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Proposed amendment to the Poisons Standard – nicotine

Submission from Cancer Council Australia, National Heart Foundation of Australia and Australian Council on Smoking and Health, February 2020

Content is authorised by [redacted], [redacted] *of the joint Tobacco Issues Committee of Cancer Council and the National Heart Foundation.*

Summary

Cancer Council Australia, the National Heart Foundation of Australia and the Australian Council on Smoking and Health strongly oppose the application to amend Schedule 7 of the Poisons Standard to exempt "tobacco prepared and packed for heating". We strongly recommend the upholding of the current scheduling of nicotine in the Standard to protect Australians from the risks of exposure to the toxicity and addictiveness of nicotine through products providing no therapeutic benefit.

In view of the evidence, the proposal carries a significant risk to public health in Australia and is inconsistent with longstanding, effective, evidence-based public policy positions which have significantly reduced the health harms of tobacco use driven substantially by nicotine addiction in Australia over the past several decades.

There is no evidence of heated tobacco products (HTPs) conferring any public health benefit; there are, however, significant risks of harm, as supported by the evidence and outlined in the following analysis.

Key points informing our recommendations:

- Nicotine is a harmful and highly addictive toxin; current protections against the toxicity and addictiveness of nicotine under the Poisons Standard should remain in place for the health and safety of the Australian public;
- There is no evidence to support the Applicant's claims in relation to the objects (i.e. controls for the quality, safety, efficacy and timely availability of therapeutic goods) or intent (i.e. public health and safety and the efficacy of therapeutic goods) of the *Therapeutic Goods Act 1989*;
- There is no evidence to support the Applicant's claims in any scientific context that HTPs are a "a better alternative for current Australian smokers who do not quit";
- The application's claims to a "better alternative…" are fundamentally inconsistent with evidence-based Australian tobacco control policy across all jurisdictions and health authorities, which is based on reduced smoking prevalence through prevention of uptake and promotion of cessation – not unsubstantiated claims about reduced harm in a recreational product;
- TGA support for the Applicant's proposal would set a dangerous precedent as it would result in a lowering of the bar for poisons scheduling in response to unsubstantiated claims with no relevance to therapeutic goods;
- HTPs cause significant health harms in the delivery of nicotine and have also been shown to undermine quit attempts, which, along with discouraging uptake, are the

only established, evidence-based method of protecting smokers from the toxicity and addictiveness of nicotine in tobacco products;

- Any form of labelling, packaging or promotion of HTPs would be contrary to the spirit and intent of existing evidence-based legal and regulatory instruments in Australia – e.g. the *Plain Packaging* and *Tobacco Advertising Prohibition* acts, intended to deter the use of the associated products; or labelling requirements under the *Therapeutic Goods Act*, which are designed for therapeutic goods only, not harmful recreational items promoted as harm-reduction products on unsubstantiated claims. These anomalies further highlight the dangers and unsuitability of approving the sale of HTPs through amendments to evidence-based Australian health policy settings;
- Despite claims of the benefits of HTPs and support for their promotion overseas, key international and national health agencies, such as the World Health Organization and the US Centers for Disease Control advise against their promotion;
- Claims in support of HTPs and other novel products are based substantially on tobacco industry-funded research, which cannot be accepted as it stands - the World Health Organization's expert Study Group on Tobacco Regulation has advised that "Independent scientific evidence is required to verify the claims of industry scientists for reduced exposure and risk".
- Take-up of HTPs in young people is high in countries where they have been made available, a major concern in Australia, which has one of the world's lowest rates of tobacco use in youth and young adults.
- Even in the past week new papers have been published in the literature confirming youth-oriented marketing as a cause for public health concern. This is critical, given overwhelming evidence over more than 50 years that tobacco companies will circumvent measures intended to protect youth from industry marketing;
- Evidence on how HTPs are marketed overseas, including through social media, with misleading, inappropriate claims appealing to youth, show their availability would risk undermining and distracting from evidence-based approaches to reducing smoking;
- The federal Minister for Health, the Hon. Greg Hunt MP, has committed to a smoking prevalence target of below 10% by 2025. Promotion of HTPs will not reduce prevalence; rather, their availability is likely to increase prevalence due to their use undermining quit attempts, their popularity with and promotion to younger age groups encouraging take-up and new levels of nicotine exposure, and distraction from evidence-based measures;
- The current exemption of nicotine from Schedule 7 for "tobacco prepared and packed for smoking" is the result of a historical anomaly, caused by the tobacco industry's uncontrolled mass-marketing of tobacco products before the health harms were fully understood and incremental control measures introduced. The only feasible way to fix this anomaly is through further evidence-based tobacco control measures to significantly reduce the prevalence of tobacco use and nicotine addiction in Australia;
- It took many years for the harms of smoking to be understood (as indeed for a range of other harmful products). The evidence on the impacts of HTPs is still at early stage, some of it confused by research funded and promoted by tobacco companies.
- Our submission addresses these concerns in respect of section 52E of the *Therapeutic Goods Act 1989* as follows.

