celebrating 30 years

Introduction

Lung Foundation Australia is a national organisation representing patients experiencing any lung disease, their families, carers and support networks, and clinicians; including doctors, nurses and allied health professionals, who specialise or have an interest in lung health. We are committed to an open, honest, evidence-based and human centred dialogue on lung health and clean air.

Lung Foundation Australia oppose the application for a scheduling exemption regarding nicotine (tobacco packed for heating) made by Philip Morris International (PMI) on the grounds that is it is:

- grossly misleading, and
- detrimental to the health and wellbeing of Australians.

PMI's application is an attempt by a well-resourced and profit-driven organisation, to manipulate Australians; by subversively calling on the Therapeutic Goods Administration (TGA) to support tobacco for heating as a better alternative to what is already legally available (combustible cigarettes); while in reality increasing their market position and offering an addictive new product to a new generation of consumers.

We strongly recommend that the TGA reject this application, and furthermore clarify its position with respect to its ostensible encouragement or "guidance" – as represented by PMI in various correspondence and press releases – for PMI to make this application at this time under the under the guise of harm reduction.

Australia, as a party to the World Health Organisation's (WHO) Framework Convention on Tobacco Control (FCTC)has a clear responsibility to protect the development and implementation of tobacco control public health polices from the "commercial and other vested interests of the tobacco industry". Consequently, we are deeply and genuinely concerned at the implication by PMI that the TGA encouraged PMI to make this application at this specific time. Furthermore, the responsibility of the TGA to protect Australian health policy – and public health gains regarding tobacco control – extends to rejecting any health claims, including unproven claims of harm minimisation by big tobacco; an industry that profits from addiction, disease and death.

Any application to sell new tobacco products to the Australian public for human consumption, should be viewed shrewdly and in light of the courage and intelligence demonstrated by the Australian people in reducing smoking rates over the past ten years. Australians have, for some time now, cleverly rejected spurious claims and cynical manipulation by the tobacco industry.

We have strong evidence that the Australian community wish to be a tobacco free and nicotine free society, and it is our privilege to share this information with the TGA and others. We believe that a tobacco free community is achievable; however, we acknowledge that the tobacco industry actively work to influence the public to believe the opposite.

Our belief in a tobacco-free future for all Australians is clear, and we support people who wish to, and find it difficult to, end their nicotine addiction. We understand the pain inflicted by big tobacco – in their pursuit of profit – on millions of Australians addicted to nicotine. Through our campaigns, programs and services, we empower individuals in their efforts to achieve a healthier, nicotine-free

lifestyle. There are better ways to end nicotine addiction; heat-not-burn products are not part of a better way.

The toxicity of tobacco packed for heating - more harmful than tobacco e-cigarettes and combustible cigarettes.

Nicotine – addictive and harmful to health

Nicotine occurs naturally in the leaf of the tobacco plant, and in smaller concentrations in other plants. It is listed in the *Poisons Schedule* because it is well-established that nicotine is an addictive drug and harmful to human health. PMI do not dispute this, however; their application attempts to minimise the harmful health effects of nicotine to human health and instead focus on the physical sequelae of combustible tobacco cigarettes. This selective argument ignores both well-established and emerging research evidence and is a grossly misleading attempt to promote heat-not-burn products as a safer alternative to combustible cigarettes.

Tobacco – whether chewed, smoked, or produced through vapour or aerosol is a particularly efficient and effective vehicle for delivering nicotine[i]. In fact, published research has determined that tobacco delivered nicotine is not only ***more toxic***, but more ***addictive*** than nicotine in a pure form (e.g. nicotine replacement therapy)[ii]. Tobacco companies know this, of course, and it is widely acknowledged and documented that they alter both the tobacco and nicotine used in their products to maximise addictive properties[iii]. This is a strategic business model - not a health model - dependent on repeated consumer purchase and use of tobacco combustible cigarettes, e-cigarettes and heat-not-burn products.

> ***"Tobacco manufacturers have long been aware that nicotine is the central component of tobacco dependence, and that sales, and ultimately profits, depend on creating and sustaining that dependence."***[iv]

Nicotine is the main psychoactive compound that **perpetuates** the use of tobacco[v]. That is, nicotine is a chemical substance that changes brain function, to create a physical dependence (need) on it.

Nicotine is highly deceptive; it says one thing to the brain (reward for choice) and does another to the body (creates dependency on that same "choice"). When absorbed by the body, nicotine activates the mesolimbic system (the reward pathway in the brain) by increasing dopamine release in the central nervous system (this makes users 'happy'); at the same time it enhances the activity of locomotor endurance that preserves appetitive behaviours ***focused*** on drug seeking and self-administration [of the drug] [vi].

In short nicotine addiction is insidious; it tricks people into ***dependence*** through an ***apparent*** self-control/choice activity focussed on a vaping/smoking/chewing action. The effect of nicotine on the human body is similar to PMI's claim that heated tobacco products are a better choice for smokers – it ostensibly seems like a good thing that you can choose; but the truth is – it's neither good or a choice. By its very nature the effect of nicotine on the human brain and body removes choice.

