



**Public Health Association**  
AUSTRALIA

**Public Health Association of Australia  
submission on the interim decision of the  
TGA to amend the current Poisons  
Standard in relation to nicotine**

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**Public Health Association**  
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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 our Board, National Office, State and Territory Branches, Special Interest Groups and members.

**We believe** that health is a human right, a vital resource for everyday life, and a 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.

**Our mission** as the leading national organisation for public health representation, policy and advocacy, is to promote better health outcomes through increased knowledge, better access and equity, evidence informed policy and effective population-based practice in public health. Members of the Association are committed to better health outcomes based on these principles.

**Our vision** is for a healthy population, a healthy nation and a healthy world, with all people living in an equitable society underpinned by a well-functioning ecosystem and a healthy environment, improving and promoting health and wellbeing for all.

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

## **Introduction**

PHAA welcomes the opportunity to provide input to the TGA's consideration of the proposed amendments to the national Poisons Standard relating to the scheduling of nicotine, which were the subject of the "interim decision" made on 23 September 2020.

PHAA notes at the outset that the TGA should exercise decision-making powers so as to protect the individual and population health of the Australian public, and that its consideration of issues and evidence should be directed to achieving that end.

We also draw TGA's attention to important Framework Convention on Tobacco Control (FCTC) obligations relevant to its decision-making (discussed below).

## **The scheduling of nicotine as a poison is entirely appropriate**

In brief, PHAA supports the changes proposed in the interim decision, and supports these changes being adopted permanently.

Nicotine is, rightly, listed as a poison in the Poisons Standard. Nicotine is a highly addictive chemical which plays a central role in the vast extent of illness and death resulting from the use of tobacco products in Australia and worldwide.

Current state and territory legal regimes dealing with poisonous substances draw on the content of the national Poisons Standard, and TGA has the task of making amendments to the Standard such as that under consideration here. Operating together, the Poisons Standard and state and territory laws apply to all products containing nicotine, with two specified exceptions:

- "tobacco prepared and packed for smoking" – an exception which is an anomaly in terms of health risks, but remains in place due to the continuing status of 'ordinary' tobacco products
- "in preparations for oromucosal or transdermal administration for human therapeutic use as an aid in withdrawal from tobacco smoking" – a continuing exemption which picks up recognised nicotine replacement therapy products (of which the TGA has approved a significant number for use in Australia)

On the basis of this existing regulatory regime – the terms of which are slightly redrafted by the interim decision – the sale and possession of nicotine-containing e-cigarettes, and other novel nicotine-based products, is generally not legal in Australia. Importantly, the interim decision deliberately maintains the current legal position relating to e-cigarettes and other novel products which contain the poison nicotine.

The general legal control on the spread of nicotine-containing e-cigarettes and other novel nicotine products is clearly a desirable outcome in terms of public health. There is worldwide evidence that the spread of such products presents two forms of harm:

- Harms to individual users flowing from the use of the products themselves
- Harms resulting indirectly from the presence of nicotine-containing novel products in the community on the effective implementation of the strategic national goal of reducing smoking rates in Australia.

In making decisions, TGA and the delegated decision-maker should take into account *both* those forms of harm. That is, TGA the delegated decision-maker should consider the evidence relating to the harms from nicotine products themselves, as well as evidence relating to the wider impact of such products on smoking cessation strategies, policies and campaigns. Those wider impacts have been recently summarised by the

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ANU National Centre for Epidemiology and Public Health (NCEPH), in research commissioned by the Australian government, which concluded (among other findings) that –

- “To maintain Australia’s world-leading progress on tobacco, it is important to avoid e-cigarette use in non-smokers and to provide evidence-based support for smokers to quit.”
- “E-cigarettes are a gateway to tobacco smoking for young people.”
- “In Australia, under current highly restrictive e-cigarette access policies, around one-fifth of current daily e-cigarette users are people who have never smoked tobacco.”
- “Use of e-cigarettes by smokers trying to quit is likely to lead to greater long-term exposure to nicotine than the use of other smoking cessation measures.”

We note in particular the highly important rate of smoking among children and young people has continued to decline over time. The latest Australian Secondary Students' Alcohol and Drug (ASSAD) survey shows that the proportion of Australian secondary school students who had *never* tried smoking has continued to rise from 77% in 2011 to 82% in 2017.<sup>1</sup> It would be deeply disturbing if this encouraging trend were put at risk by the growth in circulation of the novel nicotine-containing products.

