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via email: medicines.scheduling@health.gov.au

To whom it may concern

Re: Public consultation on proposed amendments to the Poisons Standard – Nicotine

Thank you for the opportunity to provide comment on the proposed amendments to the Poisons Standard regarding the scheduling of nicotine.

The South Australian Health and Medical Research Institute (SAHMRI) is South Australia's flagship health and medical research organisation. Our vision is to conduct inspired research that will lead to better health outcomes. SAHMRI houses the Health Policy Centre, which is a collaboration with the University of Adelaide. The Health Policy Centre is focused on primary prevention of non-communicable diseases through the core drivers of tobacco use, diet, alcohol consumption, and metabolic risk factors including overweight/obesity. This centre includes the Tobacco Control Research and Evaluation program which conducts research and monitoring into contemporary issues surrounding tobacco use in South Australia.

The Health Policy Centre strongly opposes the proposed amendment to the scheduling of nicotine to exempt tobacco prepared and packed for heating. For reasons outlined below supplemented by evidence herein, such an amendment:

1. Carries considerable risk of harm to the public (Section 52E(1a) of the *Therapeutic Goods Act 1989*);
2. Does not clearly provide a public health benefit based on current evidence (Section 52E(1a) of the *Therapeutic Goods Act 1989*);
3. Has the potential for abuse of a substance (Section 52E(1e) of the *Therapeutic Goods Act 1989*); and
4. Would be inconsistent with Australia's obligations as a party to the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC).

Evidence of a public health risk

Independent research has found that heated tobacco product (HTP) aerosols contain many of the same harmful or potentially harmful substances also found in cigarettes (e.g. polycyclic aromatic hydrocarbons, carbon monoxide, formaldehyde cyanohydrin, tobacco-specific nitrosamines), including known carcinogens (1-5). Independent animal studies have found that exposure to HTPs is associated with harms to pulmonary function of a similar magnitude as exposure to cigarette smoke (6). Most research regarding HTPs has focused on the HTP named [redacted]'. An independent assessment of data from animal and human studies conducted by the manufacturer of [redacted] found that these studies also failed to show significant improvements in pulmonary function after three months of using [redacted] in place of combustible cigarettes (7). The manufacturer has also reported several cases of worsening pulmonary function and respiratory infection associated with human [redacted] use in their adverse data reports (7). Based on a review of the current evidence, the WHO advises that all forms of tobacco use are harmful, including HTPs, reflecting that tobacco is inherently toxic and contains carcinogens even it is natural form (8).

In addition, while HTPs may produce lower emissions than cigarette smoke of some harmful and potentially harmful constituents, they produce significantly higher emissions of other constituents (4). The impact of these other constituents on the overall toxicity of HTPs is not known (4), but may signal the potential for additional harmful effects not found with combustible cigarettes. Preclinical and clinical data submitted to the US Food and Drug Administration (FDA) regarding [redacted] indicate possible unexpected liver toxicity (9). The potential for harm from secondhand exposure to HTP aerosols requires further research, with a study finding that people exposed to secondhand HTP emissions experienced symptoms including sore throat, eye pain, and feeling ill (10).

Amending the schedule to exempt HTPs also risks renormalising smoking behaviour by creating a new market for tobacco products, undermining Australia's successes in significantly reducing the prevalence of tobacco use (11). In Italy, where the HTP [redacted] is available, a representative survey found that the number of never-smokers who had tried [redacted] was comparable to that of current smokers, and the number of non-smokers intending to try [redacted] exceeded that of current smokers (12). Studies regarding the marketing of novel tobacco products (including HTPs and e-cigarettes) have found these products tend to be attractive to youth (13). HTPs may also serve as a gateway product for tobacco use: non-cigarette tobacco product use, including use of smokeless tobacco products like HTPs, has been found to increase the odds that young non-smokers progress to combustible cigarette smoking (14).

Insufficient evidence to support a public health benefit

Contrary to the reasons for the proposal put forward by the Applicant, independent research has not indicated that heated tobacco products (HTPs) cause significantly less harm to users than combustible cigarettes. Despite claims by HTP manufacturers that HTPs reduce risk because they produce lower emissions of harmful and potentially harmful constituents than combustible cigarettes, this reduced exposure has not been shown to translate to reduced health risks, with [redacted] and conventional cigarettes showing no significant differences in most biomarkers of potential harm (15), and no improvements in pulmonary function from switching from conventional cigarettes to [redacted] (7), in the manufacturer's own research data. Also, as noted above, HTPs produce higher emissions than combustible cigarettes of other constituents (4) and there are some indications of unexpected harms such as organ toxicity (9). In addition, in markets where HTPs are currently available, HTPs users typically use HTPs in conjunction with combustible cigarettes (dual use), rather than as an alternative to combustible cigarettes (10, 16), suggesting that making HTPs available via the proposed amendment is unlikely to substantially reduce use of combustible cigarettes.