The true impact of nicotine on a human body is disease and ultimately death.

Nicotine is principally absorbed through oral mucosa; the alkalinity of saliva enhancing absorption. It takes only 15 seconds for nicotine to pass the lipophilic blood brain barrier and reach 50% of its concentration in the cerebral areas[vii]. After absorption, nicotine is highly concentrated in the hepatic tissue, kidney, lung, spleen, and fat tissue[viii]. Nicotine input is regulated by the consumer, by his smoking habits (frequency and depth of inhaling), the wellness of the pulmonary system, and the environmental quality.

Once absorbed in the human body, nicotine ***alters*** a variety of neurological processes, from molecular biology, to cognition[ix].

Each time an individual consumes nicotine they experience an increase in blood pressure, heart rate, cardiac contractions, release of adrenaline, and increases in the activity of the gastrointestinal tract. The stimulation of the heart typically dilates coronary arteries resulting in more blood flow to the heart. However, if arteries are unable to sufficiently dilate, the lack of blood flow and oxygen will put additional stress on the heart's functioning, increasing the likelihood of heart pain or a heart attack[x].

It has been established that nicotine can reduce the activity of some nerves, resulting in a decrease in muscle tone and some relaxation effects, alter taste bud sensitivities[xi], age the skin, lead to neurodegenerative disease and have a negative impact on learning and cognitive function[xii]. Over time, nicotine use will make a genotoxic contribution (that is, it damages genetic material) to the etiology of cancer[xiii].

The impact of nicotine on the developing brain is devastating and irreversible. Studies have demonstrated that exposure to nicotine during prenatal life may impact upon brain development.[xiv] Summarizing current knowledge, Wawryk-Gawda et al, concluded that:

> "….Nicotine leads to serotonin, dopamine, and norepinephrine disorders in the forebrain and midbrain. Moreover, the offspring of mice exposed to aerosol with e-cigarettes exhibited gene alterations in the frontal cortex that can cause cognitive and behavioural deficits later in life. Indeed, [studies] suggest that alterations in cerebellar cholinergic transmission in certain areas of the foetus' brain of smoking mothers may be the cause of sudden unexplained fetal and infant death, as they had observed a negative or low expression of a7-nAChRs in the granular layers of the cerebellar cortex in 66% of the sudden unexplained perinatal deaths, as compared to the 11% of the (non-smoking) controls. Furthermore, as seen by Mohamed, Loy, Lim, Al Mamun, & Jan Mohamed (2017) prenatal nicotine concentration levels were negatively associated with communication and fine motor skills, while postnatal nicotine concentration levels were inversely associated with fine motor and problem-solving skills."

Nicotine is listed as poison for very good reason: it is toxic to health and kills human beings. PMI's application to list 'tobacco prepared and packed for heating' as an exempt item under the *Poisons Standard*, whilst seemingly broad would, if accepted by the TGA, allow PMI – and other tobacco companies – to immediately sell their heat-not-burn (HnB) tobacco products or what they term "smoke free products" alongside regular tobacco cigarettes.

PMI's 'market leading'[xv] HnB product is the I Quit Other Smoking ([redacted] device.

The [redacted] device contains nicotine **at concentrations** (per gram of tobacco) similar to tobacco cigarettes and the levels of nicotine delivered to the aerosol of the heat-not-burn products are only ***marginally lower*** than tobacco cigarette, but higher than e-cigarettes at low puff duration[xvi]. In their submission, PMI state that the range of tobacco in their HnB tobacco product is 260 – 320mg compared to conventional cigarettes at 600 – 800mg. They go on to state that the composition of the tobacco in heated tobacco products (HTPs) is different to that in (combustible) cigarettes because HnB products are "specifically manufactured to deliver nicotine at a lower operating level"[xvii] . It is well known and independently established that tobacco manufacturers have successfully developed and utilised physical and chemical product design changes to **control** the quantity, form, and perception of nicotine dose. Methods include altering physical construction parameters, such as the tobacco …"[xviii] Tobacco companies do this because they have long been aware that nicotine is the central component of tobacco dependence, and that sales, and ultimately profits, depend on creating and sustaining that dependence[xix].

PMI is deliberately misleading the TGA when they present the nicotine content in their [redacted] device as being designed to facilitate an acceptable "profile" for current smokers in order to transition from combustible cigarettes[xx]. That is, they claim that the [redacted] devices must contain an adequately high

enough level of nicotine so current smokers will be motivated to choose to use it. The truth is and it is well established; that tobacco companies create their products specifically to ensure consumers of their products obtain sufficient nicotine to ensure dependence[xxi]. The [redacted] product is specifically designed to be highly addictive.

Maintaining dependence on nicotine (a harmful substance itself) through particular delivery systems (whether combustible cigarettes, e-cigarettes or Hnb devices) exposes users to a range of other known and unknown toxic compounds. PMI do not dispute this. In fact, their submission is clear that the [redacted] "still exposes users to HPHCs and may expose users to chemicals that are not present in the emission from combustible cigarettes. These chemicals could carry some degree of toxicity, but the risk is low and outweighed by the reduction in exposure to HPHCs[xxii]". This is grossly misleading, irresponsible and insulting to widely-acknowledged science evidencing demonstrable harm.