For these solid, evidence-based public health reasons, PHAA supports the continued scheduling of nicotine as a poison, and the continuation of controls on nicotine-containing e-cigarettes and other novel nicotine products. The interim decision clearly maintains that position.

We note that the interim decision is also consistent with the clear and strong policy position of the Australian Government on this issue, as most recently outlined in the Government’s June 2020 response to the House of Representatives Standing Committee on Health, Aged Care and Sport *Report on the Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia*.<sup>2</sup>

The Australian Government is continuing a clearly precautionary approach to regulation of nicotine-containing e-cigarettes and other novel nicotine products. The Government is also supporting that approach by investing in a range of research efforts to improve knowledge of the health impacts of such products. Moreover, all state and territory governments policies are aligned with the Australia Government position, and governments have a strong track record of coordinating policy-making in the national interest through the Ministerial Drug and Alcohol Forum (MDAF).

PHAA also notes the importance of complementing the regulatory alterations TGA is currently considering with further action to reduce smoking in the Australian community through a comprehensive approach, including public education, regulation, price signals, special programs in relation to priority groups, and system-wide cessation supports.

### **Textual revisions to the limited ‘personal use’ exemption are appropriate**

Despite this strong broad national policy direction, we note that there currently exist limited and conditional exemptions allowing for possession and small-scale importation (but not sale) of nicotine-containing e-cigarettes for personal use where supported by medical advice and for the specific purpose of assisting a specific individual with quitting smoking. (Corresponding exemptions apply to the associated actions of medical advisers and prescribers.)

We note that this exemption regime has two significant present flaws:

- Enforcement of this exemption regime is inherently difficult, leading to large numbers of users of nicotine e-cigarettes in Australia beyond what might be expected from a well-enforced application of this exemption

- There is evidence that many products labelled and marketed as ‘non-nicotine’ currently being sold in Australia, and as such lying outside the main regulatory rules, do indeed contain nicotine, in serious contravention not only of the laws based on the Poisons Standard but also wider Australian consumer law.<sup>3</sup>

In addition to these difficulties in practical enforcement, it has become clear that the existing drafting of the Poisons Standard, customs law and therapeutic goods law are somewhat misaligned, with the result that regulatory loopholes have opened up, increasing the practical impediments to effective implementation of the law.

As a matter of good public policy, regulatory arrangements should be clear, and they should be effective. It is appropriate for Governments and regulators to amend existing rules to close loopholes and improve the effectiveness of the law.

PHAA notes that the Australian Government and its agencies are indeed working to address these loopholes. The current interim decision to amend the Poisons Standard is one element of the efforts of the Government (including the TGA) to improve the regulatory landscape and close these loopholes. Other regulatory improvements have been separately proposed by the government in regard to customs law, with the effect of ensuring that controls on importation of nicotine products outside the intended scope of the medical-prescription exemption are better given effect. These regulatory improvements have PHAA’s support.

### **Claims that nicotine vaping may have therapeutic use are not proven**

It is also important to address claims that nicotine vaping products can serve a therapeutic role assisting smokers to quit smoking.

Claims made by the vaping products sector and its associated lobbying entities include that e-cigarettes are inherently therapeutic as a smoking cessation aid. Some of these arguments further include dramatic suggestions that failing to reduce or remove current regulatory controls would result in continued or larger-than-otherwise death rates from smoking.

These claims are clearly contested by credible independent research (see below). Indeed, it is commonplace for these arguments to be entirely unsupported by independent research evidence, cite industry-funded and otherwise non-independent research, or cite published evidence from credible health researchers and institutions only selectively.

PHAA urges TGA, and the decision-making delegate responsible for considering the interim decision, to fully investigate such claims and take note of the clear rebuttals being provided by major independent centres of health research.

