PROPOSED AMENDMENT TO EXEMPT 'TOBACCO PREPARED AND PACKED FOR HEATING' FROM SCHEDULE 7 OF THE POISONS STANDARD

Submission to the Joint ACMS-ACCS #24

medicines.scheduling@health.gov.au

Australian Tobacco Harm Reduction Association

30 January 2020

Australian Tobacco Harm Reduction Association
11 Carlotta Rd, Double Bay NSW 2028
T: 0415 976 783 E: colin@athra.org.au W: www.athra.org.au

ATHRA is registered as a charity with the Australian Charities and Not-for-profits Commission | ABN 72 6222 11223

Table of contents

Executive summary 3
1. What is ATHRA? 4
2. Smoking in Australia 4
3. Tobacco Harm Reduction 5
4. Heated Tobacco Products 6
5. Potential public health benefit 7
Harmful and Potentially Harmful Constituents (HPHCs) 7
Biomarkers of exposure 8
Second-hand exposure 8
Modelling outcomes 8
6. Potential risks of HTPs 8
Uptake by youth and non-smokers 8
Tobacco company ownership 9
Unknown long-term risks 9
Dual use 9
7. Risk analysis 9
8. Other considerations 10
Human rights 10
Social justice 10
Ethical considerations 11
Obligations and treaties 11
Consistencies with other jurisdictions 11
References 12

Executive summary

- Smoking rates in Australia have stalled over the last 6 years. New and effective strategies are needed to supplement existing tobacco control approaches
- Tobacco harm reduction (THR) is a pragmatic strategy to reduce the harm in smokers who are unable or unwilling to quit nicotine with approved therapies
- THR includes substituting lower-risk nicotine products for the higher-risk combustible tobacco products
- Heated tobacco products (HTPs) are a far safer substitute for combustible tobacco products for adult smokers who are unable to quit
- Countries where tobacco harm reduction options (HTPs, vaping, snus) have become popular have reported a rapid decline in smoking rates and cigarette consumption
- HTPs deliver far fewer HPHCs (Harmful and Potentially Harmful Constituents) than tobacco smoke and dramatically reduce biomarkers of exposure
- Second-hand emissions are substantially less harmful than from second-hand smoke
- HTPs are approved for use in most western countries and have proven to be an effective and satisfying alternative for smokers wanting to reduce the harm from smoking
- The US Food and Drug Administration recently approved the marketing and sale of the leading brand of HTPs as “appropriate for the protection of the public health” after a rigorous review of the science
- In March 2018 a New Zealand court found in favour of a tobacco company which had applied to sell its heated tobacco product, dismissing a case by the New Zealand Ministry of Health
- The availability of HTPs will help to reduce smoking rates in Australia and improve public health
- It is scientifically and ethically wrong to allow the sale of lethal cigarettes while banning the sale of a far less risky alternative
- HTPs should be available to smokers on human rights grounds as the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being
- HTPs could help reduce health inequalities in Australia due to higher smoking rates in disadvantaged groups who have the highest smoking rates and lowest quit rates
- HTP approval is consistent with Australia’s National Tobacco Strategy and its obligations under the WHO Framework Convention on Tobacco Control. Both include support supply reduction, demand reduction and harm reduction
- The potential risks from introducing HTPs include youth and non-smoker uptake, unknown long-term risks and dual use. These require ongoing monitoring and can be managed with sensible regulation, marketing and education rather than a ban.

Recommendation

ATHRA supports the application to exempt "tobacco prepared and packed for heating" from the current nicotine entry in Schedule 7 of the Poisons Standard.

[Proposed amendments referred for scheduling advice to the Joint ACMS-ACCS #24 3.1 Nicotine CAS Number 54-11-5]

This submission outlines the role of Heated Tobacco Products available as a harm reduction tool for Australian smokers who are otherwise unable to quit. We examine the potential benefits and risks from HTPs and conclude that the overall public health impact is positive. In addition, there are several other considerations, such as human rights and ethical issues which support the proposal.