Firstly, independent studies have found that there is no "significant" reduction in concentrations of volatile organic compounds, hydrocarbons or inorganic compounds between HnB produces and combustible cigarettes. For example, the proportion of Acrolein and Formaldehyde present in HnB device aerosol, as compared to cigarette smoke was 85% and 74% respectively[xxiii]. This is not a significant reduction. Furthermore, Acenaphthene, a polycyclic aromatic hydrocarbon (PAH) – detectable in gasoline exhaust condensates and present in coal tar produced during the high-temperature carbonization or coking of coal, petroleum processing, shale oil processing, used as a dye intermediate in the manufacture of some plastics, and as an insecticide and fungicide - was present in the aerosol of the [redacted] device at a level **295% greater** than conventional combustible cigarettes[xxiv]. Repeated or high exposures to Acenaphthene may cause lung irritation, bronchitis with cough, phlegm, and/or shortness of breath. Acenaphthene may affect the liver and kidneys. The most thoroughly investigated effect of Acenaphthene is its ability to produce cytological changes in microbial and plant species. Most of these changes, such as an increase in cell size and DNA content, are associated with disruption of the mitotic spindle (ie. it damages DNA).[xxv] However, very little is known about the effects of such a high dose of acenaphthene through aerosol on human beings.

Furthermore, the molecular interaction between known and ***unknown*** toxicants (including toxicants present in HnB products which are not present in combustible tobacco cigarettes) – at varying levels, and the short and long-term health effects on human beings is **currently unknown.**

Secondly, whilst there are some short-term studies that show that some specific emitted and inhaled toxicants generated by HnB devices are lower than the same toxicants in conventional cigarettes[xxvi], there is **no currently available** evidence from any clinical trials or observational studies that unequivocally demonstrates that HnB products reduce the risk of tobacco-related illnesses[xxvii]. PMI acknowledge this, when they wildly claim in the absence of supporting evidence, that "a significant reduction in exposure to HPHCs leads to a reduction in adverse health effects according to the fundamental principles of toxicology"[xxviii]. In fact, studies show that despite lower levels of some toxicants in the [redacted] aerosol, this does not translate lower harm (or clinical benefit) when people use the product[xxix].

> "Like cigarettes (and e-cigarettes), [redacted] uses an aerosol of ultra-fine particles to deliver the nicotine. These ultrafine particles cause heart and lung disease. The adverse effects of these particles and many of the other toxins do not drop in proportion to reducing the dose, so even low levels of exposure can be dangerous… In addition, while the [redacted] does not set the tobacco stick on fire, it heats it to 350 degrees celsius, which is still hot enough to cause pyrolysis. There is already independent evidence that [redacted] compromises functioning of arteries, a key risk factor for heart disease and heart attacks, as badly as a cigarette. Even if the levels of [some] carcinogens delivered by [redacted] are lower than conventional cigarettes on a per puff basis, these lower exposure levels may not yield proportionately lower cancer risks because both the intensity and duration of the exposure impact cancer risk."[xxx]

In addition, an Australian study[xxxi] demonstrated that exposure to [redacted] has the same damaging effect on human lung cells as traditional combustible tobacco cigarettes and e-cigarettes. It is also established that emissions from heated tobacco products damage bronchial epithelial cells, and their cytotoxic effect ***is higher*** compared with e-cigarettes[xxxii].

Emerging evidence is demonstrating that HnB products are more harmful to health than nicotine e-cigarettes. The TGA have previously rejected an application to authorise nicotine (liquid) for use in e-cigarettes[xxxiii], because of its health impact, whilst retaining the exemption for tobacco packed for smoking (combustible cigarettes). Current Australian policy with respect to e-cigarettes is to protect the health of children and young people and take a precautionary approach to prevent harm and protect public health gains[xxxiv]. We strongly encourage the TGA to implement this approach when deciding the PMI application.

90% of Australians* believe the Australian authorities should wait until there is more evidence about the effects of novel tobacco products before approving them for use in Australia.

It is not disputed that nicotine packed for heating is a toxic substance, designed to create addiction and deliver harmful compounds; it is a substance that will always result in disease and death of individuals. HnB products, and [redacted] in particular – regardless of the levels of toxicants – will continue to deliver the same addiction and disease as combustible cigarettes; these products are deliberately designed by Big Tobacco to create a nicotine dependence. People who become dependent on nicotine **do not choose** to use nicotine. They do not choose to consume a product which unequivocally causes disease and death. They become addicted to a substance that generates significant financial profit for Big Tobacco and immeasurable pain for themselves, their families and the Australian community.

Without nicotine addiction there would be no tobacco industry. Nicotine addiction destroys the industry's PR and legal stance that smoking is a matter of choice - WHO

The risks and benefits of a product designed to create addiction which results in disease and death.

As noted above there are ***no beneficial features*** of tobacco packed for heating.