Analysis

The current scheduling of nicotine recognises that nicotine is a dangerous and addictive poison, consistent with the safety and efficacy provisions of the *Therapeutic Goods Act 1989*

(Cth)('the Act'). The exemption for preparations for human therapeutic use applies to smoking cessation aids that are shown through rigorous evaluation to be safe and effective.

The Applicant's proposal seeks to circumvent the safety and efficacy provisions of the Act. As well as being out-of-step with the provisions and intent of the Act, the Applicant's proposal highlights that HTPs are a tobacco product, not a therapeutic good. Therefore, amending the Poisons Standard in response to a proposal designed to promote the use of a product of no therapeutic benefit is also out-of-step with the provisions and intent of the Act and the function of the TGA.

The exemption for tobacco prepared and packed for smoking is an historical anomaly; it is not a reference point against which proposals to amend the scheduling of nicotine should be assessed. To do so would in our view be a logical and legal error, as it would set a very low threshold for exercise of the power to amend the Poisons Standard. Such an approach is contrary to the text and intent of the *Therapeutic Goods Act 1989* (Cth)('the Act').

In exercising the power to amend the Poisons Standard, the Secretary must carefully consider the matters outlined in s 52E(1) of the Act. The task at hand is not to determine whether HTPs are a 'better alternative' to combustible cigarettes, as claimed by the Applicant.

The relevant matters in s 52E(1) are in relation to 'a substance', defined by s 52A(1) as an 'ingredient, compound, material or preparation which, or the use of which, may cause death, illness or injury to persons or animals.' In this case, we submit that the substances are nicotine, tobacco and more specifically, HTPs.

The evidence shows there is significant risk in amending the Schedule to enable the sale and promotion of HTPs in relation to all key matters covered by Section 52E (a-) of the Act, as summarised below.

(a) the risks and benefits of the use of a substance

Nicotine

While TGA-approved nicotine replacement therapy (NRT) products are aids for smoking cessation, nicotine in tobacco products confers no health benefit. There is no substantive evidence to support the use of HTPs as a smoking cessation aid. The availability of nicotine in registered NRT products is the result of an independent TGA process based on evidence of therapeutic benefit – i.e. the established benefits of smoking cessation.

Nicotine as a substance is a highly toxic and addictive poison. The documented harms of nicotine as a toxin are wide-ranging and include, inter alia: psychosis (across the life course including through antenatal exposure); carcinogenesis; tumour progression; cardiovascular, respiratory and gastrointestinal disease; impaired organ development; abdominal aortic aneurysm; compromised responses to medical care; and perinatal morbidity. (See page 7)

Given the high toxicity of nicotine in relation to multiple significant harms, the evidence supports the current scheduling of nicotine as a Schedule 7 poison in relation to health claims with the exemption for therapeutic goods as approved by the TGA. (Noting that the exemption of tobacco prepared and packed for smoking is an historical anomaly caused by mass-marketed tobacco products, as discussed in Appendix A.)

Heated tobacco products

Heated tobacco products (HTPs) have not been demonstrated to be safe for use by humans. Most studies to date on the health effects of HTPs have been funded by the manufacturers

of the products. Of 11 trials of HTP use by humans, only one was not affiliated with a tobacco manufacturer.[1] Manufacturers researching their own or competitor products experience a conflict of interest that can bias findings and interpretations. [2] Furthermore, none of these trials of HTP use by humans registered a protocol before the enrolment of the first participant.[1] Five RCTs demonstrated that switching from combustible cigarettes to HTPs reduces but does not eliminate exposure to harmful and potentially harmful compounds (HPHC).[1] HPHCs are chemicals or chemical compounds in tobacco products or tobacco smoke that cause or could cause harm to smokers or non-smokers. Whether reduced exposure will lead to meaningful reductions in human health risks is yet to be established.[3]

Several independent studies found that the vapour from HTPs contained toxic compounds including carcinogens such as polycyclic aromatic hydrocarbons.[4-10] The US Food and Drug Administration (FDA) found that the [redacted] (Phillip Morris International (PMI) HTP product) vapour contains several probable carcinogenic chemicals that are unique to [redacted] or present in higher levels than combustible cigarette smoke.[11]

Toxicants like tobacco-specific N-nitrosamines, formed primarily during curing and processing of tobacco rather than by combustion, were also present in the filler of HTP consumables. Other substances, such as propylene glycol, glycidol, acetol, and 2-propen-1-ol have been shown to be elevated in comparison to combustible cigarettes, due to the higher amount of humectants in the tobacco filler of the HTP consumable.[11]

Independent studies demonstrate that the use of HTPs impacts lung health. One study reviewed the data on pulmonary and immune toxicities associated with [redacted] from PMI's application to the US FDA.[12] Researchers found no evidence of improvement in pulmonary inflammation or pulmonary function in cigarette smokers who switched to [redacted] These researchers concluded that [redacted] use was associated with significant pulmonary and immunomodulatory toxicities with no detectable differences between conventional cigarette smokers and those who were switched to [redacted] in PMI's studies.