1. What is ATHRA?

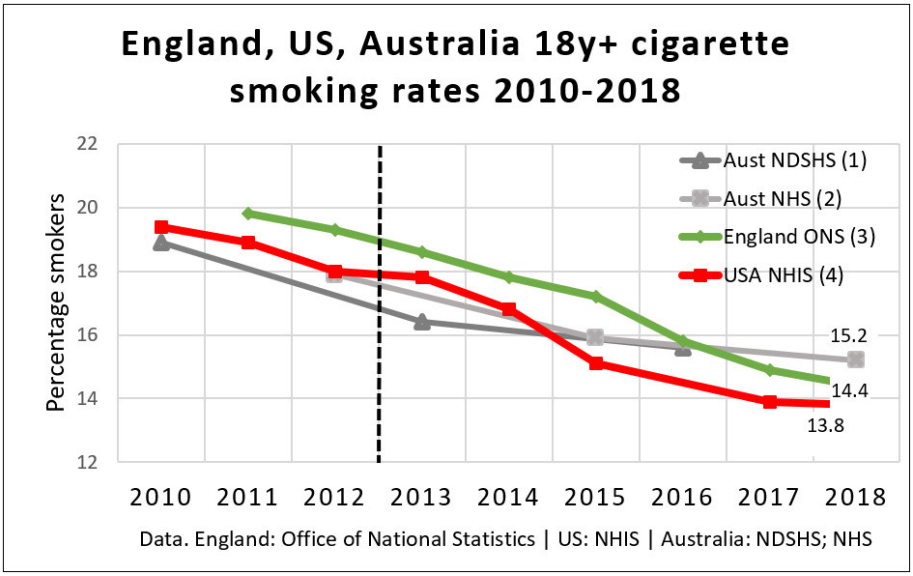
The Australian Tobacco Harm Reduction Association (ATHRA) is a registered health promotion charity established to help reduce the harm from tobacco smoking in Australia. ATHRA's aim is to provide smokers and health professionals with evidence-based information on safer alternatives to smoking. ATHRA's broader goal is to encourage the complete cessation of tobacco smoking in Australia.

ATHRA is funded by public donations. We do not accept donations from tobacco companies or their subsidiaries or the vape industry. ATHRA accepted financial support from the small vape retail sector to establish the charity in 2017 but has not accepted any industry funding since March 2019.

2. Smoking in Australia

In 2017-18, 15.2% of Australian adults smoked tobacco products. [1] Of these, 13.8% were daily smokers, while a further 1.4% of people reported smoking on a less than daily basis.

Smoking rates in Australia have been declining steadily since the 1970s but have recently slowed in spite of Australia having the highest cigarette prices in the world [2], plain packaging and strict tobacco control laws. For the first time in decades there was no statistically significant fall in the rate of adult smoking in two consecutive national surveys covering the period 2013-2016 and 2014/5-2017/8. [1, 3]



Smoking is still the leading cause of preventable death and illness in Australia, responsible for 21,000 premature deaths and 9.3% of the total burden of disease. [4] Up to two in three long-term Australian smokers will die prematurely from a smoking-related condition. [5]

Smoking disproportionately affects disadvantaged populations and is a major contributor to health disparities and financial stress. The daily smoking rate for adults in the most disadvantaged areas is three times higher than in the least disadvantaged areas (21.7% vs 6.8%). [1] 43.4% of Indigenous adults smoked in 2018-19. [6] High smoking rates are also found in other vulnerable populations including people with mental illness, substance use, prisoners and homeless people.

Tobacco smoking is a powerful addiction and quitting is extremely difficult for many smokers. Unaided cessation (cold turkey) has a quitting rate of 4-5% after 6-12 months. Quit rates with behavioural support and or medication are only 2-15% greater than placebo, according to Cochrane reviews. [7]

The average 40-year-old smoker has had 20 unsuccessful quit attempts. [8] Of those who do finally quit, there is a steady attrition over time due to high relapse rates. After being abstinent for 12 months, one in two quitters will subsequently relapse. [9]