Despite this, PMI claim that tobacco packed for heating is a "better alternative for current Australian smokers who do not quit"[xxxv]. There is an unequivocal lack of evidence to support the hypothesis that conventional smokers make a permanent and single-use switch to HnB products from combustible tobacco cigarettes. Indeed, there is emerging evidence – from a tobacco industry funded study – that smokers rate HnB products as less satisfying in terms of smoking satisfaction, psychological rewards, enjoyment of respiratory tract sensation and craving reduction compared to combustible cigarettes[xxxvi]. This would suggest that smokers are actually unlikely to permanently transition to HnB products. The experience in Korea was that users of [redacted] became smokers of both e-cigarettes and traditional cigarettes[xxxvii]. In addition, recent studies and surveys indicate that novel tobacco products such as [redacted] rapidly acquire first-time users. A survey carried out in Italy after the launch of [redacted] found approximately half of [redacted] users (45%) and more than half (51%) of people interested in trying it **had never been** smokers[xxxviii]. Similar trends regarding e-cigarettes use, first introduced in 2007, in the United States have also been observed; 32.5% of e-cigarette users (during 2010 – 2013) were never- or former smokers[xxxix].

It is important to note that most smokers want to quit nicotine. They genuinely want to exercise their choices to attain their highest level of health and many make attempts to do so however most of these attempts fail largely because of the ***powerful addictive qualities of nicotine*** and non-nicotine sensory and behavioural cues[xl].

[redacted] Story

How has tobacco impacted my life?

Most recently I lost my younger sister to lung cancer. She was a heavy smoker for much of her life and I have no doubt that her smoking was a major contributor to her cancer diagnosis. Both my parents were smokers when they were younger and both died and relatively young ages, while the to connection to tobacco might not be as strong as in my sister's case, I do believe it was a factor. I, myself, took up smoking in my early teens. While I was fortunate enough to give tobacco away in my 20's I still have to live in the shadow of not knowing if the damage done in my earlier years will come back to bite me. I also know, first- hand, of the addictive grip tobacco has and the lengths you will go to satisfy cravings when your supply runs out.

Is the government doing enough to stop the introduction of new tobacco products that are designed to appeal to the young?

Definitely not. The last thing we need is new tobacco products, especially, those aimed at a younger target group. We all know that when we were younger we paid far less importance on the long term consequences of our actions and are more easily lead by slick and deceptive advertising. The last thing we want is a new generation addicted to tobacco products. The harmful effects of tobacco are now well known and it would be foolish to think that heat-not-burn might make it any safer. We have already heard accounts of "vaping" being directly blamed for the deaths of some users. The government should be working towards the total eradication of tobacco products from society and any attempt by the tobacco industry to expand its reach by going through the "back door" needs to be meet with vigorous and determined opposition. It's the government's job to do this through education and legislation.

Would you recommend this product?

Bahahahaha! This must be a trick question. Yes I would recommend this product…..be BANNED!!

80% of Australians* do not believe that Governments have learned lessons from past public health disasters.

PMI's harm reduction claim could only be considered transparent and legitimate if:

- PMI had made an application to have its [redacted] devices listed on the Australian Register of Therapeutic Goods pursuant to section 9A of the *Therapeutic Goods Act 1989* (Cth) – that is, available by prescription from a medical practitioner; **and**
- an application to remove tobacco prepared and packed for smoking from schedule 7 of the Poisons Standard – that is remove all combustible cigarettes from sale in Australia.

It is telling that PMI made no such applications.

We note that PMI make references to the authorisation of the [redacted] and other heat-not-burn devices by authorities in the United States, the United Kingdom and Europe. The legal basis, and community context, for these authorisations is completely different to the Australian legal and social context; in no way should these decisions be interpreted as binding or even persuasive to Australian decision makers. Decisions on matters of Australian public health must be made in accordance with Australian law and policy; supported by independent evidence applicable to the Australian context.

The purposes for which tobacco packed for heating is to be used and the extent of its use – *addiction, market share and profit.*

PMI's application to list tobacco prepared and packed for heating as an exempt item under the *Poisons Standard*, is seemingly quite broad. It is not clear whether tobacco packed for heating will be limited to oral personal devices, or whether PMI (or others) intend to market other tobacco heated products such as 'scented' room vapourisers. However, it is clear; that should the TGA approve the exemption, PMI would be able to immediately sell their HnB tobacco products or what they term "smoke free products" alongside regular tobacco cigarettes.

Sales of all tobacco products, especially tobacco cigarettes, in Australia have been steadily decreasing. In March 2017, the Australian Bureau of Statistics (ABS) released figures that show the total consumption of tobacco and cigarettes, as measured by estimated expenditure on tobacco products to be:

- $7.174 billion in September 1959;
- $4.712 billion in December 2012; and
- $3.415 billion in March 2017.[xli]

Tobacco clearances data (including excise and customs duty) are an indicator of tobacco volumes in the Australian market and provide a useful approximation of tobacco consumption over time. It should be noted that the excise on a packet of cigarettes increased significantly (by 62.5%) between 2012 and 2017. As at the end of 2016, tobacco clearances had fallen a total of ***16.5%*** since 2012.[xlii]

Sales of combustible cigarettes in Australia are consistently falling.

