Submission from [redacted] in response to the application to the Therapeutic Goods Administration to exempt nicotine for use in tobacco prepared and packed for heating from Schedule 7 of the Poisons Standard (CAS Number 54-11-5)

Summary Comment

An application has been received by the Therapeutic Goods Administration (TGA) proposing that nicotine be exempted from Schedule 7 of the Poisons Standard for use in tobacco prepared and packed for heating.

While the applicant claims that heated tobacco products are likely to be less harmful than smoking conventional tobacco products, current evidence does not confirm whether these products are less harmful.

These products can be lawfully sold in some countries but there is limited information on their prevalence and impact given the burgeoning nature of this product's market. Information from the United States[1] and Japan[2] indicates that consumption of this type of product has increased in a short period. Additionally, the experience in the United States with e-cigarettes, where approximately 1 in 4 twelfth-grade students are vaping[3], illustrates the potential for a rapid increase in the popularity of alternative nicotine delivery devices among young people. In New Zealand, where heated tobacco product sales are lawful, there is an absence of official data regarding the use of these products. However, marketing and community engagement strategies have been deployed by industry in an effort to promote heated tobacco products as a reduced risk alternative[4].

As of 21 January 2020, 2,711 reported hospitalised cases of e-cigarette, or vaping, product use – related lung injury have been reported to the US Centers for Disease Control and Prevention, including 60 deaths[5]. While these cases are not connected with heated tobacco specifically, they broadly illustrate the risks connected with the widespread use of alternative nicotine delivery systems when safety has not been established.

If heated tobacco products were approved for sale in Australia, there are risks that:

- these products will have short and long-term health effects on users, as well as exposing others to potentially harmful to second-hand emissions
- these products will be appealing to young people, including minors (as seen in overseas examples), possibly serving as an entry point for nicotine dependence and progression to conventional tobacco smoking
- usage of these products will increase the number of people with a nicotine dependence in the community by both encouraging uptake of these devices and hindering smoking cessation

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[1] Nyman, Amy, et al. "Awareness and use of heated tobacco products among US adults, 2016-2017." *Tobacco Control*, vol. 27, no. 1, 2018, pp. 55–61. doi: 10.1136/tobaccocontrol-2018-054323

[2] Tabuchi, Takahiro, et al. "Heat-not-burn tobacco product use in Japan: Its prevalence, predictors and perceived symptoms from exposure to secondhand heat-not-burn tobacco aerosol." *Tobacco Control*, vol. 27. No. 1, 2018, pp.25-33. doi:10.1136/tobaccocontrol-2017-053947

[3] Miech, Richard, et al. "Adolescent vaping and nicotine use in 2017–2018 — U.S. National Estimates." *New England Journal of Medicine,* vol. 380, 2019, pp. 192-193. DOI: 10.1056/NEJMc1814130

[4] Elder, Vaughan. "Legality of tobacco product in question. *Otago Daily Times*. https://www.odt.co.nz/news/national/legality-tobacco-product-question

5 *Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products*. United States Centers of Disease Control and Prevention. 2020, January 28. https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html

[redacted]

- these products will be labelled and presented by producers as a reduced risk product, thereby increasing the use of the product and exposing a larger population of users to possible health risks
- it may justify the future approval of e-cigarette devices, which also pose potential health risks and are currently used by a significant number of Australians

Considering the lack of evidence on the safety of these products, as well as other broader risks to population health, [redacted] does not support the proposal to exempt nicotine from Schedule 7 of the Poisons Standard for use in tobacco prepared and packed for heating.

Discussion

Under section 52E of *the Therapeutic Goods Act 1989*, the following matters are taken into account when consideration is given to amending the Poisons Standard:

- the risks and benefits of the use of a substance
- the purpose for which a substance is to be used and the extent of use of a substance
- the toxicity of a substance
- the dosage, formulation, labelling, packaging and presentation of a substance
- the potential for abuse of a substance
- any other matters that the Secretary considers necessary to protect public health

The following discussion identifies a range of issues in relation to heat-not-burn products (also known as heated tobacco products) that may be relevant to consideration of the matters under section 52E.

1. The risks and benefits of the use of a substance

The current evidence in relation to the safety of these products is primarily from tobacco industry data and there is a lack of research on the long-term health impact of using heated tobacco products.