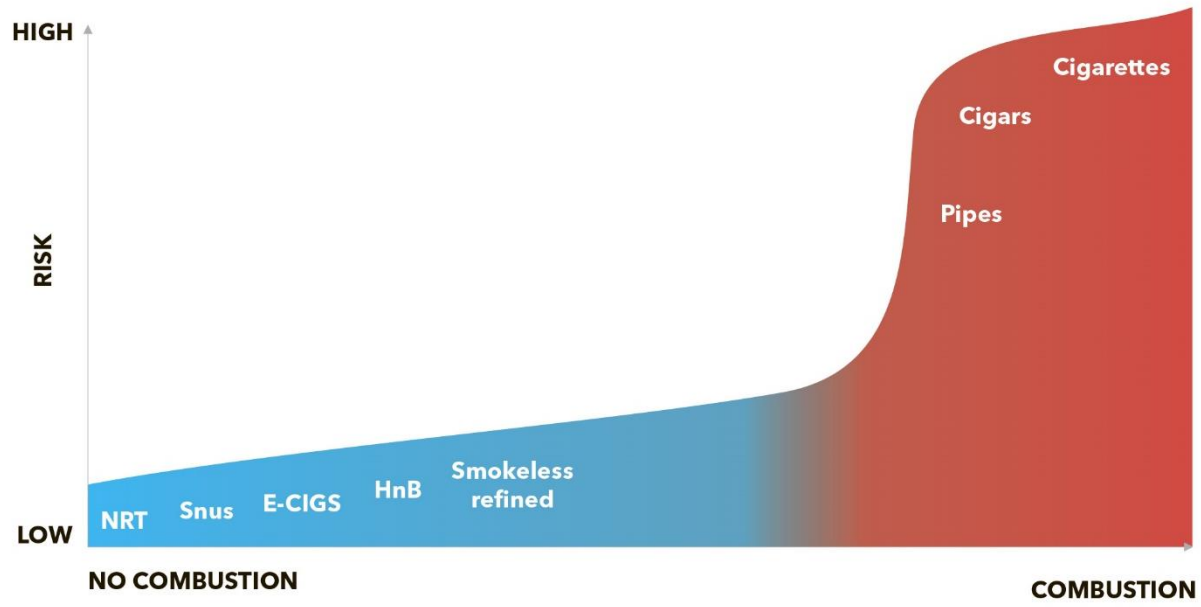
3. Tobacco Harm Reduction

Complete cessation of all tobacco and nicotine consumption is always the ideal goal. However, a large proportion of smokers are unable or unwilling to quit unaided or with conventional therapies and therefore remain at high risk. Tobacco harm reduction (THR) aims to reduce the health risks in continuing smokers. This involves switching from combustible tobacco to a lower-risk smokeless alternative that delivers the nicotine smokers are addicted to, but without the smoke. Smokeless products are not risk-free but are much safer than smoking.

Almost all the harm from smoking is caused by burning tobacco, which produces thousands of chemicals, tars, carbon monoxide, other toxic gases and solid fine particles. Contrary to popular belief, nicotine has only a minor role in smoking-related disease. [10] It does not cause cancer or lung disease and plays only a small part in cardiovascular disease. [11]

Nicotine-containing products exist on a continuum of risk. Combustible products such as cigarettes and cigars are very high risk whereas non-combustible products like heated tobacco products (HTPs), nicotine vaporisers and snus are located at the lower end of the risk spectrum. This submission focusses on HTPs, also known as Heat not Burn products (HnB).

Continuum of risk for nicotine containing products



Reference [12]

THR can complement traditional tobacco control strategies. For smokers who cannot quit, a range of safer alternatives is needed from which smokers can choose.

4. Heated Tobacco Products

HTPs are nicotine delivery devices which provide nicotine in levels similar to smoking. All products are currently made by tobacco companies and brands include [redacted] (PMI), glo (BAT) and Ploom Tech (JT).

HTPs heat processed tobacco to a temperature below combustion (<350^0 C) and release a liquid aerosol of nicotine and other vaporised chemicals which the user inhales. There is no combustion, carbon monoxide or tar and greatly reduced particulate matter.

HTPs are effective smoking alternatives and deliver nicotine to the brain much more quickly than nicotine replacement products. Delivery is as fast as smoking a cigarette but with lower peak concentration and total exposure to nicotine. HPTs effectively suppress the urge to smoke and nicotine withdrawal. [13]

To be successful, HTPs need to be a satisfying alternative to smoking as well as having a high uptake. Satisfaction levels are high in smokers who switch to HTPs, rating 8/10 in one online survey. [14] However, they rate lower on sensory and psychological satisfaction compared to smoking.

