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Dear Sir/Madam

Re: TGA CONSULTATION – PROPOSED AMENDMENTS TO THE POISON STANDARD (NICOTINE)

As the voice of stroke in Australia, Stroke Foundation is writing to provide comment on the proposed amendment to the listing of nicotine under Schedule 7 of the Poisons Standard, to exempt tobacco prepared and packed for heating.

The Stroke Foundation does not support the proposed amendment.

People who smoke tobacco are twice as likely to have a stroke compared with those who have never smoked.¹⁻⁴ The more an individual smokes the greater their risk of stroke.⁴ Importantly, an individual's risk of stroke decreases after they quit smoking and stopping smoking has been shown to have both immediate and long-term health benefits. Two to five years after quitting, there is a large drop in an individual's risk of stroke⁵, and after 15 years their risk of stroke is similar to that of a person who has never smoked.⁵ Therefore, Stroke Foundation is strongly supportive of measures to reduce the prevalence of the smoking of tobacco, in any form, in the Australian community.

Stroke is one of this nation's biggest killers and the leading cause of adult acquired disability. This year there will be more than 56,000 strokes in Australia, and there are more than 475,000 stroke survivors living in our community.⁶ Yet, Research indicates that 80 percent of strokes can be prevented.⁷

The Applicant for the proposed amendment to the listing of nicotine claims heated tobacco products (HTPs) are safer than conventional combustible cigarettes (CCs) as their technology limits combustion and the generation of toxicants and hazardous compounds, making them a better alternative for those who would otherwise continue to smoke CCs.

The Stroke Foundation does not support the proposed amendment, and the key reasons for this are outlined below.

Evidence of the risk and harms associated with HTPs

Tobacco contains nicotine. Nicotine is toxic and is linked to health harms, particularly in children, adolescents and pregnant women⁸, but more importantly it is highly addictive. While

the nicotine in TGA-approved nicotine replacement therapy products has a proven therapeutic benefit and assists smoking cessation, there is currently no evidence of HTPs as an effective smoking cessation aid.

As HTPs are relatively new to the market, the long-term health effects of these products are largely unknown. However, systematic reviews of the available evidence have shown toxicants generated by HTPs are similar to those generated by CCs, and that exposure to a number of harmful and potentially harmful toxicants is lower compared with CCs.^{9, 10} There are some chemicals, such as the potentially carcinogenic substance acenaphthene, which are released in higher amounts in HTPs compared with CCs.¹¹ In addition, there is limited evidence of new chemicals in HTPs that are not present in CCs, which could have some degree of toxicity and related harm.⁸ Importantly, there is no evidence to suggest that the use of HTPs will result in a reduction in tobacco-related diseases compared with CCs.

To date, the majority of available studies on HTPs have been sponsored by the tobacco industry, as such there is a need for independent studies examining the long-term health impacts of HTP use.

Manufacturer claims about reduced exposure with HTPs are likely to be misinterpreted by the public as claims of reduced risk

For many years, the tobacco industry has used claims of reduced exposure to mislead consumers into believing that the products in question have reduced risk. The most noteworthy example of this was the use of 'light' and 'filter' cigarette claims. Studies have now examined if manufacturer claims of reduced exposure for new HTPs are perceived by consumers as claims of reduced risk.^{12, 13}

One paper examined studies evaluating perceptions of reduced risk claims submitted by ██████████ to the United States of America (US) Food and Drug Administration (FDA) as part of its application seeking authorisation to market its HTP named ██████████.¹³ It was found adult consumers in the US perceived reduced exposure claims as reduced risk claims.¹³

Another study focused on the company's statement that 'switching completely to the HTP ██████████ reduces risk'.¹² It was found the evidence provided did not support the company's claims current smokers: (1) would understand what is meant by the phrase 'switching completely'; (2) the proposed claims would not decrease smokers' intentions to quit; and (3) ██████████ users would in fact 'switch completely' from smoking cigarettes to using ██████████.¹²

The vast majority of smokers regret having taken up smoking^{14, 15}, and between 50 and 75 percent want to quit. If the proposed amendment is introduced, there is a risk smokers who otherwise would have quit, may instead switch or partially switch to HTPs. Dual use with CCs is high for other harm reduction products such as e-cigarettes (between 70 and 80 percent)¹⁶,¹⁷, and evidence suggests this is also likely to be the case for HTPs.¹⁸ Importantly, dual use is unlikely to result in a reduction in overall harm.

The take-up of HTPs by non-smokers and young people

If the proposed amendment was introduced, it may contribute to the renormalisation of smoking in the community. There is potential non-smokers may be recruited. A 2019 study

examining HTP awareness and use in Italy found three years after the launch of ██████ (the only HTP available in the country), 739,000 people had tried the product, including 329,000 never smokers.¹⁹ In addition, among Italian adults who expressed their intention to try ██████ in the future (1,250,000), the number of non-smokers (never or ex-smokers) (619,000) exceeded current smokers.¹⁹

HTPs are being marketed as 'modern, hightech and high-end lifestyle products, with minimalist designs, a presence in flagship stores, and high-profile product launches'.⁸ HTPs are portrayed as 'attractive and harmless luxury consumer products'.⁸ These tactics, which have been used previously to promote cigarettes, are proven to be effective in targeting young people.⁸

One study which examined data from tobacco company ██████ own studies submitted to the FDA, found that these studies failed to provide evidence that young people would not find ██████ appealing, would not initiate use of the product and would not perceive these products as risk free.²⁰ In addition, evidence from independent scientific studies suggested that the introduction of the HTP ██████ would result in adolescent and young adult non-users initiating tobacco use with ██████.²⁰

Australia's obligations under the World Health Organisation Framework Convention on Tobacco Control

The WHO Framework Convention on Tobacco Control (FCTC), to which Australia is a Party, As outlined in Article 5.3 of the FCTC, Australia must protect public health policies with respect to tobacco control from interference by the tobacco industry. The proposed amendment would undermine the Australian Government's current tobacco control policies and is therefore inconsistent with the FCTC. While this issue is beyond the scope of the *Therapeutic Goods Act 1989*, it is still an important consideration for the Government.

The Australian Government's current tobacco control regulatory arrangements, as part of a suite of public health policy initiatives including health promotion and increased taxation on tobacco products, has had a significant impact on the prevalence of smoking over the last three decades. Specifically, the daily tobacco smoking rate for people aged 14 years and over has fallen steadily from 24 percent in 1991 to 12 percent in 2016.²¹ Tobacco advertising and plain packaging legislation have helped achieve this by discouraging people from using tobacco products, encouraging people to give up using tobacco products, and discouraging relapse of tobacco use. It is likely that this fall in the prevalence of smoking in the Australian community has contributed in part to the observed reduction in the rate of stroke events in recent years (26 percent fall between 2000 and 2015).²²

The proposed amendment does not support the Australian Government's effective tobacco control policy initiatives, and may ultimately undermine its goal of reducing smoking and Stroke Foundation's goal of reducing the number of preventable strokes, in Australia.

Stroke Foundation is a member of the Australian Chronic Disease Prevention Alliance (ACDPA), and endorses the ACDPA's submission to this consultation, as well as the joint submission of Cancer Council Australia and Heart Foundation.

Thank you for the opportunity to provide comment on the proposed amendment.

Yours sincerely,

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About Stroke Foundation

Stroke Foundation is a national charity that partners with the community to prevent stroke, save lives and enhance recovery. We do this through raising awareness, facilitating research and supporting stroke survivors.

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