

Therapeutic Goods Administration

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To whom it may concern

I am writing to provide a submission from the Australian Alcohol and other Drugs Council (AADC) to the *Proposed reforms to nicotine vaping products* consultation process. AADC welcomes the opportunity to provide comment on the regulatory model for nicotine vaping products in Australia. AADC is particularly concerned about outcomes of the current regulatory model which create criminal penalties for individuals accessing and using NVPs. This has the potential to exacerbate harms associated with NVP use. We believe that Australian and international experiences with illicit drug prohibition provide key principles to inform a future regulatory model for NVPs in a complex and rapidly changing landscape.

About the Australian Alcohol and other Drugs Council

The Australian Alcohol and other Drugs Council (AADC) is the national peak body representing the alcohol and other drugs (AOD) sector. We work to advance health and public welfare through the lowest possible levels of AOD related harm, including tobacco and smoking-related harms, by promoting effective, efficient and evidence-informed prevention, treatment and harm reduction policies, programs and research at the national level. AADC's founding members comprise each state and territory peak body for the AOD sector, other national peak bodies relating to the AOD sector, and professional bodies for those working in the AOD sector.

AADC is a member-based organisation and represents:

- over 550 AOD specialist health services working to prevent and reduce harms which can be associated with the use of AOD, including more than 80% of the non-government organisations that receive federal funding to deliver services and support to people using AOD;
- more than 1600 specialist practitioners working in AOD services in the areas of prevention and early intervention, as well as treatment settings representing all treatment types including counselling, detoxification, residential and non-residential rehabilitation, opiate replacement therapy, and harm reduction and prevention services;
- researchers and policy specialists dedicated to building the evidence-base to support robust, high impact practice and programs; and
- people who use or have used AOD, and their families.

The current membership of AADC is:

Alcohol, Tobacco and Other Drug Association ACT (ATODA)	Alcohol, Tobacco and Other Drugs Council Tasmania (ATDC)	Association of Alcohol and Other Drug Agencies NT (AADNT)
Australasian Therapeutic Communities Association (ATCA)	Australian Injecting and Illicit Drug Users League (AIVL)	Drug and Alcohol Nurses Australasia (DANA)
Family Drug Support	National Indigenous Drug and Alcohol Committee (NIDAC)	Network of Alcohol and Other Drug Agencies (NADA)
Queensland Network of Alcohol and Other Drug Agencies (QNADA)	South Australian Network of Drug and Alcohol Services (SANDAS)	The Australasian Professional Society on Alcohol and other Drugs (APSAD)
Victorian Alcohol and Drug Association Inc (VAADA)	Western Australian Network of Alcohol and other Drug Agencies (WANADA)	Drug Policy Modelling Program* <i>*AADC associate member</i>

An evolving and rapidly changing landscape

The research and knowledge landscape in relation to vaping products and e-cigarettes, particularly regarding the efficacy of nicotine vaping products (NVPs) as a harm reduction or smoking cessation aid, is dynamic and continuously changing. This continually evolving knowledge base creates a complex environment in which to regulate access and sale of NVPs and minimise the potential for harm.

However, the TGA discussion paper, emerging research such as from the Cancer Council NSW and University of Sydney’s *Generation Vape* study and media reporting from outlets such as ABC’s *Four Corners*¹, indicates that NVPs are widely accessible in the community outside of the prescription model established in 2021. AADC believes the experiences of illicit drug prohibition and criminalisation in Australia, along with evidence in relation to related public health measures, provide some key principles which can inform a future model of NVP regulation. These principles are:

- Possession and/or use of an NVP should not be a criminal offence
- Delaying uptake of NVPs by people under 18 years of age is a desirable public health outcome
- Utilising the knowledge of people currently using NVPs will be integral to the development of effective regulatory frameworks

Possession and/or use of an NVP should not be a criminal offence

The classification of NVPs as a Schedule 4 prescription medicine as part of 2021’s regulatory changes created a subsequent offence under state and territory legislation. In all Australian jurisdictions, it is an offence to possess a Schedule 4 medication without valid authorisation. Maximum penalties vary according to jurisdiction and are outlined in Table 1. By way of comparison, Table 1 also outlines the maximum penalties associated with possession for an illicit drug for personal use.