HTPs simulate the behavioural ritual, sensory and social aspects of smoking and the pleasure that many smokers derive from the habit, easing the transition from smoking. [15]

Qualitative surveys have found that most users use HTPs to quit smoking, reduce smoking or reduce the harm from smoking. [14, 15] All were current or former smokers and dual use (concurrent smoking and HTP use) was moderately high. Most reported physical health improvement after switching. Adverse health effects were uncommon.

The leading brand (PMI [redacted] claims to have a total of 12 million users globally in Q3 2019, of which 71% were reported to have completely ceased smoking. [16]

HTPs are available in over 50 countries and there is steady growth in sales. [16] PMI claims that [redacted] has 17% of the tobacco market in Japan, 6% in Korea and 4% in Russia. [16]

In Japan HTPs are disrupting the combustible cigarette market. Cigarette sales by Japan Tobacco fell by an unprecedented 27% over 2 years from 2016-2018 after HTP products were introduced in late 2015. [12] Euromonitor International expects that HTPs will be at least 22% of the Japanese market for tobacco by 2021. [12]

Independent research has found that cigarette sales began to substantially decline when HTPs were introduced in Japan and that HTPs were the likely cause of reduced cigarette sales. [17]

5. Potential public health benefit

The majority of the research on HTPs has been performed by tobacco companies and caution in accepting the results of this research is therefore justified. However, most has been published in peer-reviewed medical journals. Independent reviews have found that tobacco company research so far has been consistent with non-tobacco company research. [18] A significant body of independent research is now appearing.

According to Public Health England's 2018 report [19]

> "The available evidence suggests that heated tobacco products may be considerably less harmful than tobacco cigarettes and more harmful than EC (electronic cigarettes)."

The UK Committee on Toxicity review concluded in 2017 [20]

> "there is a likely reduction in risk for smokers switching to heat-not-burn tobacco products"

HTPs are not risk-free. The key issue is **relative risk** – ie the reduction in risk compared to continuing to smoke.

Harmful and Potentially Harmful Constituents (HPHCs)

Independent reviews have confirmed a substantial reduction in Harmful and Potential Harmful Constituents (HPHCs) in the aerosol from HTPs compared to smoking. In many cases, the exposure to HPHCs was similar to levels from smoking abstinence.

An independent review of 31 studies by Simonavicius concluded [18]

> "Compared with cigarettes, HnB delivered up to 83% of nicotine and reduced levels of harmful and potentially harmful toxicants by at least 62% and particulate matter by at least 75%. Experimental HnB use studies were limited to one product, reductions of human exposure to toxicants varied between 42% and 96%"

The German Federal Institute of Risk Assessment, a branch of the Federal Ministry for Food and Agriculture reported in 2018 that testing of the leading HTP brand ([redacted] concluded [21]

> "Our study confirms that levels of major carcinogens are markedly reduced in the emissions of the analyzed HNB product in relation to the conventional tobacco cigarettes"

British American Tobacco undertook a comprehensive assessment of all key tobacco toxicants listed by Health Canada, WHO /TobReg and the FDA in the aerosol of its product 'glo', compared to cigarette smoke and found a significant reduction in all chemical classes [22]

> "For the nine toxicants proposed by TobReg for mandated reduction in cigarette emissions, the mean reductions in THP1.0 aerosol were 90.6-99.9% per consumable with an **overall average reduction of 97.1%.** For the abbreviated list of harmful and potentially harmful constituents of smoke specified by the US Food and Drug Administration Tobacco Products Scientific Advisory Committee for reporting in cigarette smoke

(excluding nicotine), reductions in the aerosol of THP1.0 were 84.6-99.9% per consumable with an **overall average reduction of 97.5%**"

It is important to emphasise that HTPs **do not eliminate toxins or risk**. However, the level of toxins and the risk of adverse health effects is **greatly reduced** compared to continuing to smoke cigarettes.

Biomarkers of exposure

A recent review of 10 trials by Australian researchers Drovandi et al [23] demonstrated dramatic reductions in biomarkers of exposure (BoEs) which are linked to adverse health effects.