Consistent with the evidence not supporting health benefits compared with combustible cigarettes, in January 2018, the FDA Tobacco Product Scientific Advisory Committee recommended against FDA approval of reduced risk claims of the HTP [redacted] (17). The Committee concluded that the evidence did not support claims that switching from cigarettes to [redacted] reduces the risks of tobacco-related diseases or presents less risk of harm than continuing to smoke cigarettes. They also concluded that while switching from cigarettes to [redacted] may reduce the body's exposure to harmful or potentially harmful chemicals, the applicant had not demonstrated that these reductions in exposure were reasonably likely to translate to a measurable and substantial reduction in morbidity and/or mortality. Regulators in Canada (18) and Europe (19) also prohibit marketing of HTPs in ways that suggest they are less harmful than other tobacco products, contrary to the Applicant's claims that HTPs have been accepted by regulators as a better alternative than continued smoking for adults who do not quit.

We also note that there is no need for an amendment to the schedule to allow nicotine-containing products on the basis of a health benefit, as the current scheduling of nicotine already has an exemption for nicotine-containing products for human therapeutic use. This existing exemption applies to products that have been through an independent Therapeutic Goods Administration process to demonstrate the evidence of their therapeutic benefit in aiding smoking cessation. Allowing the proposed amendment would circumvent this rigorous process.

Potential for abuse of a substance

Evidence shows that nicotine is highly addictive, and as a result, nicotine-delivering products such as HTPs have a high potential for abuse by inducing nicotine dependence. Nicotine in HTPs appears to be more readily absorbed than from combustible cigarettes: in animal studies, nicotine levels have been found to be 4.5 times higher in rats exposed to HTPs compared to combustible cigarettes, despite lower levels of nicotine in the HTP aerosol than in the cigarette smoke (6). HTPs may also be smoked more heavily due to elements of the product design and marketing, increasing the risk that users will become nicotine dependent. The product design may encourage users to smoke at a rapid pace to fully maximise each tobacco plug, leading to an increased intake of nicotine (2). Design features in the [redacted] such as Bluetooth functionality are used to deliver messages to consumers such as 'you haven't used your [redacted] device today' and reminding them to reorder tobacco plugs, encouraging continuous use of nicotine (11). There is also a risk that dual use of HTPs alongside combustible cigarette may increase these users' total nicotine absorption (16). The above-noted risk of uptake by never-smokers means that amending the schedule to exempt HTPs may lead to an increase in the proportion of the Australian population addicted to nicotine (12).

Obligations under the WHO Framework Convention on Tobacco Control (FCTC)

As noted in the TGA's consultation documents regarding Australian regulations for HTPs, the Australian Government supports the cessation of smoking rather than harm reduction, and is a Party to the WHO FCTC (20). This obliges Australia to implement laws to reduce tobacco use and nicotine addiction. As argued above, amending the schedule to exempt HTPs and thereby allowing them into the Australian market is likely to increase tobacco consumption and nicotine addiction, undermining efforts to reduce tobacco use. Therefore, the simplest and most effective way for Australia to deal with HTPs under the FCTC is to prohibit them, as under the current scheduling for nicotine (11). Prohibiting HTPs is consistent with:

- the objective of the FCTC to "protect past and future generations from the devastating health, social, environmental and economic consequence of tobacco consumption and exposure to tobacco smoke" (Article 3);
- FCTC guidelines to "take measures to prevent the initiation, to promote and support cessation, and to decrease the consumption of tobacco products in any form" (Article 4), which the WHO has confirmed includes HTPs (8);

- FCTC general obligations to “adopt and implement effective legislative, executive, administrative and/or other measures…for preventing and reducing tobacco consumption, nicotine addiction and exposure to tobacco smoke” (Article 5); and
- The Conference of Parties to the WHO FCTC decision 8 (22) regarding novel and emerging tobacco products, which recommends that parties prioritise measures “to regulate, including restrict, or prohibit, as appropriate, the manufacture, importation, distribution, presentation, sale and use of novel and emerging tobacco products, as appropriate to their national laws, taking into account a high level of protection for human health” (21).

Based on the above analysis, the Health Policy Centre of the South Australian Health and Medical Research Institute and the School of Public Health at University of Adelaide strongly oppose the proposed amendment to the scheduling of nicotine to exempt tobacco prepared and packed for heating.

Please do not hesitate to contact me if you have any questions regarding this submission.

Sincerely

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