On this matter, a number of well-placed, expert Australian authorities, free from commercial interests, have undertaken recent and/or ongoing examination of these issues, including:

- National Health and Medical Research Centre (NHMRC) *CEO’s statement on e-cigarettes* to assist consumers and policymakers in understanding the current evidence about the safety and efficacy of e-cigarettes (2017)<sup>4</sup>
- CSIRO literature review into the use and impacts of e-cigarettes and personal vaporisers (2018-19)<sup>5</sup>
- National Industrial Chemicals Notification and Assessment Scheme (NICNAS) study into the chemistry of liquids used in e-cigarettes in Australia (2018-19)<sup>6</sup>

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- ANU National Centre for Epidemiology and Population Health (NCEPH) assessment of electronic cigarette use for the Australian context, commissioned by the Australian Government (2019-20; summary report September 2020, final report expected in 2021)<sup>7</sup>

Another major recent paper being widely cited is the 2018 paper by the US National Academies of Sciences Engineering, and Medicine (NASEM) on the *Public Health Consequences of E-Cigarettes*, which opens with this summary of the state of research –

“Millions of Americans use e-cigarettes. Despite their popularity, little is known about their health effects. Some suggest that e-cigarettes likely confer lower risk compared to combustible tobacco cigarettes, because they do not expose users to toxicants produced through combustion. Proponents of e-cigarette use also tout the potential benefits of e-cigarettes as devices that could help combustible tobacco cigarette smokers to quit and thereby reduce tobacco-related health risks. Others are concerned about the exposure to potentially toxic substances contained in e-cigarette emissions, especially in individuals who have never used tobacco products such as youth and young adults. *Given their relatively recent introduction, there has been little time for a scientific body of evidence to develop on the health effects of e-cigarettes.*”<sup>8</sup> (emphasis added)

(We note in passing that the NASEM paper has recently been the subject of a number of cases of selectively quotation by the vaping products sector, its associated lobbying entities, and others. We draw the TGAs attention to the need to go to the source and fully consider the content of this paper (and indeed all sources) rather than take selective extracts at face value.)

In short, notwithstanding much research currently underway worldwide, there is as yet no adequate evidence that nicotine-containing vaping products have a safe and therapeutic value in helping individuals quit smoking, particularly at the population level. By way of overview, after reviewing the available research the recent NCEPH summary report concludes that –

- “There is insufficient evidence as to whether or not e-cigarettes are an effective aid for quitting smoking.”
- “The large majority of people who successfully quit smoking do so unaided.”

If manufacturers and retailers believe that their products do have a therapeutic value, the obligatory course of action under Australian therapeutic goods law is to submit such claims for evaluation by the TGA. It is noteworthy that to date, no retailing entity has sponsored such an application for vaping products.

### **TGA has responsibilities under international law relating to decision-making**

Finally, PHAA wishes to draw the attention of TGA, and the decision-making delegate responsible for considering the interim decision, to the responsibilities of the Australian Government under the WHO Framework Convention on Tobacco Control (FCTC) (article 5.3) regarding the exclusion of industry influence from public policy making.

Such industry influence is evident whenever Australian government agencies or parliamentary inquiries are held on topics such as the present consultation on the interim decision amending the poisons scheduling of nicotine. Sadly, agents of such influence do not reveal their full identity and the interests they represent.

As an agency of the Australian government, TGA has responsibilities to examine any submissions made to it on such issues, and actively ensure that it does not take into account any material which has its origins in FCTC-proscribed industry influence. For TGA to be directly or indirectly influenced by such sources could bring into question both the policy correctness, and also the legal strength, of its decisions.

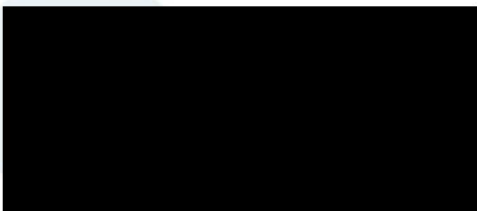
## **Conclusion**

PHAA appreciates the opportunity to contribute to this important regulatory decision.

In concluding, we note that it will be especially important to ensure that impacts of the proposed changes to the Poisons Standard are carefully monitored, with effective controls to ensure that tobacco companies and other commercial interests are not permitted to promote their products directly or indirectly, or in any other way to undermine the continuing and very welcome rate of decline in smoking in Australia.

Finally, we also note that we are aware of the submission to TGA on this matter being provided by the Cancer Council Australia and the Australian Council on Smoking and Health, and we support the approach taken therein.

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



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