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Medicines Scheduling Secretariat
Therapeutic Goods Administration
Via email: medicines.scheduling@tga.gov.au

Submission regarding Proposed Amendments to the Joint ACMS-ACCS #24 (3.1 Nicotine) under the Commonwealth Poisons Standard section 52E of the Therapeutic Goods Act 1989.

To whom it may concern,

This submission is in opposition to the application made by Philip Morris International (**PMI**) to the Therapeutic Goods Administration (**TGA**) seeking to amend *Commonwealth (Cth) Poisons Standard section 52E of the Therapeutic Goods Act 1989 (the Act)*; to exempt “tobacco prepared and packed for heating”, also known as Heated Tobacco Products (**HTPs**), under the *Poisons Standard*.

HTPs produce aerosols containing nicotine and other chemicals, which are inhaled by users, through the mouth. In order to produce the nicotine-infused vapor, HTPs heat tobacco up to 350°C (lower than 600°C as in conventional cigarettes) using battery-powered heating-systems.ⁱ HTPs heat tobacco to generate nicotine, which makes all HTPs highly addictive and dangerous products.ⁱⁱ

If accepted by the TGA, the exemption would allow PMI to sell HTPs alongside regular tobacco cigarettes in Australia. The Minderoo Foundation strongly oppose this application. We believe that an exemption of HTPs would be a catastrophic step backwards for public health, and lead to many unintended consequences that undermine years of tobacco control policy in Australia. The daily smoking rate in Australia has reduced from 19% in 2008 to 13.8% in 2018,ⁱⁱⁱ as a result of these effective policy mechanisms. The current objective of the Australian Government is to reduce the daily smoking rate to 10% by 2025.^{iv}

The Department of Health, in its enquiry into e-cigarettes in 2017, stated that they have concerns about the marketing and use of HTPs due to the limited evidence on their ability to reduce the risk associated with conventional tobacco products and the risks they may pose to population health in Australia.^v

Renormalisation of smoking

The rapid youth uptake of e-cigarettes in the United States has led to evidence arguing that claims of harm-reduction and safer alternatives result in the perception that alternative devices such as HTPs are ‘safe for use’, which they are not.^{vi} It is not disputed by PMI that HTPs are harmful to health. The perception of harm-minimisation creates an enhancement of smoking appeal and initiation of tobacco products among young persons, and is a deterrence to quit attempts among habitual smokers.^{vii}

There is a lack of evidence that conventional smokers make a permanent and single-use switch to HTPs.^{viii} Indeed, there is emerging evidence – from a tobacco industry funded study – that smokers rate HTPs as less satisfying in terms of smoking pleasure, psychological rewards, enjoyment of respiratory tract sensation and craving reduction than cigarettes.^{ix} This would suggest that smokers are unlikely to permanently transition to HTPs. In Korea, it was found that users of PMI’s HTP ‘I Quit Ordinary Smoking’ (██████) became dual smokers, using both ██████ and traditional cigarettes.^x

PMI claim that ‘the greatest contribution PMI can make to society is to replace cigarettes with less harmful alternatives.’^{xi} Despite this new social responsibility, PMI has taken no active moves to cease selling cigarettes and continues to fight effective tobacco control measures.^{xii}



Nicotine addiction

The most dangerous component of any tobacco product is nicotine, due to its extremely addictive, psychoactive properties which are known to chemically alter the composition of adolescent developing brains, in any means of delivery.^{xiii} It is the addiction to nicotine, defined as a poison in the Act,^{xiv} which has led to tobacco being the largest cause of disease and cancer related mortality in the world.^{xv} Tobacco use kills more than 15,500 Australians every year and remains the leading cause of preventable burden in Australia.^{xvi}

There is no evidence from any long-term clinical trials and/or observational studies that HTPs reduce the risk of tobacco-related illnesses.^{xvii} There is now increasing evidence, including long-term studies, that demonstrate alternative products contribute to primary nicotine addiction and the renormalization of tobacco use.

