapeutic Goods Administration by Philip Morris International to make tobacco prepared and packed for heating available in Australia.

In late 2019, Philip Morris International (**PMI**) – the tobacco giant producing more than 800 billion tobacco cigarettes each year – made an application to the Therapeutic Good Administration (**TGA**) seeking to list tobacco prepared and packed for heating as an exempt item under the *Poisons Standard*. Whilst the proposed application is seemingly broad and may have interesting and unintended consequences, it would, if accepted by the TGA, allow PMI – and other tobacco companies – to immediately sell their heat-not-burn (**HnB**) tobacco products or what they term 'smoke free products' alongside regular tobacco cigarettes to all Australians over the age of 18. This would be a public health disaster.

The application is an attempt by a well-resourced and shrewd organisation, to manipulate Australians; by calling on the TGA to support tobacco for heating as a better alternative to what is already legally available traditional cigarettes; while in reality increasing their market position and offering a new product to a new generation of consumers.

The most dangerous component of any tobacco product is the presence of nicotine, due to the extreme addictive properties of the poison, which are known to chemically alter the composition of adolescent developing brains, whether used in combustible cigarettes, personal vaporisers, chewing products or HnB devices.ⁱ It is the addiction to a harmful product, which has led to tobacco being the largest cause of disease and cancer related mortality in the world.ⁱⁱ Tobacco use kills more than 15,500 Australians every year and remains the leading cause of preventable burden in Australia, comprising 9.3% of the total burden of disease and injury in 2015.ⁱⁱⁱ

Through the implementation of world-leading tobacco control strategies, the daily smoking rate in Australia was reduced from 19% in 2008 to 13.8% in 2018^{iv}. The stated objective of the Australian Government is to reduce the daily smoking rate to 10% by 2025.^v



Australians do not want - nor do they need - another means to acquire nicotine addition, chronic disease, and early death.

PMI's principal claim that its HnB products are a "*better alternative for current Australian smokers who do not quit*",^{vi} whilst presented with evidence to ostensibly achieve legitimate harm reduction for some smokers, is in fact a carefully crafted Trojan horse with no proven benefit for the Australian community.

Based on the current evidence available and the youth epidemic of e-cigarette use in the United States, it is our belief, that the introduction of HnB products would likely expand the tobacco market by: attracting new users, in particular young people, to new bespoke tobacco products, and significantly reduce smoking cessation rates. These products will result in an increase in nicotine dependency in our community.

The current evidence on heat-not-burn health impacts

It is not disputed by PMI that tobacco HnB products are harmful to health. They claim, however, that HnB products reduce the levels of emitted and inhaled toxicants generated by combustible tobacco products; because the tobacco is heated rather than burned.^{vii}

Whilst there are some short-term studies that support this position,^{viii} there is no evidence from any long-term clinical trials and/or observational studies that HnB products reduce the risk of tobacco-related illnesses.^{ix}

We – and tobacco companies – do know, from long-term evidence-based studies that the best, proven way to prevent or reduce the risk of tobacco-attributable diseases is to quit smoking. Australia already has a range of authorised non-nicotine replacement therapies, such as Champix, which help people quit. Australian public health policy is not founded, nor should it be founded, on the principle of offering our citizens a lesser evil.

It is the right of all Australians to enjoy the highest attainable standard of physical health and mental health and wellbeing.^x Preventing disease and ill-health, such as preventing a nicotine addiction, seeks to achieve this right. Education and evidence-based approaches - free from the influence and claims of commercial organisations seeking profit, rather than public health benefits,^{xi} - must remain our focus in the fight against preventable disease. Australia must not be fooled into facilitating addiction by varying degrees. Decision makers must acknowledge that ostensible public health claims made by tobacco companies are simply the continuation of a well-established practice of attempting to "*subvert the role of governments in developing and implementing public health policies to combat the tobacco epidemic*".^{xii}

We believe that a tobacco free community is achievable; we realistically acknowledge that the tobacco industry work to influence the community to believe the opposite.

Harm reduction/better alternative claim

There is a lack of evidence that conventional smokers make a permanent and single-use switch to HnB products. Indeed, there is emerging evidence – from a tobacco industry funded study – that smokers rate HnB products as less satisfying in



terms of smoking satisfaction, psychological rewards, enjoyment of respiratory tract sensation and craving reduction than cigarettes.^{xiii} This would suggest that smokers are unlikely to permanently transition to HnB products. The experience in Korea was that users of PMI HnB device 'I Quit Ordinary Smoking' (██████) became smokers of both e-cigarettes and traditional cigarettes.^{xiv}

In April 2019,^{xv} after a two-year assessment, the US Food and Drug Administration (FDA) permitted the marketing and sale of PMI's HnB product. The FDA, acknowledging there is no independent well-established evidence which supports the PMI claim that smokers of traditional cigarettes transition to HnB products, and concerned about the impact on youth use of nicotine, placed strict marketing and post market review obligations on PMI. These requirements include monitoring market dynamics such youth uptake and transition from combustible cigarettes. However, this information is not available; leading health organisations to believe that results have been unsatisfactory.

The rapid uptake of e-cigarettes by young Americans, has led to emerging evidence, arguing that better alternative claims – such as those outlined in PMI's application – coupled with the approval by Regulatory authorities responsible for governing and protecting public health, results in the perception that HnB products are 'safe for use', rather than 'potentially not as harmful as traditional cigarettes'.^{xvi} These circumstances are expected to create an enhancement of smoking appeal and initiation of tobacco products among young persons, and a deterrence to quit attempts among habitual smokers.