> "This review found that the potential for harm to humans is reduced when using HNB devices compared to conventional cigarettes. These novel devices lead to reduced exposure to key biomarkers, which are linked to the health consequences attributed to tobacco use"

> "In comparison to conventional cigarettes, all 12 BoEs assessed were significantly lower for participants assigned to a HNB device. In comparison to smoking abstinence, HNB devices were statistically equivalent for eight BoEs and significantly elevated for four BoEs."

Second-hand exposure

Research on second-hand emissions suggests that HTPs expose users and bystanders to substantially lower but measurable levels of HPHCs. As the aerosol consists of liquid droplets, it dissipates much more quickly than smoke. The evidence suggests this is likely to be considerably less harmful than tobacco smoke.

Simonavicius [18] concluded that HTPs

> "expose users and bystanders to substantially fewer harmful and potentially harmful compounds than smoking cigarettes"

Modelling studies

In the absence of long-term epidemiological data, simulation modelling can help to predict the population health impact of an intervention. Two peer-reviewed studies funded by Philip Morris International concluded that introducing HTPs into Japan [24] and the US [25] would prevent substantial numbers of smoking-related deaths. The exact benefit depends on the relative-risk assumptions made compared to smoking and the uptake of HTPs.

6. Potential risks of HTPs

There are potential and legitimate risks of HTPs which should be taken into consideration. These include the following.

Uptake by youth and non-smokers

One study found evidence of awareness of HTPs and interest in trying them by youth in Canada, the US and England. [26] Both findings were much higher in smokers than non-smokers. 91-96% of smokers were interested in trying [redacted] compared to 23-33% of non-smokers. It is difficult to know how many who express interest will actually progress to try HTPs. Trying HTPs would be a concern for those non-smokers would not otherwise have taken up smoking. Interest in HTPs was less than for vaping.

However, there is little real-world evidence of uptake of HTPs by non-smoking youth. Youth access can be restricted by sensible risk-proportionate regulation, such as minimum age of sale limits with strict enforcement and penalties for

retailers and advertising restrictions. HTP products should be framed as smoking cessation products for adults. Post-marketing surveillance could monitor for any youth uptake.

However, if an addicted smoking youth switches to a HTP there is likely to be a potential health benefit.

The evidence to date suggests that regular use is overwhelmingly by adult smokers as a safer substitute for smoking and that uptake by non-smoking adults is low. [14] Surveys have found some interest in HTPs by non-smokers. [27] If non-smoking adults who would have smoked uses a HTP instead, there would be a net health benefit.

Tobacco company ownership

It is a concern that this industry is dominated by the tobacco industry whose past behaviour has been appalling and dishonest. More independent research is important to verify the tobacco-industry findings.

Some opponents are reluctant to allow the tobacco industry any further revenue from a new product. However, ATHRA believes the primary focus should be on the improvement of public health. Safer alternatives to smoking will save lives. Furthermore, allowing reduced-risk options for nicotine may enable tobacco companies to escape from selling only the most dangerous options for delivering nicotine – combustible cigarettes.

Unknown long-term risks

Like all new products, the precise long-term risk of HTPs won't be known for another 20-30 years. It is possible that some additional harms may emerge over time and we need to monitor for any new side-effects.

Long-term research is needed. However, based on what we know now – and we know a lot – about

- The chemistry and toxicology of the aerosol
- The absence of products of combustion, and
- The substantially lower levels of biomarkers of exposure

the risk of harms to health from HTPs is likely to be far less than from smoking combustible tobacco products which are freely available.

The distinguished UK epidemiologist Sir Austin Bradford Hill wrote [28]

> "All scientific work is incomplete – whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action that it appears to demand at a given time."

Dual use

HTP users should be encouraged to switch completely as dual use (concurrent smoking and HTP use) is likely to carry much greater risk than using HTPs alone. Dual use is a temporary phase for some users but others still continue to dual use long-term. Public education should inform users of the importance of complete switching and total smoking cessation.

7. Risk analysis

HTPs are substantially safer than smoking for smokers and bystanders. Smokers who are unable to quit combustible tobacco products who switch to HTPs will substantially reduce their exposure to HPHCs and biomarkers of exposure and their risk of smoking related-disease and death. HTPs are popular in many countries and have a wide take-up. The combination of an effective reduction in risk and acceptability for smokers is likely to lead to a substantial public health benefit.