Evidence on second-hand emissions on HTP suggests that users and bystanders are exposed to measurable levels of particulate matter and harmful constituents.[1]

There is also a lack of data the on long-term effects on health from HTPs. Tobacco use is a risk factor for 16 types of cancer [13], as well as chronic lung diseases such as chronic obstructive pulmonary disease (COPD), asthma, pulmonary fibrosis.[14] It took nearly five decades to understand the detrimental health effects of cigarette smoke on humans.

The Applicant's claim that HTPs are a 'better alternative' is unsubstantiated and obfuscates significant risks to public health. These risks are addressed below in relation to both non-smokers and smokers. The sale of HTPs in Australia risks increasing the prevalence of tobacco use by attracting young people and non-smokers to a new product and by reducing rates of smoking cessation. Based on overseas evidence, at a population level the outcome would be a net increase in exposure to nicotine and the burden of tobacco-related disease.

<u>Non-Smokers</u>

As a result of effective tobacco control measures over the past few decades, smoking prevalence among adolescents in Australia is at a record low. HTPs are currently aggressively marketed at young people in other countries. HTPs have been extensively promoted overseas as modern, technology-centric lifestyle products. Their sleek, minimalist designs (which researchers have observed closely mimic Apple's iPhone and other high-tech electronic products) are particularly appealing to youth.[15] The fact that HTPs come in a range of characterising flavours such as lime and blueberries reinforces their likely appeal to young people. Even at this early stage in their history, there is both evidence and major

concern from countries where they have been marketed about their appeal and promotion to young people, and risks that they will increase the onset of smoking.

Research suggests that the introduction of HTPs will result in adolescent and young adult non-smokers initiating tobacco use and could also increase poly-use of [redacted] along with other tobacco products. [16] Introduction of HTPs risks contributing to nicotine addiction and tobacco use among young people who would otherwise have been at low risk of initiation.

Research from countries which have already introduced HTPs have raised concerns that HTPs may represent a gateway for nicotine addiction among non-smokers as over half of the people interested in these products have never smoked. [17]

The only certain way to prevent uptake by vulnerable groups is to uphold the current scheduling of nicotine, which prevents the sale of HTPs in Australia.

International trends and risks posed in Australia

Smoking rates in Australians aged 18-24 are significantly lower than in 25-29-year-olds (12% compared with 16%, with a greater differential in males); rates are lower still, on a sharper descending trajectory, in Australian teenagers (e.g. 8.5% in 16-17 years-olds etc).[18,19]

Since 1984, smoking rates in Australian teenagers have declined at sharper rates than those of adults, which is thought to be the effect of comprehensive approaches to tobacco control and the de-normalisation of smoking in adult age groups. [18,19]

Trends in uptake and interest in HTPs in countries where they are available are a major concern in relation to smoking prevalence trends in Australia. That is, while the greatest net public health benefit in tobacco control in Australia has been through reduced prevalence and nicotine addiction in younger age groups, HTP marketing strategies and evidence of their impact overseas poses major risks to Australia's historic, world-leading low youth prevalence rates and their continued reduction on current trends.

For example, new research shows Philip Morris International's HTP-marketing claims of reduced risk and reduced exposure may entice youth to try and also continue to use these products [20], as reflected in trends in the US. In view of this evidence, the US FDA has been advised to "take great caution when considering MRTP [modified risk tobacco product] claims on any tobacco product packaging or in marketing campaigns, and should deny MRTP authorisation unless the manufacturer wishing to make such claims demonstrates that they are not misunderstood by adolescents and young adults". A recent study concluded misperceptions of associated harm, unsupported by the evidence, lead to tobacco-use initiation in this age group and warns that the "negative impact on public health could be great". [20]

The Applicant's proposal to exempt HTPs from Schedule 7 of the Poisons Standard in Australia would open the gate for this type of hazardous product promotion in Australia.

Smokers

The Applicant claims that HTPs would be for a large proportion of Australian smokers who are unwilling or unable to ever quit smoking. This purports that as smoking prevalence has declined, remaining smokers must therefore be hardened – the 'hardening hypothesis'. In fact, this hypothesis is not supported by Australian data. The proportion of smokers with 'hardcore' attributes was found to be just 6% in a study of smokers in New South Wales.[21] Prevalence of seven 'hardening' indicators also declined significantly in Victoria between 2001 and 2016: daily smoking, heavy consumption, no quit attempt in the past five years or past 12 months, no intention to quit in the next six months or next 30 days, and happiness to

keep smoking. The proportion of smokers who could be defined as ‘hardcore’ almost halved despite prevalence reducing from 20 to 13%. [22]

The vast majority of smokers regret having started to smoke and have made at least one quit attempt.[23] It follows that almost all current smokers in Australia are amenable to anti-smoking campaigns and cessation support (such as through the Quitline), which have been used successfully to drive down smoking rates.

The introduction of HTPs threatens to undermine quit attempts in this majority population of smokers. Evidence shows that most smokers will make many quit attempts before maintaining abstinence.[24] A person’s level of nicotine dependence is the strongest predictor of his or her ability to abstain, but motivational factors are also very important.

