

16 January 2023

Submission: Proposed reforms to the regulation of nicotine vaping products

Overview

Thank you for the opportunity to make a submission on the proposed reforms to the regulation of nicotine vaping products (NVPs). In our submission, we wish to strongly encourage the TGA to consider the regulation of NVPs in the context of the National Drug Strategy and to put the harm reduction front and centre of any regulation.

The evidence is clear that NVPs are significantly (95%) less harmful than tobacco cigarettes and therefore the wider availability of these products is likely to have a significant impact on harms from tobacco. The research is clear that increasing access to NVP is beneficial for those trying to quit smoking.

We support the overarching sentiment of the reforms to allow nicotine vaping products to be used as a harm reduction tool by adults, while limiting the access of children and adolescents, but have concerns that the pathway currently being mooted will have unintended consequences and increase net harms.

We know from attempts with other drug policy that severely restricting a desired product has at least two key unintended consequences: a. The development of a flourishing black market with limited ability to control quality and access, and b. some people switching to more dangerous substances.

About 360Edge

360Edge is Australia's leading specialist alcohol and other drugs consultancy. We provide a full suite of policy and practice advisory services across the spectrum of alcohol and other drug use, as well as allied areas such as mental health, justice and education, supporting governments and frontline services to improve policy and practice in line with the latest evidence.

Our four main programs are Workforce Development, Service Improvement, Evaluation and Health Systems Modelling. 360Edge also supports the development and implementation of workplace alcohol and other drug policy through its WorkEdge program and alcohol and other drug prevention in schools through our Schools of Substance program.

CEO, Professor Nicole Lee, is an international leader in alcohol and other drug responses, with 33 years' experience in policy and practice implementation. She is also Adjunct Professor at the National Drug Research Institute, Curtin University; Board Member and Chair of the Clinical Governance Committee of Hello Sunday Morning; and Board Member of The Loop Australia. She is a member of the Australian National Council on Alcohol and other Drugs (ANACAD) - Australia's key expert advisory council to the Australian

Government on alcohol and other drugs, which provides policy advice directly to the Health Minister and their Department.

Harm reduction principles

We see a significant gap in the consultation paper approach, which does not mention the National Drug Strategy 2017-2026,¹ and does not contextualise the current approach to regulation within the strategy. Given the position of the TGA in Australia's drug policy framework, any regulatory or other responses to this issue need to be clearly embedded within our National Strategy.

In particular, appropriate weight should be given to the harm reduction pillar.¹ In the context of reforms related to NVPs, this includes carefully considering the significant potential for nicotine vaping products to reduce smoking-attributable mortality in adults. It is essential that all alcohol and other drug policy consider net harms to the community.

Recent research that has modelled the impact of increasing access to NVPs in Australia found that there is likely to be significant public health gains achieved by relaxing the current restrictive NVP policy and increasing access to NVPs for adults.²

There isn't any current evidence that vaping or nicotine causes cancer. There is some evidence of increased risk of cancer among people who use NVPs regularly and long term, but the risk of cancer from NVPs is estimated to be less than 0.5% of the cancer risk from smoking cigarettes.³ Causation and risk are not the same thing. Cancer-causing properties of tobacco cigarettes are from the chemical additives in smoking and chewing tobacco. These chemicals are absent or at barely detectable levels in NVPs and pose little cancer risk to people who use them.

By comparison, NVPs are 95% less risky than smoking tobacco cigarettes.^{8,9} NVPs have significant potential as an accessible tool to combat the largest preventable cause of morbidity and mortality in Australia, tobacco,¹⁰ as demonstrated in other countries which have taken a less restrictive, more harm reduction approach to NVPs.

The main harm associated with nicotine is its addictive properties. It is worth noting that most people who vape are already addicted to nicotine through cigarettes. Other harms associated with use of NVPs are much lower than use of tobacco. Nothing is risk free, including vaping, but if someone is addicted to a substance that has few other harms then net harms are low. Tobacco continues to be the most dangerous and most common form of youth exposure to nicotine.

There is a limited amount of evidence from animal studies that chronic high doses of nicotine has harmful effects on the brain.⁴ However, the animal studies tend to administer nicotine in doses that do not reflect teen use patterns.⁵⁻⁷ Extrapolating from animals to humans with unrealistic exposure protocols is speculative at best and should not be relied upon as evidence of harm.

While research continues to shape our understanding of the impact of alcohol, tobacco and other drugs, we can only make policy decisions based on the current state of the evidence.

While NVPs alone will not be able to produce an end to tobacco smoking, it can certainly complement the many other successful public health measures Australia has put in place to reduce harms from tobacco use.

Vaping and young people

The main concern among anti-NVP advocates is access to vaping among children and adolescents. We support a regulatory framework that restricts access to young people, in a similar way to alcohol and tobacco currently.