There are legitimate risks from HTPs. However, these are small in comparison to the benefits and can be managed by sensible risk-proportionate regulation, education and ongoing monitoring. Access of young people to HTPs should be restricted as is the case for cigarettes, alcohol and other adult products.

The overall risk analysis is strongly in favour an overall public health benefit. Therefore, ATHRA supports the submission.

8. Other considerations

There are other important considerations which support this submission.

Human rights

The right to health is a fundamental human right and is enshrined in a number of international treaties and conventions including

1. Constitution of the World Health Organisation 2006, preamble [link]
2. The Universal Declaration of Human Rights, UN 1948 [link]
3. International Covenant on Economic, Social and Cultural Rights. UN 1966 [link]
4. International Covenant on Civil and Political Rights UN 1966 [link]
5. International Convention on the Elimination of All Forms of Racial Discrimination. UN 1969 [link]

For example, The WHO constitution states,

> 'The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.' [link]

The scientific evidence supports the use of HTPs as a far safer substitute for smokers who are unable to quit cigarettes. Governments have a responsibility for making safer products available for adults who wish to use them to reduce the harm from smoking. To deny smokers access to these safer products deprives them of an opportunity to reduce their health risks and breaches international law and human rights.

A switch from smoking to HTPs also protects the rights of bystanders to cleaner air with minimal adverse health risks.

Social justice

There is a strong social gradient in smoking rates with decreasing socio-economic status associated with higher smoking prevalence. [1] As a result, smoking is a leading cause of health and financial inequalities. [29]

Smokers from disadvantaged groups have higher smoking rates and lower quit rates than more advantaged smokers. They are disproportionately affected by smoking-related disease and have higher mortality rates than more advantaged populations. [30] This is especially true for Indigenous smokers, smokers with mental illness, low income smokers, homeless people and prisoners.

HTPs have the potential to reduce smoking rates in these priority populations and reduce health inequalities. Disadvantaged populations "have many stressors, few resources and a paucity of other rewards in their lives, thus making the transitory 'pleasures' of smoking and the challenges of nicotine withdrawal more salient. For those for whom the "loss of smoking" is too great, tobacco harm reduction approaches, such as switching to non-smoked nicotine products, should be considered". [31]

Tobacco prices in Australia are now the highest in the world [2] and smoking is an important cause of financial hardship. [32] A pack-a-day smoker on Newstart spends an estimated 72% of their annual income on smoking, leaving very little for food, accommodation and other essentials (based on a pack of 20 cigarettes of the leading brand daily and the maximum Newstart payment for a single person without children).

We support risk-proportionate taxation so that smokers who switch to HTPs have a financial incentive to change. This will also relieve the financial stress in low income smokers.

Ethical considerations

A ban on HTPs denies smokers the right to make an informed decision to improve their health and is paternalistic and unethical. Adults should have the right to make informed choices which do no harm (or minimal harm) to others. [33]

A ban of HTPs is an incoherent form of health risk management because it prohibits the sale of a less harmful way of obtaining nicotine while allowing the sale of the most harmful nicotine delivery system, the combustible cigarette. [33]

Obligations and treaties

Australia has a commitment to tobacco harm reduction under the National Tobacco Strategy and as a signatory to the World Health Organisation's Framework Convention on Tobacco Control (FCTC). Legalising HTPs would be consistent with these obligations.

Tobacco harm reduction is one of the three pillars of Australia's National Tobacco Strategy. [34] One objective of the NTS is to "reduce harm associated with continuing use of tobacco and nicotine products" (p11).

Australia is legally obligated to support tobacco harm reduction as a signatory to the FCTC. [35] The FCTC provides an obligation on governments to not only allow reduced-risk products but actively promote them as part of implementing their tobacco control policies.

Article 1(d) defines tobacco control as meaning "a range of supply, demand and harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke."

Currently Australia is in breach of its international obligations as no harm reduction strategies are supported in practice.

