



# Comment on an interim decision coversheet

This form accompanies a submission on 'Interim decision consultation: Proposed amendments to the Poisons Standard, [Committee] Meeting, [Month] [Year]'

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**Public Health Association**  
AUSTRALIA

# Public Health Association of Australia submission on rescheduling of nicotine

*Proposed amendments to the Poisons Standard (Medicines)*

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1 September 2016

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# Introduction

## The Public Health Association of Australia

The Public Health Association of Australia Incorporated (PHAA) is recognised as the principal non-government organisation for public health in Australia and works to promote the health and well-being of all Australians. The Association seeks better population health outcomes based on prevention, the social determinants of health and equity principles. PHAA is a national organisation comprising around 1900 individual members and representing over 40 professional groups.

The PHAA has Branches in every State and Territory and a wide range of Special Interest Groups. The Branches work with the National Office in providing policy advice, in organising seminars and public events and in mentoring public health professionals. This work is based on the agreed policies of the PHAA. Our Special Interest Groups provide specific expertise, peer review and professionalism in assisting the National Organisation to respond to issues and challenges as well as a close involvement in the development of policies. In addition to these groups the Australian and New Zealand Journal of Public Health (ANZJPH) draws on individuals from within PHAA who provide editorial advice, and review and edit the Journal.

In recent years PHAA has further developed its role in advocacy to achieve the best possible health outcomes for the community, both through working with all levels of Government and agencies, and promoting key policies and advocacy goals through the media, public events and other means.

## Preamble

The PHAA welcomes the opportunity to provide input to the Therapeutic Goods Administration (TGA) on the ***“Proposed amendments to the Poisons Standard (Medicines)”*** regarding nicotine.

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. The Australian Government, in collaboration with the States/Territories, should outline a comprehensive national cross-government framework on reducing health inequities. All public health activities and related government policy should be directed towards reducing social and health inequity nationally and, where possible, internationally.

### **This submission regarding the proposed rescheduling of nicotine**

The rescheduling of nicotine has widespread public health implications that should be taken into account in any consideration of amendments to the Poisons Standard (Medicines).

This submission is provided on behalf of the Public Health Association of Australia (PHAA) in relation to the proposal to amend the Poisons Standard to exempt nicotine from Schedule 7 at concentrations of 3.6% or less for self-administration with an electronic nicotine delivery system.

The PHAA wishes to register its strong concern about the dangers associated with nicotine. At this stage any consideration of a change in the schedule should be considered in the light of the developing evidence on the general use and possible harms of e-cigarettes and the broad implications regarding possible adverse impacts in relation to the successful reduction in smoking in Australia.

# Cancer Council of Australia

## General support

We are aware of the submission from the Cancer Council Australia. In the interests of avoiding duplication, we would therefore wish to note that in general terms we support the approach taken in their submission and reiterate the concerns raised by them.

## Concerns

### Nicotine

We wish to note in particular that:

- There is compelling evidence that nicotine is a highly toxic substance.
- There are specific concerns about the role of nicotine in relation to a wide range of harmful health consequences
- The WHO International Agency for Research in Cancer (IARC) has listed nicotine as a high priority agent for investigation for carcinogenicity, and has specifically noted “increasing population exposure via electronic nicotine delivery system” and “recent mechanistic data suggest an association with DNA damage and other pathways of carcinogenesis.”

### Harmful effects of electronic cigarettes

- There is clear and emerging evidence about the potentially harmful health effects of e-cigarettes.
- Given the novelty of e-cigarettes, there is particular further concern about the range of products and flavourings and potential harms from these
- There is further evidence of potential harms to those exposed to second hand vapour.

### Electronic Cigarettes as smoking cessation aid

- The evidence supporting electronic cigarettes as a smoking cessation aid is at best conflicting; and at this stage there is insufficient evidence to support their promotion for this purpose.