For many smokers, concerns about the health effects of smoking are a prompt to make a quit attempt. This is reinforced with graphic health warnings and anti-smoking mass media campaigns. The sale of HTPs, which are likely to be *perceived* as less harmful than combustible cigarettes, may therefore de-motivate smokers to quit.

It is entirely plausible that smokers who may have otherwise made a quit attempt on their path to cessation, will instead maintain their nicotine addiction by using HTPs. This is concerning because the long-term use of HTPs may not reduce the risk of chronic disease. In this scenario, the sale of HTPs would increase the prevalence and health burden of tobacco use and exposure to nicotine toxicity and addiction in Australia.

The World Health Organization (WHO) advises that there is no evidence to demonstrate that HTPs are less harmful than conventional tobacco products. Some tobacco industry-funded studies have claimed that there are significant reductions in the formation of and exposure to harmful and potentially harmful constituents relative to combustible cigarettes. However, there is currently no evidence to suggest even that reduced exposure to these chemicals translates to reduced risk in humans.[25]

Health authorities worldwide agree that the most effective, evidence-based way to reduce the harms of tobacco use and nicotine exposure is to reduce smoking prevalence, through a comprehensive approach, as outlined in the WHO Framework Convention on Tobacco Control, which entails the prevention of uptake in non-smokers and promotion of smoking cessation in smokers. As well as being inconsistent with systematic review evidence, internationally and in Australia, the Applicant’s proposal is out-of-step with the interpretation and application of the evidence in Australia and the functions and remit of the independent statutory authorities tasked with evaluation and policy advice. Australia’s fundamental position on tobacco control, across all statutory health agencies and jurisdictions, is based on this overall approach to prevalence reduction.

The only effective way to protect the population from the harms of nicotine toxicity is to reduce, and ultimately eliminate, smoking prevalence, which has fallen from 35% of the adult population (41% male, 30% female) in 1980 to circa 14% (16% male, 12% female) in 2016. (Note also a current Australian Government commitment to reduce smoking prevalence to 10% by 2025.)

(b) the purposes for which a substance is to be used and the extent of use of a substance

Nicotine

In view of the Applicant’s core business, shareholder-based/multinational business model and long history and current activity in undermining evidence-based tobacco control

measures, the likely purpose of the proposal is to establish new markets for the promotion of nicotine products. On all available evidence and analysis, the purpose of HTPs and the extent of their use is to promote a commercial market opportunity, with no evidence of therapeutic benefit.

As demonstrated, nicotine is a highly addictive substance and proven lucrative business opportunity – for which there is no public health benefit apart from via registered NRT products, designed and approved under specified conditions as therapeutic goods to support smoking cessation.

Tobacco

As above, in view of the Applicant's likely intent, the purpose is likely to be the opening of new markets for the promotion of highly addictive (and toxic) nicotine, naturally occurring in HTPs, alongside continued marketing and promotion of cigarettes - the companies' "core" tobacco products, and efforts to renormalise the industry and its products.

HTPs

The Applicant claims that HTPs are intended to be used for harm reduction by adult smokers who are unable to quit. However, evidence of the promotion and positioning of HTPs in countries where they are available indicates: the tobacco industry's intent to glamorise HTPs in a way contrary to the use of therapeutic goods; aggressive promotion of HTPs to young people, who do not suffer long-term nicotine addiction; activities contrary to the only evidence-base method to reduce the harms of tobacco, which is to reduce exposure to tobacco and nicotine.

(c) the toxicity of a substance

Nicotine

Nicotine is not a harmless substance. In addition to being addictive, evidence suggests that nicotine is a highly toxic substance, which is capable of producing adverse biological effects on virtually all systems of the body, including the cardiovascular, respiratory, renal and reproductive systems.[26]

Various studies have shown that nicotine also directly contributes to both the cause and growth of various forms of cancer.[27-28] Researchers have observed that nicotine can contribute to cancer in a number of ways 'through its genotoxic effects, as well as by facilitating tumour cell survival, growth, metastasis, resistance to chemotherapy or radiotherapy, and creating a tumour supporting environment…'[28] In this regard, we note the Advisory Group for the International Agency for Research on Cancer (the WHO's source for information about cancer) has included nicotine on its list of 'high priority' agents for assessment as a potential carcinogen in 2020-2024.[29]

In addition to contributing to the growth and onset of various forms of cancer, research indicates that the use of nicotine during pregnancy can affect foetal brain development. Prenatal exposure to nicotine appears to increase the risk of severe mental illness.[30] Furthermore, studies indicate that adolescent exposure to nicotine can lead to long-term changes in neural circuitry and behaviour, and may have severe consequences for adolescent addiction, cognition and emotion regulation.[31]

Tobacco

Tobacco is a highly toxic substance. Tobacco use is a risk factor for 16 types of cancer [13], as well as chronic lung diseases such as chronic obstructive pulmonary disease (COPD), asthma, pulmonary fibrosis.[14] WHO considers all forms of tobacco are harmful, including HTPs. WHO estimates that tobacco use kills more that 8 million people annually.[32] Claims about the reduced harms of HTPs do not stand up to independent scientific analysis.