According to the World Health Organization, while some tobacco industry-funded research has concluded that there are significant health benefits of using heated tobacco products relative to standard cigarettes, there is currently a lack of evidence to confirm the accuracy of this conclusion[1]. The World Health Organization has also advised that additional independent research is required to confirm the validity of claims in relation to the reduced risk of harm from heated tobacco product use[6]. Additionally, the FDA has released a statement specifically in relation to heated tobacco products, which included the advice that all tobacco products have the potential to initiate nicotine dependence and contain 'toxic, cancer-causing chemicals that can cause serious health problems'[7]. Furthermore, Public Health England, in its latest evidence review, concluded that '…it is currently not clear whether heated tobacco products provide any advantage as an additional potential harm reduction product'[8].

[6] *Heated tobacco products information sheet.* World Health Organization, 2018, https://www.who.int/tobacco/publications/prod_regulation/heated-tobacco-products/en/

[7] *How are Non-Combusted Cigarettes, Sometimes Called Heat-No-Burn Products, Different from E-Cigarettes and Cigarettes?* United States' Food and Drug Administration website, 2019, https://www.fda.gov/tobacco-products/products-ingredients-components/how-are-non-combusted-cigarettes-sometimes-called-heat-not-burn-products-different-e-cigarettes-and

[8] McNeill, Ann Denise, et al. "Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England." 2018, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/684963/Evidence_review_of_e-cigarettes_and_heated_tobacco_products_2018.pdf

[redacted]

Therefore there is currently insufficient evidence to demonstrate that heated tobacco products will substantially reduce health risks among users compared to smoking and that they will replace conventional cigarette use among current smokers without attracting youth uptake[9].

2. The purpose for which a substance is to be used and the extent of use of a substance

According to the proposal outlined in the application, the purpose of heated tobacco products is to provide current Australian smokers, who are not able to quit, access to an alternative product which is safer to use. Additionally the application indicates that these products have generally low attractiveness to never smokers and former smokers, do not generally interfere with quitting intent, and have generally low attractiveness to youth[10].

Due to a lack of scientific evidence on the health effects of these products, conclusions cannot yet be drawn about the ability of these products to assist with smoking cessation, the potential that they will attract new youth tobacco users, or their interaction with conventional tobacco use and/or e-cigarettes for 'dual users'[6].

In order to assess the safety of heated tobacco products as a reduced risk product, future independent research is required.

3. The toxicity of a substance

Research indicates that aerosol from heated tobacco products contains toxic compounds, including carcinogens[11,12]. Additionally, the US FDA has concluded that the aerosol from the heated tobacco product - IQOS (I Quit Ordinary Smoking) - contains several probable or possible carcinogenic chemicals that are unique to these products or present in higher levels than conventional cigarette smoke. The aerosols also contain a range of chemicals that may have genotoxic properties, as well as pulmonary and immune toxicities and other potential health effects[12,13].

In relation to exposure to second-hand emissions, heated tobacco products used indoors can also result in exposure to potentially harmful submicronic particles[14].

4. The dosage, formulation, labelling, packaging and presentation of a substance

In its submission, the applicant states that '…HTP [Heated Tobacco Products] have a role to play in risk reduction by facilitating a move to a lower risk product'[10]. Therefore, in the event

[9] Bilaous, Stella A, and Stanton A Glantz. "Heated Tobacco Products: Another Tobacco Industry Global Strategy to Slow Progress in Tobacco Control." *Tobacco Control*, vol. 27, supp. 1, 2018, pp. s111-117. https://tobaccocontrol.bmj.com/content/27/Suppl_1/s111.info

[10] *Application to Amend the Poisons Standard, Request for Scheduling Exemption*. Philip Morris Limited, 2019. http://www.medianet.com.au/releases/release-details.aspx/?id=926112&k=4246458

[11] Ruprecht, Ario Alberto, et al. "Environmental pollution and emission factors of electronic cigarettes, heat-not-burn tobacco products, and conventional cigarettes." *Aerosol Science and Technology*, vol. 51, no. 6, 2017, pp. 674–684. https://doi.org/10.1080/02786826.2017.1300231

[12] *Premarket Tobacco Product Marketing Orders*. Food and Drug Administration, 2019. https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders

[13] Moazed, Farzad, et al. " Assessment of industry data on pulmonary and immunosuppressive effects of IQOS." *Tobacco Control*, vol. 27, no. 1, 2018, pp 20 – 25. https://www.ncbi.nlm.nih.gov/pubmed/30158203

[14] Protano, Carmela, et al. "Second-hand smoke exposure generated by new electronic devices (IQOS(r) and e-cigs) and Traditional Cigarettes: Submicron particle behaviour in human respiratory system." *Annali Di Igiene*, vol. 28, no. 2, 2016, pp. 109–12. 10.7416/ai.2016.2089

that these products were approved for sale in Australia, it is likely that their labelling and presentation by the producer would emphasise the safety of these products compared to conventional cigarettes. Presenting the product in this way is likely to attract new users, including smokers who find it difficult to quit. Consequently, it is unknown whether the sale of these products as a safer alternative to tobacco products will decrease population smoking cessation rates. Furthermore, it is possible that these products, if approved for sale in Australia, would become popular among young people, undermining the success in achieving significant decreases in tobacco product use among young people nationally in recent years. Research supports the notion that these products are attractive to youth and young adults, as they are often depicted as sophisticated, high-tech and aspirational items[15].