The largest proportion of the reduction in smoking we have seen in Australia to date comes from young people not taking up smoking in the first place. This means that we can continue this approach to improve knowledge, skills and confidence among young people to not take up vaping, as well as allowing access to the last smokers who have difficulty quitting. The vast majority of these are people with health and mental health problems without the resources and supports to quit tobacco smoking.

The evidence shows quite clearly that youth vaping, as with other drugs, is typically experimental, transient, and infrequent⁵⁻⁷ The small number of young people who use NVP products regularly are usually already smokers or at risk of smoking.⁵⁻⁷

Vaping rates are very low among teens 14-17 (around 1.8%).⁷ Regular vaping among teens who have never smoked is extremely low. Vaping is highest among young adults 18-29, which is a pattern seen with all other drugs, including alcohol and tobacco. As age increases the likelihood of vaping decreases suggesting that most young people use for a short time and then quit. As vaping is relatively new this pattern may change over time, but it is the same pattern seen with other drugs, including alcohol.

The 'gateway theory' has been debunked many decades ago. There is no good evidence that vaping is a gateway to smoking.

Our response to select submission questions

Changes to border controls for NVPs

The proposed changes are based on a desire to reduce the black market, but it is unlikely that any of the proposed border control options will do this. Heavier law enforcement 'crackdowns' have not reduced black market operations in the past for any illegal drug.¹¹ Law enforcement and border control efforts have minimal long term impact on the supply of drugs in the community.

Despite heavy restrictions and penalties for other illicit drugs, consistent proportion of the population continue to access them. When substances are banned, suppliers find more creative ways to hide and sell their products, leaving the buyer at risk of buying unregulated, unsafe products of often unknown quality and potency.^{11, 12}

Therefore, there is not likely to be benefit in making further restrictive legislative changes to border controls at this time. The additional cost of greater restrictive border control policies would be better spent in education, harm reduction and supporting regulatory controls in the community. The consultation paper itself acknowledges the risk that illegal suppliers will go to even greater lengths to hide vaping product imports to get past border controls with some of the proposed changes.

Rather than further investing in border control options, it would be beneficial for the government to shift focus to ensuring that there are safe, quality TGA approved options available to the public for purchase.

Regulations on NVPs should not be more restrictive than those for more harmful smoking,¹³ because it risks people returning to more accessible cigarettes. The availability of approved, accessible, and safe NVP options is, in fact, likely to reduce the black market, rendering further restrictive border control policies redundant.

Pre-market TGA assessment of NVPs against a product standard

We support the TGA's intent to regulate nicotine products. This includes ensuring that there are pre-market assessments in place for quality and safety. The focus should be on public health and harm reduction. Public access to safer alternatives to smoking, such as NVPs, will save lives.²

Ideally ARTG-registered NVPs, that consumers can trust as safe, should be readily accessible through the same methods as other nicotine replacement therapies (i.e. not requiring a prescription).

We acknowledge that the TGA expects ARTG-registered NVPs to be several years away. So the immediate implementation of Option 3 will have significant unintended consequences. Ceasing the supply of NVPs available through legal means will both increase harms and increase the already extensive black market.

If the TGA chooses to pursue Option 2, we encourage the costs of TGA pre-market assessment be borne by the government to encourage NVP companies to take this route.

We also support other options to encourage ARTG applications so that there will be one or more ARTG registered NVPs available through the same methods as other NRTs (i.e. not requiring a prescription). The ARTG status should give both the government and consumers piece of mind when it comes to the quality of the product. This will likely result in a decline in the black market.

Strengthening the product standard regarding minimum quality and safety standards for NVPs.

Flavoured products

The issue raised in the consultation paper is that flavoured products are attractive to young people and adolescents, and therefore should be banned.

However, adults also prefer non-tobacco flavours.^{14, 15} Sweet NVP flavours are associated with more successful quit efforts by smokers than those using tobacco or menthol flavours.¹⁶ Adults who use sweet flavours to quit smoking are also no more likely to continue vaping than people who use tobacco flavoured NVPs.¹⁶

There is also the risk that by banning flavours, it will only increase the black market for nicotine vaping products, or possibly result in increased at-home mixing of flavours which could result in its own unwanted effects.¹⁴ This increases the accessibility for young people.

The evidence is that flavours are not the main reason young people take up vaping, so they are unlikely to have reduce likelihood of youth vaping.⁷ And some studies have shown that bans on flavours increases youth tobacco smoking.^{17, 18}

Taking a harm reduction first approach, if sweet or fruity flavoured nicotine vaping products assist people in reducing or ceasing their tobacco consumption, then they should be available to people who want to reduce their tobacco consumption. Tobacco remains as the leading cause of morbidity and mortality in Australia¹⁰ and we need lower-harm options, like NVPs, readily available to assist in reducing tobacco related harms and deaths.