Evidence also shows the only effective way to reduce the harms of tobacco is to reduce smoking prevalence, through evidence-based interventions to prevent uptake in non-smokers and to support cessation in smokers.

Moreover, promotion of tobacco products (and nicotine products of no established therapeutic benefit) confers significant risk of increasing, not reducing, harms associated with the toxicity of tobacco.

HTPs

Studies show that HTPs such as [redacted] are no less toxic than combustible cigarettes.[33] HTPs expose users to lower levels of some toxicants than combustible cigarettes, but they also expose users to higher levels of other toxicants.[33]

This is supported by the US FDA's finding that vapour from HTPs, such as [redacted] contains several probable or possible carcinogens that are unique to [redacted] or present in higher levels than combustible cigarette smoke.[34] The vapour from HTPs were found to contain 15 other chemicals that are possibly genotoxic and 20 more compounds that have potential health effects.[34]

Several independent studies found that the vapour from HTPs contained toxic compounds including carcinogens such as polycyclic aromatic hydrocarbons.[4-10]

Independent studies have examined second-hand emissions of HTPs. These studies have demonstrated that toxic components increase above background air levels with the use of HTPs.[35-37] A study in Japan, where HTPs have been sold since 2014, found that nearly half of non-smokers who had been exposed to second-hand emissions from HTP reported at least one acute symptom.[38]

(d) the dosage, formulation, labelling, packaging and presentation of a substance

Under current legislation, the packaging and labelling requirements for other tobacco products may not apply to HTPs. This is because the term 'tobacco product' is essentially defined in the *Plain Packaging Act* as 'processed tobacco, or any product containing tobacco that is manufactured for smoking, sucking, chewing or snuffing'.

The *Plain Packaging Act's* express purpose was to deter purchase of a highly addictive, dangerous substance. As discussed in Appendix A, the availability of smoked tobacco is a historical anomaly. All policy reform in Australia relating to the promotion and availability of tobacco, since the banning of broadcast tobacco advertising in the 1970s, has been designed to discourage its use. It would be a fundamental contradiction of the intent and effectiveness of the *Plain Packaging Act* to amend it to cover the promotion of new tobacco products being promoted by commercial interests to *encourage* use. At the same time, there are no provisions under the *Therapeutic Goods Act* through which the labelling, packaging and presentation of a product of no therapeutic benefit, could be mandated. This further emphasises the problems of the Applicant's proposal and its fundamental inconsistency with legal and regulatory instruments established in Australia to protect public health and safety.

Nicotine

Nicotine is a naturally occurring, and the most biologically active, constituent of tobacco delivered in heated form. The dosage of nicotine in HTPs is similar to that occurring in combustible cigarettes. Studies have further suggested that the delivery of nicotine through HTPs can occur at higher levels than in combustible tobacco products, through higher consumption levels among users, incorrectly thinking they are consuming a "healthier" product. Moreover, matters of dosage, formulation, labelling, packaging and presentation, as they relate to the intent of the *Therapeutic Good Act*, do not apply to the delivery of nicotine through HTPs, given there is no evidence of therapeutic benefit.

Tobacco

"Heated tobacco unit" in HTPs (also called HEETS or HeatSticks) contains a tobacco plug made from dried tobacco leaves, ground and re-constituted into tobacco sheets. The HeatSticks include a tobacco plug, hollow acetate tube, polymer-film filter, cellulose-acetate mouthpiece filter, and outer and mouth-end papers.

In shape and appearance, HeatSticks closely resemble combustible tobacco cigarettes, but are smaller. Therefore, as well as posing significant health risks, against which the community is protected by the *Therapeutic Goods Act*, HTP products as promoted in countries where they are available would likely contravene sections of the *Tobacco Advertising Prohibition Act*.

HTPs

As above, the dosage, formulation, labelling, packaging and presentation of nicotine in HTPs in particular is likely to contravene a number of Australian legislative and regulatory instruments.

In addition, their presentation in countries where they are available presents significant problems in relation to the intent of the Poisons Standard and the harms of nicotine, including:

- The high-tech, modern look/style of the product and appeal to young people.
- Packaging – See page 5.
- Presentation and associated use of the product (hand to mouth action, emission of tobacco vapour) and associated normalisation of smoking behaviours.

(e) the potential for abuse of a substance

HTPs

There is high risk of abuse of HTPs in the context of section (e), because the tobacco heating units (HeatSticks) contain a similar amount of nicotine as a combustible cigarette. If heating increases absorption of nicotine, then smokers may increase their nicotine addiction. This may also occur if smokers perceive HTPs as mild and use them more frequently. As previously discussed, the risk of abuse by young people and non-smokers is high. Smokers may also abuse HTPs as an alternative to TGA-approved NRTs.