Consistencies with other jurisdictions

In April 2019, U.S. Food and Drug Administration (FDA) rigorously reviewed all the evidence and determined that authorising PMI's "Tobacco Heating System" for the U.S. market is "appropriate for the protection of the public health because, among several key considerations, the products produce fewer or lower levels of some toxins than combustible cigarettes". [link]

HTPs are approved for sale in most other western countries that Australia compares itself with, such as the UK, US, New Zealand, Canada and the European Union.

References

1. Australian Bureau of Statistics. National Health Survey: First Results, 2017-18. Catalogue no 4364 0.55.001. 2018.Available at: http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/by%20Subject/4364.0.55.001~2017-18~Main%20Features~Smoking~85 (accessed July 2019).
2. Numbeo. Price Rankings by Country of Cigarettes 20 Pack (Marlboro) 2019. Available at: https://www.numbeo.com/cost-of-living/country_price_rankings?displayCurrency=AUD&itemId=17 (accessed 14 January 2020).
3. Australian Institute of Health and Welfare. National Drug Strategy Household Survey detailed report 2013. Drug statistics series no. 28. Cat. no. PHE 183. Canberra: AIHW., 2014. http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=60129549848. Accessed 1 October 2017
4. Australian Institue of Health and Welfare. Burden of tobacco use in Australia: Australian Burden of Disease Study 2015. Australian Burden of Disease series no. 21. Cat. no. BOD 20. Canberra: AIHW.; 2019.Available at: https://www.aihw.gov.au/reports/burden-of-disease/burden-of-tobacco-use-in-australia/contents/table-of-contents (accessed 16 January 2020).
5. Banks E, Joshy G, Weber MF, Liu B, Grenfell R, Egger S, et al. Tobacco smoking and all-cause mortality in a large Australian cohort study: findings from a mature epidemic with current low smoking prevalence. BMC Med. 2015;13:38.
6. Australian Bureau of Statistics. National Aboriginal and Torres Strait Islander Health Survey, 2018-19 2019. Available at: https://www.abs.gov.au/ausstats/abs@.nsf/mf/4715.0 (accessed 13 January 2020).
7. Zwar NA, Mendelsohn CP, Richmond RL. Supporting smoking cessation. BMJ. 2014;348:f7535.
8. Borland R, Partos TR, Yong HH, Cummings KM, Hyland A. How much unsuccessful quitting activity is going on among adult smokers? Data from the International Tobacco Control Four Country cohort survey. Addiction. 2012;107(3):673-82.
9. Yudkin P, Hey K, Roberts S, Welch S, Murphy M, Walton R. Abstinence from smoking eight years after participation in randomised controlled trial of nicotine patch. BMJ. 2003;327(7405):28-9.
10. Royal College of Physicians. Nicotine without smoke: Tobacco harm reduction. London: RCP. 2016 Available at: https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0 (accessed September 2019).
11. US Department of Health and Human Services. The health consequences of smoking - 50 years of progress. A report of the Surgeon General.; 2014.Available at: https://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf (accessed 14 January 2020).
12. Knowledge-Action-Change. No Fire, No Smoke: The Global State of Tobacco Harm Reduction 2018.; 2018.Available at: www.gsthr.org (accessed 14 January 2020).
13. Adriaens K, Gucht DV, Baeyens F. [redacted]TM) vs. e-Cigarette vs. Tobacco Cigarette: A Direct Comparison of Short-Term Effects after Overnight-Abstinence. Int J Environ Res Public Health. 2018;15(12).
14. Queloz S, Etter JF. An online survey of users of tobacco vaporizers, reasons and modes of utilization, perceived advantages and perceived risks. BMC Public Health. 2019;19(1):642.
15. Tompkins CNE, Burnley A, McNeill A, Hitchman SC. Factors that influence smokers' and ex-smokers' use of [redacted] a qualitative study of [redacted] users and ex-users in the UK. Tob Control. 2020.
16. Philip Morris International. Investor information, October 2019 2019. Available at: https://philipmorrisinternational.gcs-web.com/static-files/b03960c6-279f-4993-aeca-9f4eb7fb2cd8 (accessed 16 January 2020).
17. Stoklosa M, Cahn Z, Liber A, Nargis N, Drope J. Effect of [redacted] introduction on cigarette sales: evidence of decline and replacement. Tob Control. 2019.
18. Simonavicius E, McNeill A, Shahab L, Brose LS. Heat-not-burn tobacco products: a systematic literature review. Tob Control. 2019;28(5):582-94.
19. McNeill A, Brose LS, Calder R, Bauld L, Robson D. Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England. 2018.Available at: https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review (accessed 14 January 2020).