Consumption of cigarettes in Australia has steadily declined since the introduction of world-leading tobacco control laws. There has been a long-term downward trend in daily tobacco smoking since 1991 (24% to 12% in 2016). This long-term decline in daily smoking has largely been driven by people **never taking up smoking rather than smokers quitting; the proportion of persons aged 14 or older who have never smoked has increased by 13 percentage points to the highest levels seen over the 25-year period (from 49% to 62%)** [xliii].

As cigarette consumption has declined, major companies, like PMI, have developed new products - and acquired independent companies producing novel products - in order to offset losses, create new markets and gain new users[xliv]. PMI has invested heavily in research and development to create its own heat-not-burn range of products; enjoying a strong competitive advantage in this sector[xlv]

PMI's 'market leading'[xlvi] HnB product is the [redacted] Rise in sales of [redacted] in Europe in particular, have increased profits for PMI beyond original expectations; volume during the second quarter of FY18/19 for HnB products spiked at 37% for all sales[xlvii].

Profit margins for PMI 's [redacted] are 30%–50% *higher* than for conventional cigarettes[xlviii], so of course PMI would prefer smokers of conventional cigarettes to transition to [redacted] and new users to take up [redacted]

Because a generation of Australians have rejected tobacco cigarettes, PMI are facing a shrinking market - there are hardly any new Australian customers - and therefore dwindling revenue. The real

purpose of this application is to offer a new addictive product - which delivers a high profit margin for its maker - to young Australians and current smokers to ensure long term consumers through addiction. As noted above if this product was developed as a genuine harm minimisation device for smokers who do not wish to quit then PMI should have made an entirely different application to the TGA.

The dosage, formulation, labelling, packaging and presentation of tobacco packed for heating – *deceptive and misleading.*

Regardless of health warnings or other control measures applied to the product, the [redacted] is a youth-appealing product with a technological design[xlix]; its name and appearance mimicking iphones. It is inevitable and intended – big tobacco and PMI have a long history of targeting young people to create lifelong addiction[l] – that these products will appeal to children under the age of 18, in addition to young adults aged between 18 -25.

It is clear: youth are at the greatest risk for using alternative tobacco products, undoubtedly due to continued efforts by the tobacco industry to exploit psychosocial characteristics of youth[li].

Mark's (35) story

I started smoking when I was teenager. What made it so appealing was that all the heros in the movies smoked; Die Hard, Lethal Weapon, Midnight Run. They smoked and not only did it look cool; the guys justified it – I think it was in midnight run where someone says, "smoking will kill you" and the hero replies with, "so will women". That gave me "permission" to smoke. It wasn't so full on at first, it became more of an ingrained habit when I joined the military; where almost everyone on deployment smokes for stress relief and 'downtime' with your mates. I regret starting, but now it is so much harder to stop.

Evidence reveals nonusers of tobacco products, particularly children and adolescents, are drawn to new products and that this could lead to a subsequent transition to traditional cigarettes[lii].

In particular, a study by McKelvey et all[liii] found that "PMI's own data and available evidence from scientific studies conducted independent of the tobacco industry regarding how novel tobacco products are currently being marketed (in the US, UK, Japan, Korea, Italy and other nations) suggest that introduction of [redacted] will 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."

McKelvey concluded that:

"No regulatory authority throughout the world should allow any new tobacco product to come to market without solid, independent evidence clearly showing that the new product will not appeal to AYA (adolescents and young adults), misinform AYA about risks or encourage use of multiple tobacco products."

No such evidence is included in PMI's application to the TGA. In fact, there is a strong emerging body of evidence that the "product's name, physical appearance, flavours and retail environment will appeal to young people[liv].

In addition, recent studies and surveys indicate that novel tobacco products rapidly acquire first-time users. A survey carried out in Italy shortly after the launch of [redacted] found that 20% of respondents were aware of the system and 1.4% had tried it. About half of [redacted] users (45%) and people interested in trying it **had never** been smokers[lv]. Similar trends regarding e-cigarettes (introduced in 2007) use in the

United States have also been observed; 32.5% of e-cigarette users (during 2010 – 2013) were never- or former smokers[lvi].

HnB products are simply next-generation e-cigarettes and combustible cigarettes; delivering nicotine addiction and associated tobacco toxins.

91% of Australians* surveyed want the age to purchase tobacco products raised to 21.

The potential for abuse of a substance.

To abuse is to; use something to bad effect or for a bad purpose; misuse[lvii]. When used as intended tobacco packed for heating will cause disease and death – that is its actual use is abuse (bad effect).

83% of Australians* do not believe the Government is proactive in protecting the lung health of the community.

Other matters necessary to protect public health.