(f) any other matters that the Secretary considers necessary to protect public health

Summary

To *protect* public health, actions are needed to keep Australians safe from harm or injury. As part of its role to *protect* public health, Australia became a party in 2005 to the WHO Framework Convention on Tobacco Control (FCTC). The objective of the WHO FCTC is to '*protect present and future generations* from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke ..… in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke' (Article 3). Article 5.2(b) requires Parties to adopt and implement effective legislative, executive, administrative and/or other measures and cooperate, as appropriate, with other Parties in developing appropriate policies for preventing and reducing tobacco consumption, nicotine addiction and exposure to tobacco smoke.

The proposal to exempt HTPs from the Poisons Standard is inconsistent with the FCTC and *poses a threat to* public health by:

- the absence of reliable evidence of health benefits from HTPs for adult smokers; and
- ignoring the need to *protect* the majority of Australians, including children and non-smokers, from the harms that would result from the widespread availability of HTPs.

International Framework to protect public health

Parties to the WHO FCTC commit to implementing a comprehensive suite of measures to reduce both the demand and supply of tobacco products. The WHO FCTC Conference of the Parties (COP) is the body that has the power to adopt decisions providing guidance to countries on how the Convention should be implemented.

The WHO FCTC and the decisions of the COP support Australia's current precautionary approach to HTPs, including the exclusion of such products from the market.

In October 2018, the COP adopted decision 8(22), titled *Novel and emerging tobacco products*, to clarify the application of the WHO FCTC to novel and emerging products including HTPs. Decision 8(22) recognises that HTPs are tobacco products, and the full range of tobacco control measures under the FCTC should be applied to them. This is consistent with the WHO's recommendations on HTPs. [20] Further, the decision means that the Convention's aim of 'reducing continually and substantially the prevalence of tobacco use and exposure to tobacco smoke' in order to 'protect present and future generations' applies fully to HTPs, as it does to other tobacco products.

In the same decision, the COP recognised that HTPs pose major regulatory challenges. It recommended that parties prioritise a range of regulatory measures for HTPs, including "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". As such, the WHO FCTC COP decision both requires Parties to apply existing tobacco control measures to HTPs, and supports them to take a stricter, precautionary approach where HTPs are kept off the market entirely if this is appropriate to their national context.

The decision of the COP to classify HTPs as tobacco products, and the WHO's recommendation that the full suite of tobacco control measures are applied to HTPs, should

therefore further indicate the need to apply vigilance in available poison control instruments to protect public health and safety. The decision of the COP and the WHO's recommendation should therefore ***not*** be seen as an endorsement of relaxing controls on HTPs where these are stricter than those for combustible tobacco products, but rather the opposite – i.e. a rationale for maintaining current protections against the harms of nicotine in tobacco products.

These recommendations must be understood in light of the WHO FCTC's goal of reducing the consumption of all tobacco products, including HTPs and preventing and reducing nicotine addiction. COP decision 8(22) also needs to be understood in light of the fact that it applies across all 181 Parties to the Convention, including many countries where HTPs were already on the market but were not being sufficiently regulated. This is particularly so in that the WHO FCTC Article 2 encourages Parties to adopt stricter tobacco control measures than specified in the Convention in order to better protect public health.

Evidence base for effects of HTPs

Most studies to date on the health effects of HTPs have been funded by the manufacturers of the products. The WHO Study Group on Tobacco Product Regulation Report on the scientific basis of tobacco product regulation concluded that, "Independent scientific evidence is required to verify the claims of industry scientists for reduced exposure and risk." The US Centers for Disease Control and Protection CDCP state, "More research is needed to understand the short- and long-term health effects of heated tobacco products".

Industry-funded studies on heated tobacco products have generally claimed that compared with cigarettes, HTPs expose users and bystanders to substantially lower levels of particulate matter and many of the harmful and potentially harmful compounds that are included in each study.[4-7, 25, 39-47] However, the rationale for inclusion of some markers and the exclusion of others is rarely provided, information on the quantitative contribution of specific harmful compounds to the risk from exposure to emissions is not available; research in this area is still at a very early stage.[8]

An example of research results being misrepresented by tobacco product manufacturers is illustrated in the letter from Philip Morris Limited sent to Australian health professionals on 20 December 2019 seeking support for this application to the TGA.

Referring to the meta-analysis by Drovandi et al (2019) [48] a quote was included,

> "This study supports claims made by tobacco manufacturers on the improved safety of heat-not-burn tobacco devices in comparison to conventional cigarettes. These novel devices lead to reduced exposure to key biomarkers, which are linked to the health consequences attributed to tobacco use. This has strong implications for international public health as well as further research and policy development relating to the safety aspects and legalities of novel tobacco products."

But the letter failed to include the preceding paragraph from the article abstract,

> "Whilst these results support tobacco manufacturer claims of improved safety, the small number of studies included, limited range of BoE assessed, and involvement of the tobacco industry necessitate further independent research to confirm the HNB devices as being a safer alternative to conventional cigarettes."

Contrary to claims by Philip Morris about evidence of reduced risks for HTPs, statements from US Centers for Disease Control and Prevention CDCP clearly refutes their assertions:

> Heated tobacco products are not an FDA-approved method for quitting smoking.
>
> As of January 8, 2020, no tobacco company has received permission from the FDA to market a heated tobacco product as a reduced-risk product.