20. UK Committee on Toxicity. Toxicological evaluation of novel heat-not-burn tobacco products - not-technical summary 2017. Available at: https://cot.food.gov.uk/cotstatements/cotstatementsyrs/cot-statements-2017/statement-on-heat-not-burn-tobacco-products (accessed 13 January 2020).
21. Mallock N, Boss L, Burk R, Danziger M, Welsch T, Hahn H, et al. Levels of selected analytes in the emissions of "heat not burn" tobacco products that are relevant to assess human health risks. Arch Toxicol. 2018;92(6):2145-9.
22. Forster M, Fiebelkorn S, Yurteri C, Mariner D, Liu C, Wright C, et al. Assessment of novel tobacco heating product THP1.0. Part 3: Comprehensive chemical characterisation of harmful and potentially harmful aerosol emissions. Regul Toxicol Pharmacol. 2018;93:14-33.
23. Drovandi A, Salem S, Barker D, Booth D, Kairuz T. Human Biomarker Exposure from Cigarettes versus Novel Heat-Not-Burn Devices: A Systematic Review and Meta-Analysis. Nicotine Tob Res. 2019.
24. Lee PN, Djurdjevic S, Weitkunat R, Baker G. Estimating the population health impact of introducing a reduced-risk tobacco product into Japan. The effect of differing assumptions, and some comparisons with the U.S. Regul Toxicol Pharmacol. 2018;100:92-104.
25. Djurdjevic S, Lee PN, Weitkunat R, Sponsiello-Wang Z, Ludicke F, Baker G. Modeling the Population Health Impact of Introducing a Modified Risk Tobacco Product into the U.S. Market. Healthcare (Basel). 2018;6(2).
26. Czoli CD, White CM, Reid JL, RJ OC, Hammond D. Awareness and interest in [redacted] heated tobacco products among youth in Canada, England and the USA. Tob Control. 2020;29(1):89-95.
27. Ratajczak A, Jankowski P, Strus P, Feleszko W. Heat Not Burn Tobacco Product-A New Global Trend: Impact of Heat-Not-Burn Tobacco Products on Public Health, a Systematic Review. Int J Environ Res Public Health. 2020;17(2).
28. Bradford Hill A. The Environment and Disease: Association or Causation? Proceedings of the Royal Society of Medicine. 1965;58:295-300.
29. Marmot M, Goldblatt P, Allen JG. Fair Society Healthy Lives. 2010.Available at: http://www.instituteofhealthequity.org/resources-reports/fair-society-healthy-lives-the-marmot-review (accessed 14 December 2020).
30. Clarke P, Tew M, McDonald S, Glover J. Mortality by Commonwealth Electoral Divisions in Australia. Public Health Information Development Unit, Torrens University Australia and Centre for Health Policy, University of Melbourne. 2016.Available at: https://mspgh.unimelb.edu.au/__data/assets/pdf_file/0020/2001746/Mortality-by-CED-in-Australia-Report-June-2016.pdf (accessed 14 January 2020).
31. Bonevski B, Thomas DP, Richmond RL. No smoker left behind: it's time to tackle tobacco in Australian priority populations. Med J Aust. 2018;208(1):52.
32. Hoek J, Smith K. A qualitative analysis of low income smokers' responses to tobacco excise tax increases. Int J Drug Policy. 2016;37:82-9.
33. Hall W, Morphett K, Gartner C. A critical analysis of Australia's ban on the sale of electronic nicotine delivery system. Neuroethics. 2019.
34. Intergovernmental Committee on Drugs. National Tobacco Strategy 2012-2018. Publications approval number: D1013 2012. Available at: https://www.health.gov.au/resources/publications/national-tobacco-strategy-2012-2018 (accessed 16 January 2020).
35. World Health Organisation. Framework Convention on Tobacco Control (FCTC). 2003.Available at: http://apps.who.int/iris/bitstream/10665/42811/1/9241591013.pdf?ua=1 (accessed