Tobacco companies use HnB products as part of their broader political and public relations activities to position them as 'partners' to address the tobacco epidemic rather than as the vectors causing it[lviii]. A 2014 Reuters investigation exposed PMI's "game plan" – an external engagement strategy which is replicated in PMI's current application before the TGA:

- Establish the concept of harm reduction as legitimate public policy in tobacco regulation.
- Establish the legitimacy of tobacco companies to be part of the regulatory debate (ie. their products are part of the solution).
- Leverage PMI's innovation and scientific research to establish credibility with stakeholders.
- Identify and engage non-traditional third-party stakeholders/allies – including harm reduction advocates – globally and locally.
- Develop compelling messages and materials to support advocacy on reduced risk products
- Amplify and leverage debate on harm reduction around global events.
- Continue to engage with regulators globally.

Decision makers must be vigilant; acknowledge the methods and means at PMI's disposal and be mindful that the ultimate objective of PMI is to make money; through addiction to their products - which leads to disease and death.

There is **no credible evidence** hnb products lessen the risk of disease and death associated with burning or heating tobacco.

There is an inherent wickedness to PMI's application and its claim that HnB products are a form of harm minimisation; and we encourage the TGA and others to not be blindsided by this spurious argument; to bear in mind that: "given the long history of the tobacco industry using reduced exposure claims to mislead ***consumers*** into believing that the products in question have reduced risk"[lix]; PMI's own qualitative and quantitative studies evaluating the marketing messages for [redacted] "consistently show that consumers misinterpret quantities of harmful chemicals as indicators of health risks…perceptions of exposure and risk are highly correlated and communication about one – either lower risk or lower exposure – ***reduces perceptions of both risk and chemical exposure***."

PMI's application is not about harm minimisation at all. If it was, PMI would have acted differently; it would have made two applications to the TGA; one to have its HnB products available through prescription as a smoking cessation device; another to remove tobacco packed for smoking from the exemptions listed in the Poisons Standard; and in a genuine demonstration of harm minimisation, it would have removed all its combustible cigarettes from sale in Australia.

The real purpose of this application is to offer a new addictive product – which delivers a high profit margin for its maker – to young Australians and current smokers to ensure long term consumers through addiction. We strongly encourage the TGA to reject this repugnant and cynical attempt to manipulate Australian authorities and ultimately the Australian community.

We also encourage the TGA, and other health authorities to consider the very real effect that an approval or endorsement of a new tobacco product will have on the community; better alternative claims – such as those outlined in PMI's application – coupled with approval by regulatory bodies (or others) responsible for protecting public health; results in the perception that these products are 'safe for use', rather than '***potentially*** not as harmful as traditional cigarettes'[lx]

We strongly recommend that the TGA adopt a protective (to the Australian community) and precautionary approach to HnB products; similar to the approach adopted regarding tobacco e-cigarettes. Such an approach is consistent with Australia's obligations under the FCTC, particularly its obligations:

- To ensure public health policy remains free from interference by big tobacco; and
- To maintain the strict focus on reducing ***access*** to tobacco products, because harm reduction is genuinely achieved through reduction in access to and consumption of tobacco products.

It is the right of all Australians to enjoy the highest attainable standard of physical health and mental health and wellbeing[lxi]. Preventing disease and ill-health, such as preventing a nicotine addition, seeks to achieve this right. Strong tobacco control legislation and policy suitable for the Australian context must be free from the influence and claims of commercial organisations seeking profit, rather than public health benefits[lxii]. Australian regulators must not be fooled into facilitating addiction by varying degrees.

Australians do not want – nor do they need – another means to acquire nicotine addition, chronic disease, and early death.

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[i] London, Edythe, et al. *Nicotine Psychopharmacology*. 1st ed. 2009. ed., Springer Berlin Heidelberg: Imprint: Springer, 2009, p. 462
[ii] Ibid.
[iii] Wayne and Carpenter, "Tobacco Industry Manipulation of Nicotine Dosing", in *London, Edythe, et al. Nicotine Psychopharmacology. 1st ed. 2009.ed., Springer Berlin Heidelberg : Imprint: Springer, 2009.*
[iv] Ibid.
[v] Benowitz. "Nicotine addiction" (2010) 362 N Engl J Med 2295
[vi] Preedy. *Neuroscience of Nicotine : Mechanisms and Treatment*. Academic Press, 2019.
[vii] Tega Y, Yamazaki Y, Akanuma S, Kubo Y, Hosoya K. Impact of Nicotine Transport across the Blood‐Brain Barrier: Carrier-Mediated Transport of Nicotine and Interaction with Central Nervous System Drugs. *Biol Pharm Bull*. 2018; 41(9): 1330‐6.
[viii] Babtan, Anida-Maria, et al. "Insights into the Pathogenesis of Nicotine Addiction. Could a Salivary Biosensor Be Useful in Nicotine Replacement Therapy (NRT)?" *Journal of Mind and Medical Sciences*, vol. 6, no. 2, 2019, pp. 196–202.
[ix] Preedy. *Neuroscience of Nicotine : Mechanisms and Treatment*. Academic Press, 2019.
[x] https://www.tobaccoinaustralia.org.au/chapter-6-addiction/6-10-acute-effects-of-nicotine-on-the-body