Additional research is needed to determine whether adult cigarette smokers who completely switch to heated tobacco products might reduce their risks of tobacco-related disease.

Deficiencies have also been identified in the evidence used by Philip Morris International (PMI) to support their claims that current smokers will understand what is meant by the phrase 'switching completely' from smoking cigarettes to using [redacted] to achieve the inferred health benefits of [redacted] Independent researchers note that the studies and measurement instruments employed by PMI suffer from design flaws and their reporting of associated findings is misleading. [49]

In fact, research conducted by PMI and confirmed by independent research highlights that reduced exposure claims are misunderstood as reduced harm claims.[33]

Need to *protect* the majority of Australians, including children and non-smokers

Advice from the US CDCP is that "The use of any type of tobacco product - including heated tobacco products - is harmful, especially for youth, young adults, or pregnant women, as well as adults who do not currently use tobacco products. If you've never used tobacco products, including heated tobacco products, don't start".

Following the US FDA authorisation of the marketing of the [redacted] device, the FDA noted that, while the action permits the tobacco products to be sold in the US, it does not mean these products are safe or "FDA approved." The FDA advises that all tobacco products are potentially harmful and addictive and those who do not use tobacco products should continue not to.

Researchers have exposed marketing strategies used by Philip Morris to promote claims of reduced risk that violate the FDA marketing authorisation. A Google search for 'heat not burn' on 1 August 2019 returned as the first result an advertisement entitled 'What is heat-not-burn? | Discover the technology | Alternatives to smoking' that promoted a link to pmiscienceusa.com, a subsidiary of Philip Morris. A clickthrough to the advertised website displayed a banner asking visitors to accept that the 'purpose of the site [was] not [for] advertising or marketing', yet Philip Morris was buying consumer-facing advertisements to promote this website. On accepting the statement, users entered the site which focused on Philip Morris-conducted research and made the claim that [redacted] is a harm reduction device.[50]

Philip Morris International claims that it markets its [redacted] HTP only to adult smokers, not youth and non-smokers. But the company's marketing around the world shows otherwise, especially its use of influencers on social media. From 20 March 2018 to 20 March 2019, social media posts using #[redacted] have been viewed 179 million times on Twitter and Instagram, according to Keyhole, a social media analytics tool.[51]

Only after the PMI claim, that [redacted] marketing was only to existing smokers, was exposed as fraudulent did they announce that some marketing strategies would be discontinued. Meanwhile, Philip Morris continues to ignore other ways that they market [redacted] to young people, including the beer fests, beach parties and fashion shows they've sponsored in other countries and that they use to present [redacted] as a fun and trendy lifestyle product. Philip Morris has pursued a strategy of marketing [redacted] in a way that reaches and appeals to the broadest range of customers, including young people - Examples of [redacted] marketing worldwide complied by Tobacco Free Kids.

The global marketing of novel tobacco products suggests that the introduction of [redacted] would result in adolescent and young adult non-users initiating tobacco use with [redacted] and could also increase poly-use of [redacted] along with other tobacco products.[15]

Australia's history of, and future goals in, tobacco control.

Smoking rates in Australia have halved over the past 25 years, through a range of evidence-based tobacco control measures working. These successes have had a significant impact on improved public health. For example, lung cancer rates in younger Australian men (those at an age who have been protected from aggressive marketing of tobacco products since the late 1970s) are returning to levels observed before the tobacco epidemic spread though lax control measures.

In August 2019, the Minister for Health, the Hon. Greg Hunt MP, announced a goal to reduce smoking prevalence in Australia to below 10% by 2025.[52] The availability of HTPs, classed as a tobacco product, will make no contribution to this goal; rather, in view of their adverse effects of undermining quit attempts and their aggressive promotion to, and take up by, young people in countries where they are available [53], their promotion is likely to increase, not reduce, the prevalence of tobacco use.

No new exemption for 'tobacco prepared and packed for heating'

Cancer Council Australia, the National Heart Foundation and ACOSH support Australia's strict, evidence-based precautionary approach to heated tobacco products and strongly opposes the proposed amendment to the schedule.

- As per WHO, there is no evidence that HTPs are less harmful than conventional tobacco products https://www.who.int/tobacco/publications/prod_regulation/heated-tobacco-products/en/
- As per WHO, unknown risks regarding uptake/gateway effects with traditional tobacco products, insufficient evidence regarding any cessation benefit, large knowledge gaps
- Heated tobacco products part of tobacco industry expansion strategy – undermines goal of reducing consumption of all tobacco products
    - misleading health claims
    - health reassurance marketing
    - opportunities to exploit loopholes in regulatory frameworks that have not yet anticipated such products (e.g. advertising bans)
    - undermine public health messaging about tobacco products
- Should not allow new range of products that have been known to have high appeal to e.g. young people while still struggling to contain damage of previous ones

The FCTC provides clear guidance to parties, including the promotion of evidence-based measures to reduce tobacco harm, through cessation support and measures to prevent uptake, and obliging Parties to avoid engagement with the tobacco industry – as noted on the consultation webpage.