Rather than limiting flavours, limiting the retail sale of flavoured NVPs to adult-only outlets is likely to be a more effective solution to restrict access to young people and reduce likelihood of uptake.¹⁹

Flavourings should fall under the pre-market assessment for safety. This would allow the TGA to control quality, safety and access of flavoured NVPs.

Restricting ingredients

Any hazardous ingredients that are not required for the function of the device, delivery of nicotine, or that assist smokers in moving away from tobacco, should be restricted. It is unlikely that banning hazardous ingredients will result in an increase in the black market as they don't significantly affect the desired user experience and are not the main reason people take up NVPs. For example, colouring agents are not required for the function of the device. They serve an aesthetic purpose and they may result in additional harms.²⁰ There is no evidence to show that they improve smoking reduction or cessation efforts.

Introducing plain packaging

Plain packaging is unnecessary in this case. NVPs are significantly safer than tobacco products and approaches to tobacco should not be merely applied to NVPs without consideration of unique and unintended consequences.

The approach in the consultation paper (eg. "some changes around minimum quality and safety standards (particularly around visible features of products) would assist law enforcement officers to better distinguish lawful from unlawful products"), places law enforcement ahead of harm reduction, which is not a health-based approach.

If nicotine vaping products are to continue to be categorised as a prescription-only product, then there is no obvious need to introduce plain packaging. They should come under the same requirements as other prescription products.

If they are available, as other NRTs, as pharmacists only products, they should come under the same packaging and labelling requirements as other NRTs.

If they are to be made more available in adult-only licenced venues, plain packaging sends a message that they are as unsafe as tobacco and risks undermining harm reduction efforts.

Introducing additional warning statements

While we believe that ultimately the TGA should broaden availability for NVPs and at least make them available as other NRTs, if NVPs remain as prescription only, they should come under the same requirements as other prescription products. This means not including warning labels that are not required of any other prescription-only medicine. Warnings about addiction, pregnancy, and consumption by children are not generally required on other prescription medicines in Australia.

Nicotine should be managed like other potential poisons that are widespread in society using a consistent management and regulation approach including warning labels and child resistant containers, rather than by bans.

Allowing the sale of pre-mixed flavoured NVPs in child-proof containers with usual warning labels would both appeal to adults seeking harm reduction options as well as reduce risk of poisoning in children in the same way as other potentially hazardous everyday products.

Restricting nicotine concentrations

Initially the TGA chose not to pursue limits to nicotine concentrations and volumes to allow medical practitioners flexibility to prescribe products appropriate for their patients.

If restrictions are now to be placed on concentration and volumes, as with some other medicines, care needs to be taken that the approach doesn't result in further restrictions to adults trying to access NVPs through lawful channels. The requirement of a prescription already acts as a potential barrier to people wanting to use NVPs for smoking reduction or cessation.

Restrictions are unlikely to stop lawfully imported products being supplied unlawfully. In fact it is likely to significantly increase the black market for higher concentration products if the restrictions are too severe.

The consultation paper highlights the Generation Vape study and Victorian Cancer Council research, which report “significant incidence of people accessing NVPs from friends or associates”.⁵ However, there is nothing in this evidence that suggests that this is related to the prescription pathways. In fact, surveys have shown that only between 3% and 9% of Australians who use vapes have a prescription.^{21, 22} It is more likely that it is via currently illegal pathways that the majority of NVPs are being imported and distributed.

Given the ease of access to black market NVPs that already exists, too severe restrictions on volume and concentration would likely have minimal impact on the black market and primarily limit harm reduction options for people legally obtaining prescriptions.

Other potential minimum requirements for unregistered NVPs

The focus of regulation should be on providing accessible, high quality, safe products to adults for harm reduction purposes. Historically, introducing bans or severely restricting substances has resulted in unintended consequences including black market spikes and potentially dangerous homemade alternatives.^{11, 12} These public health risks need to be front of mind when determining the regulation of substances.

The concerns about youth vaping can be managed without restricting adult access to this evidence-based harm reduction measure.

Status of NVPs as ‘therapeutic goods’.

All nicotine containing products should be regulated for quality and safety. NVPs should be treated like any other nicotine replacement therapy for regulatory purposes.

Thank you for the opportunity to provide feedback on this important and significant topic. 360Edge are specialists in alcohol and other drug policy and can be called upon to provide further advice if required.

Yours sincerely,

Professor Nicole Lee
Founder and CEO

A handwritten signature in black ink, appearing to read 'Nicole Lee', enclosed in a thin black rectangular border.