[xi] Ibid.
[xii] Ibid.
[xiii] Li, Ming D. *Tobacco Smoking Addiction : Epidemiology, Genetics, Mechanisms, and Treatment*. Springer, 2018.
[xiv] Preedy. *Neuroscience of Nicotine : Mechanisms and Treatment*. Academic Press, 2019.
[xv] See: https://www.bloomberg.com/news/articles/2019-10-17/philip-morris-earnings-beat-estimates-as-[redacted]gains-market-share
[xvi] Farsalinos, Konstantinos E, et al. "Nicotine Delivery to the Aerosol of a Heat-Not-Burn Tobacco Product: Comparison With a Tobacco Cigarette and E-Cigarettes." *Nicotine and Tobacco Research*, vol. 20, no. 8, 2018, pp. 1004–1009.
[xvii] P. 8, Philip Morris International "Request for Scheduling Exemption", 31 October 2019.
[xviii] Nicotine Psychopharamcology, Tobacco Industry Manipulation of Nicotine Dosing.
[xix] Ibid.
[xx] Pages 11-13, Philip Morris International "Request for Scheduling Exemption", 31 October 2019.
[xxi] Ibid iii.
[xxii] P.28 Philip Morris International, "request for Scheduling Exemption", 31 October 2019.
[xxiii] Auer, Reto, et al. "Heat-Not-Burn Tobacco Cigarettes: Smoke by Any Other Name." *JAMA Internal Medicine*, vol. 177, no. 7, 2017, pp. 1050–1052.
[xxiv] Ibid.
[xxv] Pohanish R.P. "Acenaphthene." *Sittig's Handbook of Toxic and Hazardous Chemicals and Carcinogens*, 4th ed., William Andrew Publishing/Noyes, 2002, p. 1.
[xxvi] Frost & Sullivan. The Pattern of Smoking in Australia. The challenge in achieving the 10% smoking target – analysis of current smoking rates by state and territory. October 2019.
[xxvii] *Ibid*, Signes-Costa, de Granda-Orive, Ramos Pinedo, Camarasa Escrig, de Higes Martínez, Rábade Castedo,(2019). Official Statement of the Spanish Society of Pulmonology and Thoracic Surgery (SEPAR) on Electronic Cigarettes and [redacted]®. *Archivos de Bronconeumologia*, *55*(11), 581–586.
[xxviii] P. 28, Philip Morris International, "Request for Scheduling Exemption", 31 October 2019.
[xxix] Glantz, Stanton. "PMI's Own in Vivo Clinical Data on Biomarkers of Potential Harm in Americans Show That [redacted] Is Not Detectably Different from Conventional Cigarettes." *Tobacco Control*, vol. 27, no. Suppl 1, 2018, pp. s9–s12.
[xxx] Ibid. See further references therein.
[xxxi] Sukhwinder Singh Sohal, et al. "[redacted] Exposure Impairs Human Airway Cell Homeostasis: Direct Comparison with Traditional Cigarette and e-Cigarette." *ERJ Open Research*, vol. 5, no. 1, 2019, pp. 00159–2018-2018.atom.
[xxxii] Leigh, Noel J, et al. "Cytotoxic Effects of Heated Tobacco Products (HTP) on Human Bronchial Epithelial Cells." *Tobacco Control*, vol. 27, no. Suppl 1, 2018, pp. s26–s29.
[xxxiii] Delegates scheduling decision March 2017 at https://www.tga.gov.au/book-page/21-nicotine-0
[xxxiv] Australian Government, Policy and regulatory approach to electronic cigarettes (e-cigarettes) in Australia. 29 November 2019.
[xxxv] Philip Morris International, Summary of Application to Therapeutic Goods Authority. Available at https://www.tga.gov.au/consultation-invitation/consultation-proposed-amendments-poisons-standard-accs-acms-and-joint-acmsaccs-meetings-march-2020.
[xxxvi] Picavet P, Haziza C, Lama N, et al. Comparison of the pharmacokinetics of nicotine following single and ad libitum use of a tobacco heating system or combustible cigarettes. Nicotine Tob Res 2016;18:557–63.
[xxxvii] Kim J, Yu H, Lee S, Paek Y-J. Awareness, experience and prevalence of heated tobacco product, [redacted] among young Korean adults. Tob Control. 2018;27 Suppl1:s74–7.60.
[xxxviii] 5. Liu X, Lugo A, Spizzichino L, Tabuchi T, Pacifici R, Galllus S. Heat -notburn tobacco products. Concerns from the Italian experience. Tob Control. 2019;28:113–4. 16.
[xxxix] Robert C. McMillen, Mark A. Gottlieb, Regina M. Whitmore Shaefer, Jonathan P. Winickoff, Jonathan D. Klein, Trends in Electronic Cigarette Use Among U.S. Adults: Use is Increasing in Both Smokers and Nonsmokers, *Nicotine & Tobacco Research*, Volume 17, Issue 10, October 2015, Pages 1195–1202, https://doi-org.ezproxy.library.uq.edu.au/10.1093/ntr/ntu213
[xl] Farsalinos, et al. *Analytical Assessment of e-Cigarettes : from Contents to Chemical and Particle Exposure Profiles*. Elsevier, 2016.
[xli] Available at https://www1.health.gov.au/internet/publications/publishing.nsf/Content/tobacco-control-toc~tobacco-sales
[xlii] Ibid
[xliii] *Alcohol, tobacco & other drugs in Australia.* Australian Institute of Health and Welfare, 21 January 2020, https://www.aihw.gov.au/reports/alcohol/alcohol-tobacco-other-drugs-australia
[xliv] For a nice summary see Mathers, Annalise, et al. "Transnational Tobacco Companies and New Nicotine Delivery Systems." *American Journal of Public Health*, vol. 109, no. 2, 2019, pp. 227–235
[xlv] Ibid.
[xlvi] See: https://www.bloomberg.com/news/articles/2019-10-17/philip-morris-earnings-beat-estimates-as-iqos-gains-market-share
[xlvii] See https://www.cnbc.com/2019/07/18/[redacted]boosts-philip-morris-internationals-quarterly-profit-revenue.html
[xlviii] World Health Organisation (WHO), Heated Tobacco Products (HTPs), Market Monitoring Information Shett, July 2018 Available at https://www.who.int/tobacco/publications/prod_regulation/htps-marketing-monitoring/en/
[xlix] Rahman Başaran, et al. "An Overview of [redacted]® as a New Heat-Not-Burn Tobacco Product and Its Potential Effects on Human Health and the Environment." *Turkish Journal of Pharmaceutical Sciences*, vol. 16, no. 3, 2019, pp. 371–374.
[l] See for example: Ling, P M, and S A Glantz. "Tobacco Industry Research on Smoking Cessation - Recapturing Young Adults and Other Recent Quitters." 2004, pp. 419–426.

