[redacted]

ACT Government Submission

to the

Therapeutic Goods Administration:

Consultation on Proposed amendments to the Poisons Standard

February 2020

Introduction

The ACT Government does not support the following proposal, referred to the Joint Advisory Committee on Medicines and Chemicals Scheduling for scheduling advice:

Amend Schedule 7 of the Poisons Standard, for nicotine, to exempt nicotine used in tobacco prepared and packed for heating.

Product description

Heated tobacco products (HTPs), also known as heat-not-burn tobacco products, heat processed tobacco in a controlled device instead of burning it. The devices heat tobacco to 350°C while traditional cigarettes burn at temperatures of at least 800°C[i].

Public health and tobacco control policy implications

Tobacco use causes the highest burden of disease in Australia and it is responsible for the deaths of up to two thirds of Australian smokers aged 45 years and older[ii].

The application indicates that nicotine prepared and packed for heating is intended to be used as a substitute for smoking tobacco and not a therapeutic product (i.e. an aid for smoking cessation). The Joint Advisory Committee on Medicines and Chemicals Scheduling should carefully consider advice from tobacco control and public health experts on the likely impacts of a decision to approve an exemption of these products. Exemption of nicotine prepared and packed for heating from Schedule 7 of the Poisons Standard would have significant health consequences beyond the remit of the Therapeutic Goods Administration (TGA). The Committee should also note that Commonwealth, and state and territory tobacco and smoking legislation may also require significant amendments if this application is successful.

It has been widely reported that the application to amend the entry for nicotine in Schedule 7 of the Poisons Standard is being made by Philip Morris International, a major tobacco company[iii,iv].

Effective tobacco control and the commercial success of the tobacco industry are fundamentally incompatible. According to the World Health Organisation (WHO), tobacco companies use a wide range of tactics to interfere with tobacco control. Such strategies include direct and indirect political lobbying and campaign contributions, financing of research, attempting to affect the course of regulatory and policy machinery and engaging in social responsibility initiatives as part of public relations campaigns[v].

[redacted]

Article 5.3 of the WHO Convention on Tobacco Control requires the protection of public health tobacco control policies from commercial and other vested interests of the tobacco industry in accordance with national law.

Philip Morris is currently running a campaign in Australia titled 'Unsmoke your world'. The campaign encourages smokers to lobby for the legalisation of nicotine e-cigarettes and HTPs and to share their story of switching to 'less harmful alternatives'. The promotion of HTP as a harm reduction tool is an attempt to renormalise tobacco use[vi],[vii]. Philip Morris's application to the TGA, together with its 'Unsmoke your World' campaign, is a clear attempt to influence public health policy.

As government entities, we are all subject to compliance with Article 5.3 and must take extreme care that this decision is not influenced in any way by the tobacco industry or anyone acting at its instigation.

Lack of evidence of health benefits

The application to the TGA claims that HTPs are a better alternative than smoking tobacco cigarettes for smokers who do not quit. Philip Morris's main HTP is called [redacted] and this product has been the subject of most of the research conducted on HTPs to date.

There is general agreement between both industry funded and independent researchers that HTPs expose users and bystanders to lower levels of some harmful and potentially harmful toxins than conventional cigarettes[viii,ix,x,xi,xix,xii]. It should be noted, however, that independent researchers urge caution in interpreting this finding, as there is no evidence that a reduced level of exposure will lead to less disease in users or bystanders. It has recently been shown that someone who smokes only one cigarette a day has half the cardiovascular or stroke risk experienced by someone who smokes a whole packet[xiii] so the reduction in harm associated with reduced exposure is not linear. There has been no viable assessment of the long-term impact of HTP on health[viii] and it is likely to be some years before reliable evidence is available.

In 2018 two separate independent researchers analysed the data that Philip Morris had provided to the US Food and Drug Administration in support of marketing [redacted] as a 'modified risk tobacco product'. One found no statistically detectable difference between [redacted] and conventional cigarettes for 23 of the 24 non-cancer biomarkers of potential harm measured in Americans, and 10 of 13 measured in Japanese people. This study concluded that, despite delivering lower levels of some toxicants, Philip Morris's data failed to show consistently lower risks of harm in humans using [redacted] compared with conventional cigarettes[xiv]. The other paper[xv] found that Philip Morris had not shown that this product would 'significantly reduce harm and the risk of tobacco-related disease to individual tobacco users'.

In January 2018, the FDA's Tobacco Products Scientific Advisory Committee voted that Philip Morris had failed to demonstrate that its proposed modified (reduced) risk labelling and advertising claims for [redacted] were demonstrated by scientific evidence[xvi].