### Electronic cigarettes recruiting young people into smoking

- There is evidence-based concern about the role of e-cigarettes and related products in recruiting adolescents to smoking. There is also concern that promotion of e-cigarettes and related products may discourage smokers from quitting and encourage some who have quit to start again

## PHAA submission on rescheduling of Nicotine

### Tobacco companies role in electronic cigarettes

Tobacco companies now have a major and growing role in electronic cigarettes in ownership, manufacture and distribution

- There is overwhelming evidence that for more than sixty years tobacco companies have lied, suppressed and distorted evidence, and misled governments, policy-makers and the community. Any evidence from tobacco companies or those associated with them cannot be taken at face value.
- Tobacco companies and others will abuse any relaxations in measures to protect the public from the harms of nicotine, including through promotion of smoking behaviour to children and young people.

### Free market approach completely unacceptable

Advocates of electronic cigarettes often distort these arguments (as they have in England) to open a new market that encourages the use of the poison while at the same time opening a free market of the type that was seen with tobacco fifty years ago and took decades of commitment and political will to turn around and reduce the extraordinary levels of harm caused by nicotine addiction in tobacco.

The attached photo (taken in Scarborough in the United Kingdom) illustrates how a free market in electronic cigarettes encourages young people in particular to take up 'vaping'.

There were at least four similar shops within a couple of hundred metres in the main shopping street in Scarborough. This is an approach that must be avoided in order to minimise the harm associated with all forms of smoking.



**The dangers of UN-controlled availability – Scarborough UK**

### Harm minimisation

There is debate within public health circles and agencies around the role of electronic cigarettes in harm minimisation terms. These arguments have been differently interpreted in some jurisdictions internationally where there has not been the success in discouraging smoking that has been achieved in Australia.

The PHAA appreciates the opportunity to make this submission and the opportunity to encourage the TGA to ensure continuing serious restrictions on the availability of such a dangerous substance. E-cigarettes and any related products should meet the same processes, requirements and standards as any other new products proposed for therapeutic use.

### Harm-minimisation is not a free-for-all.

Where there are claims of use in terms of harm minimisation, any approach to such products, if permitted following normal TGA processes should be consistent with a controlled availability approach that has been adopted as part of the Australian National Drug Strategy which is based on three significant pillars:

- **Demand reduction**
  - prevent uptake and delay onset of drug use
  - use of drugs in the community
  - support people to recover from dependence and reconnect with the community
  - support efforts to promote social inclusion and resilient individuals, families and communities.
- **Supply reduction**
  - reduce the supply of illegal drugs (both current and emerging)
  - control and manage the supply of alcohol, tobacco and other legal drugs.
- **Harm reduction**
  - reduce harms to community safety and amenity
  - reduce harms to families
  - reduce harms to individuals.

(Australian Federal Department of Health (2010) The National Drug Strategy 2015)

In order to apply these three pillars nicotine should remain available only in the most restricted manner. As the Cancer Council of Australia submission sets out, there are serious limitations in our understanding of the dangers associated with nicotine inhaled through electronic cigarettes. The currently available information is very limited because we remain at early stages of sound, peer reviewed academic evidence. The evidence currently available does raise serious concerns about efficacy and harmful side-effects across all of the areas set out in this submission and that of the Cancer Council of Australia.

For these reasons, the process for e-cigarettes and similar products should remain the same as for any products proposed for therapeutic use. Manufacturers should take their products to the TGA with evidence of safety and efficacy; it is then for the TGA to consider their submissions and the evidence and make appropriate determinations as to whether the products may be sold, to whom, and under what (if any) circumstances and restrictions.

## Conclusion and Recommendation

We are particularly keen that the following points are highlighted as key public health concern:

- the dangers of nicotine
- harms from the use of electronic cigarettes
- the impacts and potential for electronic cigarettes to recruit young people and encourage smokers to return to smoking
- the distortion of messages of harm minimisation that do not include supply and demand reduction, and
- the involvement of tobacco companies and those associated with them.

## *PHAA submission on rescheduling of Nicotine*

For these reasons, and those set out in the Cancer Council Australia submission, the Public Health Association of Australia recommends that at this stage the Poisons Schedule not be amended as proposed, and that e-cigarettes and similar products should remain subject to standard TGA processes.

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



Michael Moore BA, Dip Ed, MPH  
Chief Executive Officer  
Public Health Association of Australia

1 September 2016