[li] Berg, C, et al. "Perceived Harm, Addictiveness, and Social Acceptability of Tobacco Products and Marijuana Among Young Adults: Marijuana, Hookah, and Electronic Cigarettes Win." *Substance Use & Misuse*, vol. 50, no. 1, 2015, pp. 79–89.
[lii] Jenssen BP, Walley SC, McGrath-Morrow SA. Heat-not-Burn Tobacco Products: Tobacco Industry Claims No Substitute for Science. *Pediatrics.* 2018;141(1): e20172383
[liii] McKelvey, K., Popova, L., Kim, M., Chaffee, B.W., Vijayaraghavan, M., Ling, P. & Halpern-Felsher, B. 2018, "Heated tobacco products likely appeal to adolescents and young adults", *Tobacco control,* vol. 27.
[liv] Ibid, summarizing 15 studies.
[lv] 5. Liu X, Lugo A, Spizzichino L, Tabuchi T, Pacifici R, Galllus S. Heat -notburn tobacco products. Concerns from the Italian experience. Tob Control. 2019;28:113–4. 16.
[lvi] Robert C. McMillen, Mark A. Gottlieb, Regina M. Whitmore Shaefer, Jonathan P. Winickoff, Jonathan D. Klein, Trends in Electronic Cigarette Use Among U.S. Adults: Use is Increasing in Both Smokers and Nonsmokers, *Nicotine & Tobacco Research*, Volume 17, Issue 10, October 2015, Pages 1195–1202, https://doi-org.ezproxy.library.uq.edu.au/10.1093/ntr/ntu213
[lvii] The New Oxford Dictionary of English, Clarendon Press, Oxford, 1998, p. 8.
[lviii] Bialous, Stella A, and Stanton A Glantz. "Heated Tobacco Products: Another Tobacco Industry Global Strategy to Slow Progress in Tobacco Control." *Tobacco Control*, vol. 27, no. Suppl 1, 2018, pp. s111–s117.
[lix] Popova, Lucy, et al. "Light and Mild Redux: Heated Tobacco Products' Reduced Exposure Claims Are Likely to Be Misunderstood as Reduced Risk Claims." *Tobacco Control*, vol. 27, no. Suppl 1, 2018, pp. s87–s95.
[lx] See for a summary of the argument: Paumgartten FJR. A critical appraisal of the harm reduction argument for heat-not-burn tobacco products. Rev Panam Salud Publica. 2018;42:e161. https://doi. org/10.26633/RPSP.2018.16.1. For additional studies see McKelvey, K., Popova, L., Kim, M., Chaffee, B.W., Vijayaraghavan, M., Ling, P. & Halpern-Felsher, B. 2018, "Heated tobacco products likely appeal to adolescents and young adults", *Tobacco control,* vol. 27.
[lxi] Article 12. International Covenant on Economic, Social and Cultural Rights. Ratified by Australia
[lxii] Article 5.3 of the World Health Organization (WHO) Framework Convention on Tobacco Control. Ratified by Australia on 27/10/04.

*Survey conducted 16/01/20 – 24/01/20 by Lung Foundation Australia. 732 Respondents from Victoria, NSW, QLD, NT, WA, SA, ACT, Tas. 40% of respondents were former smokers.