

**Australian Health Promotion Association
submission to the
Therapeutic Goods Administration
*Potential reforms to the regulation of nicotine vaping
products: Consultation Paper***

January 2023



Contact for submission:
Department of Health and Aged Care
Therapeutic Goods Administration (TGA)
nvp@health.gov.au

INTRODUCTION

Australia is one of the healthiest countries in the world largely because of effective public health, including action to create and support the social and environmental conditions that enable Australians to enjoy a healthy and happy life. We are now more aware than ever of just how complex the circumstances are by which human health is influenced – policies and actions shaped by the unfair distribution of wealth, power, and resources, both locally and internationally. Strong policy action is required to support individuals and communities to act to address those forces.

The Australian governments' commitment¹ to maintaining a precautionary approach to nicotine vaping products (NVPs) is supported by the Australian Health Promotion Association, particularly given the increasing evidence of youth uptake² and the harms resulting from vaping product use (nicotine and non-nicotine)³. The Australian Health Promotion Association shares the concerns of the TGA⁴ that existing requirements for NVPs are not meeting the aim of preventing children and adolescents from accessing these products, whilst allowing smokers to access them for smoking cessation with a doctor's prescription.

About Us

The Australian Health Promotion Association Ltd (AHPA®) is the peak body for health promotion in Australia. AHPA advocates for the development of healthy living, working and recreational environments for all people. Through our work we support the participation of communities and groups in decisions that affect their health. Incorporated in 1990, AHPA is the only professional association specifically for people interested or involved in the practice, policy, research, and study of health promotion. Our member-driven national Association represents over 1000 members and subscribers and is governed by a Board at the national level with operational branches representing all states and territories.

Membership of AHPA is diverse, and includes designated health promotion practitioners, researchers, and students, as well as others involved in promoting physical, mental, social, cultural and environmental health, whose primary profession or area of study may be something different, but whose responsibilities include promoting health. Members represent a broad range of sectors including health, education, welfare, environment, transport, law enforcement, town planning, housing, and politics. They are drawn from government departments and agencies, universities, non-government organisations, community-based organisations and groups, private companies, and students.

Our activities include: national registration of health promotion practitioners for the International Union for Health Promotion and Education in Australia; national health promotion university learning and teaching network; early career support; national and local conferences and events; a tri-yearly Population Health Congress (with partners: Public Health Association of Australia, Australasian Epidemiological Association and Australasian Faculty of Public Health Medicine); a website providing professional and membership information; a national listserv providing members with sector news, employment, advocacy and events information; stakeholder and member communication across a range of platforms; advocacy action; strong partnership working with a range of organisations; awards; traineeships; mentoring; scholarships and bursaries; and the Health Promotion Journal of Australia.

Our Vision

A healthy, equitable Australia.

Our Purpose

Leadership, advocacy and workforce development for health promotion practice, research, evaluation and policy.

Our Principles

- Ethical practice - Supporting culturally informed, participatory, respectful, and safe practice.
- Health equity - Addressing the sociocultural, economic, political, commercial, and ecological determinants of health in order to build health equity.
- Innovative and evidence informed approaches - Promoting and supporting evidence informed research, policy and practice.
- Collaboration - Working in partnership with other organisations to improve health and wellbeing.

Our Strategy

1. Promote the health promotion profession and our members
2. Advocate for health promotion
3. Build the professional capacity of AHPA members
4. Support career pathways in health promotion
5. Promote equity, diversity, and inclusion
6. Provide responsible and sustainable governance and management

Detailed actions to achieve the strategy can be found in our [Strategic Plan](#) document.

The Australian Health Promotion Association supports comprehensive restrictions to halt avenues of illegal supply of NVPs and welcomes the opportunity to comment on the reform of the regulations of vaping products.

Below we outline the options we support to achieve this outcome.