References

1. Department of Health. National Drug Strategy 2017-2026. Canberra: Australian Government; 2017.
2. Levy DT, Gartner C, Liber AC, Sánchez-Romero LM, Yuan Z, Li Y, et al. The Australia Smoking and Vaping Model: The Potential Impact of Increasing Access to Nicotine Vaping Products. *Nicotine Tob Res.* 2022.
3. Stephens WE. Comparing the cancer potencies of emissions from vapourised nicotine products including e-cigarettes with those of tobacco smoke. *Tob Control.* 2017.
4. Yuan M, Cross SJ, Loughlin SE, Leslie FM. Nicotine and the adolescent brain. *The Journal of Physiology.* 2015;593(16):3397-412.
5. Watts C, Egger S, Dessaix A, Brooks A, Jenkinson E, Grogan P, et al. 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.* 2022;46(6):814-20.
6. Guerin N, White V. ASSAD 2017 Statistics & Trends: Australian Secondary Students' Use of Tobacco, Alcohol, Over-the-counter Drugs, and Illicit Substances. Second Edition.: Cancer Council Victoria; 2020.
7. Australian Institute of Health and Welfare. National Drug Strategy Household Survey 2019. Drug Statistics series no. 32. PHE 270. Canberra: AIHW; 2020.
8. Royal College of Physicians. Nicotine without smoke: Tobacco harm reduction. London: RCP; 2016.
9. McNeill A, Simonavičius E, Brose LS, Taylor E, East K, Zuikova E, et al. Nicotine vaping in England: an evidence update including health risks and perceptions, September 2022. A report commissioned by the Office for Health Improvement and Disparities. . London: Office for Health Improvement and Disparities; 2022.
10. Australian Institute of Health and Welfare. Australian Burden of Disease Study: Impact and causes of illness and death in Australia 2018. Canberra: AIHW; 2021.
11. Coyne CJ, Hall AR. Four Decades and Counting. The Continued Failure of the War on Drugs. Washington, DC: CATO Institute; 2017.
12. Global commission on drug policy. Regulation: The responsible control of drugs. Geneva, Switzerland: Global Commission on Drug Policy; 2018.
13. Cahn Z, Drope J, Douglas CE, Henson R, Berg CJ, Ashley DL, et al. Applying the Population Health Standard to the Regulation of Electronic Nicotine Delivery Systems. *Nicotine Tob Res.* 2021;23(5):780-9.
14. Gravely S, Smith DM, Liber AC, Cummings KM, East KA, Hammond D, et al. Responses to potential nicotine vaping product flavor restrictions among regular vapers using non-tobacco flavors: Findings from the 2020 ITC Smoking and Vaping Survey in Canada, England and the United States. *Addictive Behaviors.* 2022;125:107152.
15. Jongenelis MI, Kameron C, Brennan E, Rudaizky D, Slevin T, Pettigrew S. E-cigarette product preferences among Australian young adult e-cigarette users. *Australian and New Zealand Journal of Public Health.* 2018;42(6):572-4.
16. Li L, Borland R, Cummings KM, Fong GT, Gravely S, Smith DM, et al. How Does the Use of Flavored Nicotine Vaping Products Relate to Progression Toward Quitting Smoking?

Findings From the 2016 and 2018 ITC 4CV Surveys. *Nicotine Tob Res.* 2021;23(9):1490-7.

17. Friedman AS. A Difference-in-Differences Analysis of Youth Smoking and a Ban on Sales of Flavored Tobacco Products in San Francisco, California. *JAMA Pediatrics.* 2021;175(8):863-5.
18. Xu Y, Jiang L, Prakash S, Chen T. The Impact of Banning Electronic Nicotine Delivery Systems on Combustible Cigarette Sales: Evidence From US State-Level Policies. *Value in Health.* 2022;25(8):1352-9.
19. Balfour DJK, Benowitz NL, Colby SM, Hatsukami DK, Lando HA, Leischow SJ, et al. Balancing Consideration of the Risks and Benefits of E-Cigarettes. *American Journal of Public Health.* 2021;111(9):1661-72.
20. Korzun T, Munhenzva I, Escobedo JO, Strongin RM. Synthetic food dyes in electronic cigarettes. *Dyes and Pigments.* 2019;160:509-13.
21. Sutherland R, Uporova J, King C, Jones F, Karlsson A, Gibbs D, et al. Australian Drug Trends 2022: Key Findings from the National Illicit Drug Reporting System (IDRS) Interviews. Sydney: National Drug and Alcohol Research Centre, UNSW 2022.
22. Bayly M, Mitsopoulos E, Durkin S, Scollo M. E-cigarette use and purchasing behaviour among Victorian adults: Findings from the 2018-19 and 2022 Victorian Smoking and Health Surveys. Melbourne, Australia: Prepared for: Quit Victoria. Centre for Behavioural Research in Cancer, Cancer Council Victoria; 2022.