In addition, recent studies and surveys indicate that novel tobacco products rapidly acquire first-time users. A survey carried out in Italy after the launch of ██████ found that 20% of respondents were aware of the system and 1.4% had tried it. About half of ██████ users (45%) and people interested in trying it had never been smokers.^{xvii} Similar trends regarding e-cigarettes (introduced in 2007) use in the United States have also been observed; 32.5% of e-cigarette users (during 2010 – 2013) were never- or former smokers.^{xviii} There is now increasing evidence, including long-terms studies, that demonstrate e-cigarettes contribute to primary nicotine addiction and to renormalization of tobacco use. HnB products are simply next-generation e-cigarettes and combustible cigarettes; delivering deliver nicotine addiction and associated tobacco toxins.

Expanding the tobacco market – young Australians

Evidence reveals nonusers of tobacco products, particularly children and adolescents, are drawn to new products and that this could lead to a subsequent transition to traditional cigarettes.^{xix}

In particular, a study by McKelvey et al found that:

"PMI's own data and available evidence from scientific studies conducted independent of the tobacco industry regarding how novel tobacco products are currently being marketed (in the US, UK, Japan, Korea, Italy and other nations) suggest that introduction of ██████ will result in adolescent and young adult non-users initiating tobacco use with ██████ and could also increase poly-use of ██████ along with other tobacco products".^{xx}



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- i World Health Organisation.
- ii World Health Organization (WHO) Framework Convention on Tobacco Control. Ratified by Australia on 27/10/04.
- iii AIHW (Australian Institute of Health and Welfare) 2019. Australian Burden of Disease Study: impact and causes of illness and death in Australia 2015. Australian Burden of Disease Study series no.19. Cat. no. BOD 22. Canberra: AIHW.
- iv Frost & Sullivan. The Pattern of Smoking in Australia. The challenge in achieving the 10% smoking target – analysis of current smoking rates by state and territory. October 2019.
- v See National Press Club Address -Long Term National Health Plan, August 2019 <https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/national-press-club-address-long-term-national-health-plan>
- vi Philip Morris International, Summary of Application to Therapeutic Goods Authority. Available at <https://www.tga.gov.au/consultation-invitation/consultation-proposed-amendments-poisons-standard-accs-acms-and-joint-acmsaccs-meetings-march-2020>.
- vii Scientific Update for Smoke-Free Products, December 2019, Issue 8, Philip Morris International Science.
- viii Frost & Sullivan. The Pattern of Smoking in Australia. The challenge in achieving the 10% smoking target – analysis of current smoking rates by state and territory. October 2019.
- ix Ibid, Signes-Costa, de Granda-Orive, Ramos Pinedo, Camarasa Escrig, de Higes Martinez, Rábade Castedo, (2019). Official Statement of the Spanish Society of Pulmonology and Thoracic Surgery (SEPAR) on Electronic Cigarettes and ██████████[®]. *Archivos de Bronconeumologia*, 55(11), 581–586.
- x Article 12. International Covenant on Economic, Social and Cultural Rights. Ratified by Australia
- xi Article 5.3 of the World Health Organization (WHO) Framework Convention on Tobacco Control. Ratified by Australia on 27/10/04.
- xii Australian Government, Department of Health, Guidance for Public Officials on Interacting with the Tobacco Industry. 2019.
- xiii Picavet P, Haziza C, Lama N, et al. Comparison of the pharmacokinetics of nicotine following single and ad libitum use of a tobacco heating system or combustible cigarettes. *Nicotine Tob Res* 2016;18:557–63.
- xiv Kim J, Yu H, Lee S, Paek Y-J. Awareness, experience and prevalence of heated tobacco product, ██████████ among young Korean adults. *Tob Control*. 2018;27 Suppl1:s74–7.60.
- xv See FDA <https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway>
- xvi See for a summary of the argument: Paumgarten FJR. A critical appraisal of the harm reduction argument for heat-not-burn tobacco products. *Rev Panam Salud Publica*. 2018;42:e161. <https://doi.org/10.26633/RPSP.2018.16.1>. For additional studies see McKelvey, K., Popova, L., Kim, M., Chaffee, B.W., Vijayaraghavan, M., Ling, P. & Halpern-Felsher, B. 2018, "Heated tobacco products likely appeal to adolescents and young adults", *Tobacco control*, vol. 27.
- xvii 5. Liu X, Lugo A, Spizzichino L, Tabuchi T, Pacifici R, Gallus S. Heat -notburn tobacco products. Concerns from the Italian experience. *Tob Control*. 2019;28:113–4. 16.
- xviii Robert C. McMillen, Mark A. Gottlieb, Regina M. Whitmore Shaefer, Jonathan P. Winickoff, Jonathan D. Klein, Trends in Electronic Cigarette Use Among U.S. Adults: Use is Increasing in Both Smokers and Nonsmokers, *Nicotine & Tobacco Research*, Volume 17, Issue 10, October 2015, Pages 1195–1202, <https://doi-org.ezproxy.library.uq.edu.au/10.1093/ntr/ntu213>
- xix Jenssen BP, Walley SC, McGrath-Morrow SA. Heat-not-Burn Tobacco Products: Tobacco Industry Claims No Substitute for Science. *Pediatrics*. 2018;141(1): e20172383
- xx McKelvey, K., Popova, L., Kim, M., Chaffee, B.W., Vijayaraghavan, M., Ling, P. & Halpern-Felsher, B. 2018, "Heated tobacco products likely appeal to adolescents and young adults", *Tobacco control*, vol. 27.
- xxi Ibid.
- xxii Ibid, summarizing 15 studies.
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