1. BORDER CONTROL

Support Option 4

Federal government to introduce an amendment of the Customs Regulations to declare all vaping products (nicotine and non-nicotine products) prohibited imports. An import permit would be required to demonstrate that the import falls within one of the exemptions for accessing unapproved therapeutic products. An integrated approach on NVPs and non-nicotine vaping products is required, otherwise the concealment of nicotine in vaping products will continue to undermine the effectiveness of any TGA reforms to end illegal access to NVPs.

Additional Actions Required:

- Therapeutic goods controls to deal with the domestic manufacture and supply of NVPs.
- Federal, State and Territory government action to ban and enforce prohibition of the importation, manufacturing, and supply of all vaping products.
- Option 2 is not supported as a standalone strategy as it has not been effective in ending the illegal supply of vaping products. Consideration should be given to reducing the allowance of NVP supply to less than 15 months; and access to NVPs via local pharmacies only (ensuring patient receive health professional advice).

2. PRE-MARKET TGA ASSESSMENT OF NVPs

Support Option 3

Option 3 is the optimal model for accessing NVPs in Australia, ensuring the quality, safety, and efficacy of prescription products for smoking cessation. This approach is expected by Australian consumers. In the event that Option 3 cannot be implemented swiftly, we support Option 1 (make no changes), until Option 3 can be implemented.

We do not want to disadvantage individuals wanting access to smoking cessation support. Option 2 is not supported as it would undermine the quality, safety, and efficacy of smoking cessation prescription products, be misunderstood by consumers as an “endorsement by the TGA” and possibly undermine the role and status of the TGA.

3. MINIMUM QUALITY AND SAFETY STANDARDS FOR NVPs

Support Option 7

To reduce the appeal and harm of vaping products through amendments to TGO 110 or by changing the terms of the exemptions under which unapproved NVPs are currently imported:

- Prohibit all flavours (except tobacco) and additional ingredients.
- Modify labelling or packaging requirements, including to require pharmaceutical-like plain packaging.
- Reduce the maximum nicotine concentration for both freebase nicotine and nicotine salt products to 20 mg/mL (base form or base form equivalent).
- Remove access to disposable NVPs.

4. CLARIFYING THE STATUS OF NVPs AS 'THERAPEUTIC GOODS'

Yes this is supported

Clarifying the status of NVPs as therapeutic goods would enable the TGA to take regulatory action in relation to NVPs that contain nicotine, but are not labelled as such, under the therapeutic goods legal framework.

We welcome further opportunities to contribute to the ongoing dialogue to support actions to better support the intent of the 2021 reforms, namely preventing children and adolescents from accessing NVPs. Please also see also our submission to the [2020 Select Committee on Tobacco Harm Reduction](#) for further information on our position relating to e-cigarette use.

Please do not hesitate to contact us with further questions.



Dr Gemma Crawford
President | Australian Health Promotion Association
national@healthpromotion.org.au

Prepared by: *Professor Jonine Jancey, AHPA Fellow*
Input by: *Dr Kahlia McCausland and Mr Luke van der Beeke, AHPA Members*

References

¹ See [Policy and regulatory approach to electronic cigarettes \(e-cigarettes\) in Australia | Australian Government Department of Health and Aged Care](#).

² Banks E, Yazidjoglou A, Brown S, Nguyen M, Martin M, Beckwith K, Daluwatta A, Campbell S, Joshy G. Electronic cigarettes and health outcomes: systematic review of global evidence. *Report for the Australian Department of Health*. National Centre for Epidemiology and Population Health, Canberra: April 2022. <https://openresearch-repository.anu.edu.au/handle/1885/262914>

³ Watts, C, Egger, S, Dessaix, A, Brooks, A, Jenkinson, E, Grogan, P and Freeman, B (2022), Vaping product access and use among 14–17-year-olds in New South Wales: a cross-sectional study. *Australian and New Zealand Journal of Public Health*.

<https://doi.org/10.1111/1753-6405.13316>

⁴ TGA Potential reforms to the regulation of nicotine vaping products. Consultation paper

<https://consultations.tga.gov.au/medicines-regulation-division/proposed-reforms-to-the-regulation-of-nicotine-vap/>