[redacted]

Safety concerns for users and bystanders

Independent research into HTPs has found that:

- volatile and semi-volatile harmful constituents of tobacco smoke still form as they tend to have boiling points of less than 300°C[xvii];
- the polymer film filters used in HTPs release Formaldehyde cyanohydrin at 90°C of heating; this is an acute toxicant often used in the production of synthetic resins and used as a solvent[xviii,xvii];
- tar levels produced by heated tobacco are almost the same as in combustible cigarettes[xix];
- Due to a six minute heat time limit imposed by the [redacted] device, users may be forced to smoke at a rapid pace in order to fully maximise the heatsticks - this could lead to an increase in intake of nicotine and carbonyls[xvii]https://tobaccocontrol.bmj.com/content/28/1/34 - ref-31;
- the [redacted] tobacco appears to char without ignition, and charring increases when cleaning is not done after each use[xvii];
- aerosols produced by [redacted] impair acute vascular endothelial function in rats in a similar way to cigarette smoke[xx]; and
- an invitro cell-based study shows HTPs have the potential to increase oxidative stress, inflammation and infection.
    - They can also cause airway remodelling and initiate pre-cancerous cellular changes in the airways of users.
    - The authors urge a need for clinical studies and caution that these devices may not be a safer option than cigarette smoking[xxi].

Two Japanese case studies have described acute eosinophilic pneumonia in young people with a history of using HTPs[xxii,xxiii]. One 16-year-old had been using the HTP for only two weeks prior to developing respiratory failure.

Impact on reducing tobacco use in Australia

HTP tobacco products do not reduce exposure to nicotine. Switching to HTP is not intended to assist people to quit and no claim has been made that switching to heated tobacco products would help people to quit cigarette smoking. New users would develop a nicotine addiction in the same way as those smoking combustible tobacco.

No level of exposure to tobacco smoke is safe. Introducing a new smoking product to the market that is marketed as 'safer' than conventional tobacco smoking would be likely to encourage existing smokers to maintain their dependence on tobacco rather than quit, and potentially increase their smoking frequency. One Japanese study found that 72 per cent of HTP users reported also smoking combustible cigarettes[xxiv]. If any health benefits were found to be conferred by HTP compared to combustible cigarettes they would be negated where dual use occurs.

A perception of greater safety is likely to make tobacco initiation more attractive to Australian adolescents and young adults. An Italian study conducted in 2017 found that 44 per cent of people who had tried an HTP were adults who had never previously smoked[xxv].

Conclusion

Under normal circumstances, where products are known to be unsafe, legislation is introduced to prohibit the sale of the products. The evidence indicates that HTPs are harmful to health and are unsafe.

[redacted]

It would not be appropriate for Schedule 7 to be amended to exempt heated tobacco products.

Australia has been extraordinarily successful in reducing smoking through increased tobacco taxes, plain packaging and smoke-free legislation. If HTP products are approved for use in Australia, this will prolong and expand the tobacco market in an environment where government initiatives are increasingly and effectively reducing tobacco use.

The TGA is asked to reject the application due to a lack of evidence of health benefits, safety concerns for users and bystanders and the likely negative impact on reducing tobacco use in Australia.

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[i] Committees on toxicity, carcinogenicity and mutagenicity of chemicals in food, consumer products and the environment 2017: Toxicological evaluation of novel heat-not-burn tobacco products – non-technical summary. https://cot.food.gov.uk/sites/default/files/heat_not_burn_tobacco_summary.pdf

[ii] Australian Institute of Health and Welfare. Australian burden of disease study: Impact and causes of illness and death in Australia 2015. Australian Burden of Disease, Canberra: AIHW, 2019.

[iii] John Kehoe: Financial Review December 13 2019: Philip Morris presses TGA for 'smoke free' tobacco approval https://www.afr.com/policy/economy/philip-morris-presses-tga-for-smoke-free-tobacco-approval-20191212-p53ja9

[iv] Ariel Bogle: ABC News: 10 January 2020. Tobacco giants lobby PM and key MPs with pro-vaping message https://www.abc.net.au/news/science/2020-01-10/tobacco-industry-sought-vaping-meetings-with-pm-and-cabinet/11855264

[v] World Health Organization: 2009: Tobacco Industry Interference with Tobacco Control.

[vi] Bialous SA, Glantz SA. *Tobacco Control 2018;27:s111-s117*. Heated tobacco products: another tobacco industry global strategy to slow progress in tobacco control.

[vii] Brian P. Jenssen, Susan C. Walley and Sharon A. McGrath-Morrow. *Pediatrics January 2018, 141 (1).* Heat-not-Burn Tobacco Products: Tobacco Industry Claims No Substitute for Science.

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[xiii] Huxley, R. *BMJ Evidence-Based Medicine April 2019, 24(2).* Light smoking confers up to half the amount of the cardiovascular risk associated with smoking a pack of cigarettes a day.

[xiv] Glantz SA. *Tobacco Control 2018;27:s1-s6*. Heated tobacco products: the example of [redacted]

[xv] Max WB, Sung H, Lightwood J, et al. *Tobacco Control 2018;27:s82-s86.* Modelling the impact of a new tobacco product: review of Philip Morris International's Population Health Impact Model as applied to the [redacted] heated tobacco product.

[xvi] Food and Drug Administration: Center for Tobacco Products (CTP). Tobacco Products Scientific Advisory Committee Minutes 24-25 January 2018. https://www.fda.gov/files/advisory%20committees/published/Tobacco-Products-Scientific-Advisory-Committee-Meeting-January-24-25--2018--Summary-Minutes.pdf Accessed 13/01/2020.

[xvii] Davis, B., Williams, M. & Talbot, P. *Tob Control 2019;28:34-41.* [redacted] evidence of pyrolysis and release of a toxicant from plastic.

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