¹ Tobin, G. (2022, June 27). “Street sales, online dealers and convenience stores: Inside the thriving black market for nicotine vapes”, *ABC Online*. Accessed 3 January 2023 at <https://www.abc.net.au/news/2022-06-27/inside-the-thriving-black-market-for-nicotine-vapes/101176544>

Jurisdiction	Penalty for unauthorised Schedule 4 medicine possession	Penalties for personal use illicit drug possession
ACT	Up to \$32,000 or two years prison, or both <i>(s35-1 Medicines, Poisons and Therapeutic Goods Act 2008)</i>	Up to \$1,110 or two years prison; \$150 fine for under 50g cannabis possession. Other diversion provisions available at police and court discretion. Note: new laws come into effect in October 2023.
NT	Up to \$16,200 or 12 months prison <i>(s39 Medicines, Poisons and Therapeutic Goods Act 2012)</i>	Up to \$13,770 and/or five years prison; diversion provisions available at police and court discretion. Fines for small amounts of cannabis.
NSW	\$5,500 or 12 months prison, or both <i>(s18B-2 Drug Misuse and Trafficking Act 1985 No.226* / Schedule 4 Medicines, Poisons and Therapeutic Goods Act 2022 No. 73)</i> <i>*Not yet in force</i>	Up to \$5,550 and/or two years prison; diversion provisions available at police and court discretion
QLD	Up to \$8,625 <i>(s146 Health Drugs and Poisons Regulation 1996)</i>	Up to 15 years prison; diversion provisions available at police and court discretion
SA	Up to \$10,000 <i>(s18-3 Controlled Substances Act 1984)</i>	Up to \$2000 or two years prison, or both. Diversion provisions available at police and court discretion, fines for small amounts of cannabis.
TAS	\$1,810 <i>(s91-11 Poisons Regulations 2018)</i>	\$905 or two years prison; diversion provisions available at police and court discretion
VIC	\$1,840 <i>(s36B Drugs, Poisons and Controlled Substances Act 1981)</i>	Up to \$5,452 and one year prison; diversion provisions available at police and court discretion
WA	\$45,000 <i>(s14-4 and s115 Medicines and Poisons Act 2014)</i>	\$2000 and/or two years prison; diversion provisions available at police and court discretion

Table 1: Maximum penalties for unauthorised possession of a Schedule 4 medication and possessing a personal use amount of an illicit drug.

Table 1 highlights that in six Australian jurisdictions the maximum penalties for possessing a liquid containing nicotine are equivalent to or exceed the penalties for possessing personal use amounts of illicit substances such as heroin, methamphetamines, cocaine and cannabis. The application of criminal penalties is particularly notable given that nicotine containing products in the form of combustible cigarettes are legally available through most supermarkets, petrol stations and speciality tobacco retail outlets across Australia. It is also important to note that where combustible tobacco products are possessed by a person under 18 years of age, these are typically confiscated by police officers and no offence is recorded.

The outcomes of criminalising the use and possession of NVPs are demonstrated in the context of South Australian custodial settings becoming smoke-free. Current South Australian legislation criminalises both supplying and possessing a prohibited item (which includes tobacco and related products) in a custodial setting. This offence is subject to up to 5 years incarceration. If the substance is a controlled drug as defined under the Controlled Substances Act 1984 (which includes Schedule 4 medications) the offence is subject to as much as 10 years incarceration. The aim of this legislation is to reduce or stop the smuggling of contraband into prisons. However, the outcome is that a person with a minor conviction or on remand prior to a conviction possessing an NVP, or a person supplying a prisoner on a minor sentence with an NVP, could receive a 10 year prison sentence.

Within the general community, Australian and global responses to illicit drug use highlight the negative consequences created by a regulatory model focused on criminalisation of individual substance uses. Criminalisation of illicit drugs impacts the health and wellbeing of people who use drugs by incentivising a market for substances of unknown quality and creating barriers to accessing support. In a criminalised environment where a substance is made illegal but is widely available through illicit markets, the quality, chemical make-up and potency of a substance is often unknown to people who use that substance, leading to harmful health impacts such as fatal and non-fatal overdose. This outcome is reflected in relation to NVPs where, as highlighted in this consultation's discussion paper, 57% of a tested sample of vaping products contained undeclared nicotine. Similar outcomes have been found in other research on vaping products, with people who use vaping products often unaware of whether their product contains nicotine.²

The stigma of engaging in an illegal activity acts as a barrier to help seeking where support is required, both in general health contexts as well as in the case of AOD related support.³ Additionally, the stigmas surrounding a criminal record have ongoing and lasting consequences, such as impacting on employment prospects. Where people are experiencing harm related to the use of NVPs, it is critical that the real or perceived risk of a criminal consequence, or stigma associated with an illegal activity, is not a barrier to accessing or receiving quality support.