Attraction to youth

Recent studies and surveys indicate that novel tobacco products rapidly acquire first-time users.^{xviii} A survey carried out in Italy after the launch of IQOS found that 20% of respondents were aware of the system and 1.4% had tried it. About half of IQOS users (45%) and people interested in trying it had never been smokers.^{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 IQOS will result in adolescent and young adult non-users initiating tobacco use with IQOS and could also increase poly-use of IQOS along with other tobacco products”.^{xx}

It was concluded by McKelvey et al that no regulatory authority should allow any new tobacco product on the market without independent evidence clearly showing that the new product will not appeal to adolescents and young adults, misinform populations about risks associated with a product or encourage use of multiple tobacco products”.^{xxi}

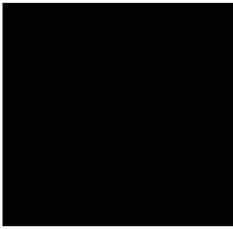
No such evidence is included in PMI’s application to the TGA. In fact, there is a strong emerging body of evidence that the “product’s name, physical appearance, flavours and retail environment will appeal to young people”.^{xxii}

Recommendation

Australia must not be manipulated into facilitating addiction by varying degrees and delivery mechanisms. We 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”.^{xxiii}

We strongly recommend that the TGA adopt a precautionary approach to HTPs similar to the approach adopted regarding e-cigarettes. No new nicotine product should be permitted for sale in Australia unless credible and long-term evidence can clarify that the product in question is an effective tobacco cessation device and will not appeal to youth. We also believe that to misinform the Australian population about risks associated with a product or encourage use of multiple tobacco products in Australia is negligent and with a single goal to addict a new generation of smokers.

Alternatively, if the TGA finds compelling evidence that HTPs are suitable for use by Australians as an effective tobacco cessation product, it **must**, as a consequence of such an approval, remove the exemption under the Schedule 7 listing for nicotine for ‘tobacco prepared and packed for smoking’ and at the same time adopt age-based point of sale restrictions such as increasing the minimum legal sales age of tobacco products to 21 years of age (**Tobacco21**) to prevent nicotine addiction in future generations.



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- ⁱ World Health Organisation, Heated tobacco products (HTPs) information sheet, 2017. Accessed from: https://www.who.int/tobacco/publications/prod_regulation/heated-tobacco-products/en/
- ⁱⁱ Ibid.
- ⁱⁱⁱ 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. Available from: <https://ww2.frost.com/frost-perspectives/the-pattern-of-smoking-in-australia/>
- ^{iv} National Press Club Address -Long Term National Health Plan, August 2019. Available from: <https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/national-press-club-address-long-term-national-health-plan>
- ^v Department of Health, Standing Committee on Health, Aged Care and sport - inquiry into the use and marketing of electronic cigarettes and personal vaporisers in Australia. Australian Government; 2017. Available from: <https://www.aph.gov.au/DocumentStore.ashx?id=4f4d5093-5468-40c0-b573-986692900aad&subId=512734>
- ^{vi} See for a summary of the argument: Paumgartten FJR. A critical appraisal of the harm reduction argument for heat-not-burn tobacco products. *Rev Panam Salud Publica*. 2018; 42: e161. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6386018/> 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.
- ^{vii} Ibid.
- ^{viii} 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.
- ^{ix} 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.
- ^x 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.
- ^{xi} Phillip Morris sustainability report 2018. Available from: <pmi-sustainability-report-2018-low-res-may-2019.pdf>
- ^{xii} Ibid.
- ^{xiii} World Health Organization (WHO), Report on the Global Tobacco Epidemic, 2008. The MPOWER package. Available from: www.who.int/tobacco/mpower/en/
- ^{xiv} The Therapeutic Goods Act 1989 & the Poisons Standard, accessed from: <https://www.tga.gov.au/therapeutic-goods-act-1989-poisons-standard>
- ^{xv} World Health Organization (WHO) Framework Convention on Tobacco Control. Ratified by Australia on 27/10/04.
- ^{xvi} 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.
- ^{xvii} 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>; Signes-Costa et al, (2019). Official Statement of the Spanish Society of Pulmonology and Thoracic Surgery (SEPAR) on Electronic Cigarettes and ██████[®]. *Archivos de Bronconeumologia*, 55(11), 581–586.
- ^{xviii} Jansen BP, Walley SC, McGrath-Morrow SA. Heat-not-Burn Tobacco Products: Tobacco Industry Claims No Substitute for Science. *Pediatrics*. 2018;141(1): e20172383
- ^{xix} Liu X, Lugo A, Spizzichino L, Tabuchi T, Pacifici R, Gallus S. Heat -not-burn tobacco products. Concerns from the Italian experience. *Tob Control*. 2019;28:113–4. 16.
- ^{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.
- ^{xxiii} Australian Government, Department of Health, Guidance for Public Officials on Interacting with the Tobacco Industry, 2019. Available from: <https://www.health.gov.au/resources/publications/guidance-for-public-officials-on-interacting-with-the-tobacco-industry>