It is common knowledge that the Applicant seeking product exemption from the Standard is Philip Morris International (the company has written extensively to not-for-profits, seeking support for the proposal). The tobacco industry's entrenched opposition to any and all evidence-based reforms to reduce tobacco-related harm is well-documented and forms the basis of the FCTC's Article 5.3 – designed to protect effective public health policies from tobacco industry interference.

Conclusion

There is no evidence to support the Applicant's proposal to amend the scheduling of nicotine in the Poisons Act. On all available evidence, the purpose is to provide a commercial opportunity to promote a toxic and addictive substance in a form that confers no therapeutic benefit, to provide additional avenues of appeal to young people, and to distract attention from evidence-based measures to reduce smoking. Rather than provide a public health benefit, all the evidence, as summarised in this submission, highlights multiple risks and safety concerns for public health in Australia associated with the Applicant's proposal.

Supporting the Applicant's unsubstantiated claim would: pose significant risk to the health and safety of Australians at a population level; set a dangerous precedent in the lowering of the TGA bar in response to an unsubstantiated claim from a commercial entity; be out of step with tobacco control policy across all jurisdictions and health authorities in Australia; risk reversing trends in reduced prevalence of tobacco use and undermining a national goal of below 10% smoking rates by 2025; and be out-of-step with the recommendations of the World Health Organization and the provisions of the Framework Convention for Tobacco Control.

About the Cancer Council and the National Heart Foundation

Cancer Council and the National Heart Foundation have been Australia's most active nongovernment organisations in tobacco control since concerted efforts to work in a multi-sectorial capacity to reduce the health harms of tobacco use gathered momentum in the 1970s. This has included successful advocacy to phase out broadcast and print tobacco advertising and increase tobacco taxation, membership on intergovernmental and intersectoral bodies advising on tobacco control policies and the delivery of programs and services.

Around 20% of all cancer deaths and 16% of all cardiovascular disease deaths in Australia are attributed to smoking. While these are unacceptably high rates of mortality and exposure risk, they have nonetheless reduced significantly in recent years through the evidence-based interventions, supported by Australian governments and statutory health authorities, that have halved smoking prevalence over the past 25 years.

Advancing evidence-based tobacco control, and protecting the population from the risks of reforms that are not supported by the evidence, are fundamental to our mission. The (standing and co-opted) membership of our joint Tobacco Issues Committee includes some of Australia's leading academics and policy advisers on tobacco control and operates within a strict evidence-based framework, reporting to Cancer Council Australia's principal Public Health Committee.

On this basis, we submit to the TGA's Joint Advisory Committee on Medicines and Chemicals Scheduling the importance of rejecting the proposal to exempt heated tobacco products from the Poisons Standard, which is not supported by the evidence and which poses a significant health risk to the Australian population.

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Appendix A

Mass-marketing of tobacco products

The historical anomaly of mass-marketed tobacco products and the subsequent tobacco epidemic (on track to cause one billion deaths globally this century) is well-documented.

Tobacco smoking became embedded in Western culture in the early 20 h century, through mass-production and promotion of tobacco products during the First World War, when smoking prevalence among Allied troops increased by more than 70%.

The tobacco industry flourished in the post-war period, with no controls over the promotion of its highly addictive, low-cost products and limited research at that time on the health harms and risks of all forms of tobacco smoking.

By 1945, 72% of Australian men and 26% of Australian women smoked. Powerful epidemiological evidence of the health harms of smoking emerged subsequently, beginning with Doll/Hill and Wynder/Graham in the 1950s through to Banks et al[1] showing that smoking kills two in three long-term Australian smokers. As the evidence on tobacco harms has strengthened, the tobacco industry has become increasingly aggressive in trying to undermine evidence-based public health polices aimed at reducing tobacco health harms and seeking new ways to flout effective policies to sell its products.

Policy makers and advocates have at times discussed the feasibility of banning tobacco - on the basis that had the catastrophic health harms of smoking been irrefutable before the tobacco industry was able to aggressively promote its products - it would have been prohibited. This is, however, a theoretical position based on hindsight.

Consensus is that it would be unfeasible to ban a highly addictive product, used daily and legally purchased by more than 2.5 million Australians, given the difficulties of enforcement and the risks of creating a large black market. This has led to the anomaly of nicotine being exempted from Schedule 7 of the Poisons Standard for “tobacco prepared and packed for smoking”. (Note that, unlike therapeutic goods, the labelling and promotion of tobacco prepared for smoking is subject to separate instruments, such as the *Tobacco Advertising Prohibition Act 1992* and the *Tobacco Plain Packaging Act 2011*, further highlighting the historical anomaly of the current scheduling exemption caused by the tobacco industry.)

Rather than an unfeasible ban, the position, supported by governments in Australia and independent, nongovernment health and medical groups, has been to continue to implement evidence-based measures to reduce smoking rates. The proposal to exempt HTPs from the Poisons Standard is not consistent with that position.

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