



Public Health Association
AUSTRALIA

Public Health Association of Australia submission on proposed amendments to Poisons Standard - Nicotine

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Joint Advisory Committee on Medicines
and Chemicals Scheduling (ACMS-ACCS)

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Preamble

The Public Health Association of Australia

The Public Health Association of Australia (PHAA) is recognised as the principal non-government organisation for public health in Australia working to promote the health and well-being of all Australians. It is the pre-eminent voice for the public's health in Australia.

The PHAA works to ensure that the public's health is improved through sustained and determined efforts of the Board, the National Office, the State and Territory Branches, the Special Interest Groups and members.

The efforts of the PHAA are enhanced by our vision for a healthy Australia and by engaging with like-minded stakeholders in order to build coalitions of interest that influence public opinion, the media, political parties and governments.

Health is a human right, a vital resource for everyday life, and key factor in sustainability. Health equity and inequity do not exist in isolation from the conditions that underpin people's health. The health status of all people is impacted by the social, cultural, political, environmental and economic determinants of health. Specific focus on these determinants is necessary to reduce the unfair and unjust effects of conditions of living that cause poor health and disease. These determinants underpin the strategic direction of the Association.

All members of the Association are committed to better health outcomes based on these principles.

Vision for a healthy population

A healthy region, a healthy nation, healthy people: living in an equitable society underpinned by a well-functioning ecosystem and a healthy environment, improving and promoting health for all.

The reduction of social and health inequities should be an over-arching goal of national policy and recognised as a key measure of our progress as a society. All public health activities and related government policy should be directed towards reducing social and health inequity nationally and, where possible, internationally.

Mission for the Public Health Association of Australia

As the leading national peak body for public health representation and advocacy, to drive better health outcomes through increased knowledge, better access and equity, evidence informed policy and effective population-based practice in public health.



Proposed Amendment

PHAA welcomes the opportunity to provide input to the consultation to the Joint Advisory Committee on Medicines and Chemicals Scheduling (Joint ACMS-ACCS) regarding the proposed amendment to the Poisons Standard for nicotine.

The proposal seeks to amend Schedule 7 of the Poisons Standard to add an exemption for “tobacco prepared and packed for heating”. The existing exemption is for nicotine “in preparations for human therapeutic use” or “in tobacco prepared and packed for smoking”.

PHAA Response to the proposed amendment

Health evidence relating to tobacco prepared and packed for heating

The current proposal seems to rely on an argument that heated tobacco products are (and are solely) a less harmful alternative for smokers. However, the World Health Organization has noted that there is currently no evidence to demonstrate that HTPs are less harmful than conventional tobacco products, and there are large knowledge gaps; further, much of the evidence provided in support of HTPs is from research funded by tobacco companies,¹ but the World Health Organization’s expert Study Group on Tobacco Regulation has noted in its most recent report that “Independent scientific evidence is required to verify the claims of industry scientists for reduced exposure and risk”.² It is also important to note that the evidence on HTPs is still at a very early stage, and there is already evidence of harms ranging from direct health harms to undermining cessation to marketing to and impact on young people.

As noted in the Cancer Council Australia, Heart Foundation, and Australian Council on Smoking and Health submission:

- 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 take-up, 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

WHO FCTC

The World Health Organization’s Framework Convention on Tobacco Control (FCTC) includes the obligation for Australia to “adopt and implement effective measures for preventing and reducing tobacco consumption, nicotine addiction and exposure to tobacco smoke”.

It is noteworthy that no attempt is being made here to prove that tobacco prepared and packed for heating is a therapeutic smoking cessation aid. Indeed, the application itself recognises heated tobacco products as a standard product rather than therapeutic. Exempting a new category of nicotine products, thereby opening these new products up to the Australian market, would increase the number, type and range of tobacco and nicotine products available. The proposed amendment not only does not comply with FCTC obligations, it carries significant risk of acting in direct contravention, by increasing tobacco consumption and nicotine addiction. A recent systematic review found susceptibility to trying heated tobacco products among non-smokers, raising concerns that these products will attract young people who would not otherwise use tobacco.³ This directly contravenes our FCTC obligations and threatens the decades of success in reducing tobacco use in Australia. Even though the literature on HTPs is still at an early stage, there is already compelling evidence on their appeal to children and young people – and even more disturbingly that they have been marketed with a particular focus on young people, and that there is a high level of adoption by young people in countries where they have been marketed.^{3,4}

Plain packaging

The current proposal clearly aligns heated tobacco products with conventional smoking tobacco products, rather than with therapeutic cessation aids. Therefore, should the proposal be successful, heated tobacco products must then be labelled and packaged in alignment with conventional smoking tobacco products. However, the *Tobacco Plain Packaging Act 2011* does not allow for this, since it defines a tobacco product as “processed tobacco or any product containing tobacco that is manufactured for smoking, sucking, chewing or snuffing”. An amendment to this Act to allow for heated tobacco products, would facilitate the promotion of a new tobacco product. This would be in direct contravention to its stated purpose which is “An Act to discourage the use of tobacco products”.

Without a demonstrated therapeutic benefit, any heated tobacco products would also not fall under the packaging and labelling requirements of the *Therapeutic Goods Act*.

It is unclear from the proposal how this issue would be resolved.

Marketing

There is overwhelming experience and evidence not only over several decades, but even very recently that tobacco companies use products such as these to promote their wider interests (particularly in conventional tobacco products), to market nicotine to the vulnerable groups, particularly the young, and to distract attention from evidence-based measures to reduce smoking.^{4,5} There is further experience and evidence that tobacco companies have promoted products including HTPs misleadingly, including through new media that are not amenable to traditional controls on tobacco promotion.^{6,7}

Conclusion

PHAA supports the submission from the Cancer Council Australia, Heart Foundation, and Australian Council on Smoking and Health, and strongly recommends that the proposed amendment is rejected.

- The WHO has determined that there is no evidence that heated tobacco products are less harmful than conventional tobacco products
- The current proposal would increase the range and availability of tobacco products in Australia, and be likely to attract new tobacco users, in direct contravention of Government policy to reduce smoking rates, and our international obligations under the FCTC
- There is specific cause for concern in relation to appeal to and use by children and young people, as well as the inevitability that they would be promoted to vulnerable groups such as these
- The current proposal would undermine Australia's plain packaging legislation and broader tobacco control activities
- Only proven therapeutic cessation aids should be approved as newly available tobacco related products
- It is of critical importance that proper public health processes should not be bypassed or weakened.

The PHAA appreciates the opportunity to make this submission and the opportunity to ensure the public health benefits from decades of reducing smoking rates in Australia are not eroded.

Please do not hesitate to contact me should you require additional information or have any queries in relation to this submission.

[REDACTED]

11 February 2020

References

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