5. The potential for abuse of a substance

The application states that heated tobacco products contain nicotine[10]. The highly addictive properties of this chemical[16], pose a significant risk of initiating nicotine dependence among young people[17]. Furthermore, existing smokers who may otherwise successfully quit might be attracted to sustain their consumption of nicotine through heated tobacco products due to their perceived relative safety.

6. Any other matters that the Secretary considers necessary to protect public health

1.1. Use of menthol

The application under consideration indicates that menthol flavours will be used in the heated tobacco products if they are approved for sale in Australia[10]. Research indicates that menthol flavouring in conventional tobacco products increases the attractiveness of the products to young people who are not experienced in using such products[18,19], as it creates a cooling effect, reduces the harshness of the taste and suppresses coughing[20]. It is likely that a similar effect would occur in heated tobacco products, increasing the consumption of these products among young people and possibly leading to nicotine dependence. Evidence also indicates that menthol can inhibit the quitting of conventional cigarettes[21], and there is a risk that this effect may extend to heated tobacco products.

The WHO FCTC's Partial Guidelines for Implementation of Article 9 and 10 specifically recommend that parties prohibit or restrict ingredients that may be used to increase the palatability of tobacco products, such as menthol, and regulate design features that increase

[15] Hair, Elizabeth C, et al. "Examining perceptions about IQOS heated tobacco product: consumer studies in Japan and Switzerland."*Tobacco Control*, vol. 27, no. 1, 2018, pp. 70-73. doi:10.1136/tobaccocontrol-2018-054322

[16] *Tobacco/Nicotine: Is Nicotine Addictive?* National Institute on Drug Abuse, 2020. https://www.drugabuse.gov/publications/research-reports/tobacco/nicotine-addictive

[17] *E-Cigarette use among youth and young adults: A report of the Surgeon General* . US Department of Health and Human Services, 2016. https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_non-508.pdf

[18] Hersey, James C, et al. "Are menthol cigarettes a starter product for youth?" *Nicotine & Tobacco Research*, vol. 8, no. 3, 2006, pp. 403–413. https://doi.org/10.1080/14622200600670389.

[19] Villanti, Andrea C, et al. "Menthol brand switching among adolescents and young adults in the National Youth Smoking Cessation Survey." *American Journal of Public Health*. vol. 102, no. 7, 2012, pp.1310–1312. https://doi.org/10.2105/AJPH.2011.300632.

[20] Hersey James C, et al. "Menthol cigarettes contribute to the appeal and addiction potential of smoking for youth." *Nicotine & Tobacco Research*, vol. 2, 2006, pp.136-146. 10.1093/ntr/ntq173

[21] Foulds, Jonathan, et al. "Do smokers of menthol cigarettes find it harder to quit smoking?" *Nicotine & Tobacco Research,* vol. 2, 2010, pp. 102-109. 10.1093/ntr/ntq166

the attractiveness of tobacco products[22]. Consistent with these guidelines, it is important to consider the impact of allowing the use of menthol in heated tobacco products.

1.2. Implications for public health

There has been a considerable downward trend in smoking rates in Australia in recent decades, achieved through a comprehensive and evidence-based approach to tobacco control. There is a significant risk that these gains could be undermined with the approval of the sale of heated tobacco products, and the subsequent uptake of these products by young people and smokers who may otherwise quit. Consequently, acknowledging the potential risks associated with the use and the likely labelling and presentation of heated tobacco products as less harmful than conventional cigarettes, [redacted] does not support the proposal to exempt nicotine from Schedule 7 of the Poisons Standard for use in tobacco prepared and packed for heating, until scientific evidence establishes the safety of these products and their broader impact on population health outcomes.

[22] *Partial Guidelines for implementation of Articles 9 and 10 of the Convention*. World Health Organization Framework Convention on Tobacco Control, 2010. https://www.who.int/fctc/guidelines/Guideliness_Articles_9_10_rev_240613.pdf?ua=1