AADC is concerned that the criminalisation of NVP use and possession will have a range of negative consequences which exacerbate harms associated with NVP use. AADC also notes that the outcome of some of the options presented within the consultation's discussion paper may increase the risk of criminal penalties related to individual NVP possession and use. As such, AADC advocates for the removal of criminal penalties for NVP possession and use by individuals and recommends supply-related issues be the primary focus of an NVP regulatory model. While AADC recognises that broader policy direction in relation to the issue of criminalisation may be beyond the remit of the TGA and the context of this specific consultation regarding regulatory processes, we believe it is an important principle to establish in determining the parameters for any regulatory framework for NVPs.

Delaying uptake of NVPs by people under 18 years of age is a desirable public health outcome

As noted within this consultation's discussion paper, research and media reporting, nicotine and non-nicotine containing vaping products are being widely accessed by young people. A majority of these young people had no previous experience with smoking.⁴

Given the high rates of vaping products containing non-declared nicotine, it is critical that a regulatory model prioritises measures aimed at delaying the uptake of NVPs for people under 18 years of age and ensuring that where young people do access a vaping product, they can make informed decisions about their use, based on evidence in relation to potential harms.

² Watts, C., Freeman, B. & Egger, S. (2022, September 27). "We asked over 700 teens where they bought their vapes. Here's what they said", *The Conversation*. Accessed 5 January 2022 at <https://theconversation.com/we-asked-over-700-teens-where-they-bought-their-vapes-heres-what-they-said-190669>

³ Farrugia, A., Fraser, S., Edwards, M., Madden, A. & Hocking, S. (2019). *Lived experiences of stigma and discrimination among people accessing South Western Sydney Local Health District Drug Health Services*. Melbourne: The Australian Research Centre in Sex, Health and Society, La Trobe University

⁴ Watts, C., Freeman, B. & Egger, S. (2022, September 27). "We asked over 700 teens where they bought their vapes. Here's what they said", *The Conversation*. Accessed 5 January 2022 at <https://theconversation.com/we-asked-over-700-teens-where-they-bought-their-vapes-heres-what-they-said-190669>

Utilising the knowledge of people currently using NVPs will be integral to the development of effective regulatory frameworks

AADC's work is guided by the key principle of respect for lived and living experience perspectives and the value that inclusion of these perspectives brings to policy making and strategy implementation. There is a wealth of evidence in the public health space in relation to the value of lived and living experience perspectives in enabling the development of tailored public health responses to improve health outcomes for specific population groups. This is exemplified in the key role that LGBTIQ+ communities, sex workers and people who inject drugs played - and continue to play - in maintaining Australia's low HIV prevalence.⁵

An important element of utilising this knowledge is engaging the diverse range of population groups using NVPs and their purposes for using them. For instance, those people seeking to use NVPs as a smoking cessation tool and people under 18 years of age who have never smoked that are using NVPs recreationally. Regulatory models should reflect the nuances and differing public health priorities for distinct market segments and population groups.

As scientific evidence on the use and harms of NVPs continues to emerge, it is important that present policy decisions are informed by the experience of the diversity of people accessing and using NVPs to ensure that any model achieves its intended purpose for end users and does not exacerbate harms for any specific population groups. Additionally, it is important that regulatory models are embedded within a wider suite of health promotion and preventative health actions and treatment models that are evidence-informed, funded to meet need and avoid sensationalising risks and harms. AADC notes that at present, there are few treatment options providing support specific to vaping.

Thank you for the opportunity to contribute to this consultation. If you require any further information, please do not hesitate to contact me at melanie.walker@adc.org.au.

Yours sincerely



Melanie Walker

CEO, Australian Alcohol and other Drugs Council

⁵ For more discussion on the role of LGBTIQ+ communities, sex workers and people who inject drugs in Australia's HIV response, see Brown, G., O'Donnell, D., Crooks, L., & Lake, R. (2014). "Mobilisation, politics, investment and constant adaptation: lessons from the Australian health-promotion response to HIV", *Health Promotion Journal of Australia*, 25(1), 35-41.